

Legal classification status of selected ingredients in the European Union of 15

Last major update: 19 December 2008

Important remarks:

- The *grouping of ingredients by use or action* follows the Anatomical Therapeutic Chemical (ATC) classification system established by the *World Health Organization* (WHO). This divides medicinal products into different groups according to the organ / system on which they act and their chemical, pharmacological and therapeutic properties. *A complete overhaul* has been carried out to clarify the table's legibility based on the *2008 version of the WHO ATC classification*. For ease of reference, ingredients are listed **only in the ATC class where non-prescription use is most likely to occur**. This does not exclude use of the ingredient in other organ systems / disease areas. It should not be interpreted as a recommendation from AESGP or WSMI.
- The acronym "OTC" means that at least one dosage or form of the ingredient has the legal status of "non-prescription medicinal product" in the country concerned. This is totally independent from the reimbursement or advertising status of a product containing the ingredient or combination of ingredients in question.
- In case the information is available, the first move of the ingredient from prescription to non-prescription status is indicated by the "year" in which this "switch" took place. "Year" therefore equals "OTC".
- Wherever possible, footnotes provide additional information. However, the absence of a footnote does not mean that there are no particular restrictions attached to the non-prescription use of the ingredient.
- The table is issued by AESGP and WSMI. However, because of the rapidly changing situation, some information may be outdated. Users are therefore invited to check with the national competent authority for official statements concerning an ingredient's legal status.
- AESGP and WSMI cannot be held responsible for the use made of the information in the table.
- Data in this overview were updated by AESGP national associations in **December 2008**.

Legal classification status of selected ingredients in the European Union (15 countries) (last major update: 19 December 2008)

(Data for *New-EU / Non-EU European countries* and data for *selected countries Worldwide* are available in separate tables)

Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
A. ALIMENTARY TRACK AND METABOLISM														
A01 Stomatological preparations														
Fluoride (sodium)	OTC ¹	OTC	Rx	OTC	OTC	1986 ²	OTC	OTC	OTC	OTC	OTC	1995	OTC	OTC ³
Hexetidine	OTC	OTC	N.R.	N.R.	OTC	OTC	OTC	OTC	OTC	OTC	OTC	1992 ⁴	N.R.	OTC
Triamcinolone (<i>oral</i>)	Rx	N.R.	Rx	2003 ⁵	Rx	2003 ⁶	N.R.	Rx		Rx		Rx	Rx	OTC ⁷
A02 Drugs for acid-related disorders														
Aluminium hydroxide	OTC	N.R.	OTC	N.R.	OTC	OTC	N.R.	Rx	N.R.	N.R.	N.R.	1982	Rx ⁸	1994
Calcium carbonate	OTC	OTC ⁹	OTC	<1965	OTC	OTC	OTC	OTC	OTC ¹⁰	OTC	OTC	1982	OTC	OTC
Carbenoxolone	OTC ¹¹	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	OTC ¹²	N.R.	N.R.	OTC	Rx	N.R.	OTC ¹³
Cimetidine	OTC ¹⁴	Rx	1989	Rx	1997 ¹⁵	Rx	Rx	Rx	1993 ¹⁶	1996	Rx	1996 ¹⁷	Rx ¹⁸	1994 ¹⁹
Famotidine	Rx	N.R.	1996 ²⁰	1996 ²¹	1997 ²²	1999 ²³	Rx	1996 ²⁴	OTC ²⁵	1996	2002	1996 ²⁶	1995 ²⁷	1994 ²⁸
Lansoprazole	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx		N.R.		Rx	2004 ²⁹	Rx
Nizatidine	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	1999 ³⁰	Rx	Rx	Rx	Rx	N.R.	1996 ³¹
Omeprazole	Rx	Rx	Rx	Rx	Rx	Rx ³²	Rx	Rx	Rx	2008	Rx	Rx	1999 ³³	2004 ³⁴
Pantoprazole	2009 ³⁵	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
Ranitidine	OTC ³⁶	2003 ³⁷	1989	1996 ³⁸	1997 ³⁹	1999 ⁴⁰	Rx	1999 ⁴¹	Rx	1996 ⁴²	Rx	1998 ⁴³	1995 ⁴⁴	1994 ⁴⁵
Sucralfate	OTC ⁴⁶	Rx	1989	1985	1994	Rx	Rx	Rx	OTC ⁴⁷	OTC	Rx	Rx	Rx	Rx
A03 Drugs for functional gastrointestinal disorders														
Dicyclomine (Dicycloverine)	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	OTC ⁴⁸	Rx ⁴⁹	N.R.	Rx	Rx	N.R.	OTC ⁵⁰
Dimeticone	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	1982	OTC	OTC

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Domperidone	Rx	OTC ⁵¹	Rx	N.R.	Rx	Rx	Rx	OTC ⁵²	1989 ⁵³	OTC ⁵⁴	Rx	Rx	N.R.	1998 ⁵⁵
Hyoscine butylbromide	Rx	1977	Rx	Rx	Rx	1966	Rx	Rx	1998	1990	2009	1952	N.R.	1955 ⁵⁶
Mebeverine	Rx	OTC ⁵⁷	Rx	N.R.	Rx	Rx	Rx	OTC ⁵⁸	Rx	Rx	Rx	Rx	N.R.	1997 ⁵⁹
Metoclopramide	Rx	OTC ⁶⁰	N.R.	Rx	Rx	Rx	Rx	Rx	OTC	Rx	Rx	Rx	Rx	Rx
Propantheline	N.R.	N.R.	OTC ⁶¹	N.R.	N.R.	Rx ⁶²	Rx	OTC ⁶³	Rx	Rx	N.R.	N.R.	N.R.	OTC ⁶⁴
A04 Antiemetics and Antinauseants														
Dimenhydrinate (diphenhydramine and chlorotheophylline)			Rx	N.R.	OTC			N.R.				1982	OTC	N.R.
Hyoscine (Scopolamine)	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	OTC ⁶⁵	OTC	Rx	Rx	Rx	Rx	1992 ⁶⁶
A05 Bile and liver therapy														
Hymecromone	Rx	OTC	N.R.	N.R.	1990 ⁶⁷	OTC	N.R.	N.R.	OTC ⁶⁸	N.R.	N.R.	Rx	N.R.	N.R.
A06 Laxatives														
Bisacodyl	OTC	OTC	OTC	<1965	OTC	OTC	1997	OTC	OTC	OTC	OTC	1982	OTC	OTC ⁶⁹
Lactitol	OTC ⁷⁰	OTC	OTC	1995	OTC	1995	Rx	N.R.	OTC	OTC	N.R.	2004 ⁷¹	OTC	1996
Lactulose	OTC	OTC	OTC	1970	OTC	OTC	Rx	OTC	OTC	OTC	OTC	2000	OTC	OTC
Picosulfate (sodium)	OTC	OTC	N.R.	<1965	OTC	OTC	Rx	OTC	OTC	OTC	OTC	1987	OTC	OTC ⁷²
A07 Antidiarrheals														
Loperamide	OTC ⁷³	OTC ⁷⁴	1989 ⁷⁵	1989 ⁷⁶	1998 ⁷⁷	1993 ⁷⁸	Rx	OTC ⁷⁹	1998	OTC	Rx	1996 ⁸⁰	1989	OTC ⁸¹
Nifuroxazide	N.R.	OTC	N.R.	N.R.	1998 ⁸²	N.R.	N.R.	N.R.	Rx	N.R.		N.R.	N.R.	N.R.

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A08 Antiobesity preparations														
Orlistat	2009 ⁸³	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009	2009
A10 Drugs used in diabetes														
Insulin	Rx	Rx	Rx	Rx OTC ⁸⁴	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
A11 Vitamins														
Vitamin A (Retinol)	OTC ⁸⁵	OTC ⁸⁶	OTC	<1965	OTC	OTC ⁸⁷	Rx	OTC	OTC	N.R. ⁸⁸	OTC	1995 ⁸⁹	OTC ⁹⁰	Rx
A12 Mineral supplements														
Selenium	OTC	OTC	Rx	<1965	OTC ⁹¹	1993 ⁹²	Rx	OTC	N.R.	N.R.	Rx ⁹³	OTC	OTC	OTC
B. BLOOD AND BLOOD FORMING ORGANS														
B02 Antihemorrhagics														
Tranexamic acid				Rx	Rx	Rx	Rx	Rx		Rx		Rx	OTC ⁹⁴	Rx ⁹⁵
B03 Antianemic preparations														
Iron and folic acid preparations	OTC	OTC	N.R.	<1965	OTC	OTC	Rx	OTC ⁹⁶	Rx	OTC	Rx ⁹⁷	OTC ⁹⁸	OTC	OTC ⁹⁹
C. CARDIOVASCULAR SYSTEM														
C01 Cardiac therapy														
Adenosine	Rx	OTC ¹⁰⁰	Rx	Rx	OTC	OTC ¹⁰¹	Rx	Rx	Rx	Rx ¹⁰²	Rx ¹⁰³	OTC ¹⁰⁴	Rx ¹⁰⁵	2004 ¹⁰⁶
Nitro-glycerine	Rx	Rx	OTC	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	OTC
Ubidecarenone	N.R.	N.R.	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	OTC ¹⁰⁷	N.R.	Rx ¹⁰⁸	N.R.	N.R.	N.R.

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C10 Lipid modifying agents														
Colestyramine	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Lovastatin	Rx	Rx	Rx	Rx	N.R.	Rx	Rx	N.R.		N.R.	Rx	Rx	N.R.	Rx
Pravastatin	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx		Rx	Rx	Rx	Rx	Rx
Simvastatin	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx		Rx	Rx	Rx	Rx	2004 ¹⁰⁹
D. DERMATOLOGICAL														
D01 Antifungals for dermatological use														
Amorolfine (topical)	OTC	Rx	Rx	Rx	Rx	OTC	N.R.	Rx		N.R.		Rx	Rx	2006 ¹¹⁰
Bifonazole	OTC ¹¹¹	OTC	N.R.	N.R.	Rx	1988	Rx	Rx	OTC ¹¹²	Rx	Rx	Rx	OTC	OTC
Butenafine	Rx	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.		N.R.	N.R.	N.R.	N.R.	N.R.
Ciclopirox Olamine	N.R.	N.R.	N.R. ¹¹³	N.R.	1987 ¹¹⁴	1986 ¹¹⁵	Rx	OTC	Rx	Rx	N.R.	Rx	N.R.	N.R.
Clotrimazole (topical)	OTC	OTC	OTC	1973 ¹¹⁶	OTC	OTC	Rx	OTC ¹¹⁷	2007 ¹¹⁸	OTC	1995	1994 ¹¹⁹	OTC	OTC ¹²⁰
Croconazole	2002 ¹²¹	N.R.	N.R.	N.R.	N.R.	1997 ¹²²	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Econazole	OTC ¹²³	OTC ¹²⁴	1989 ¹²⁵	Rx	1983	OTC ¹²⁶	Rx	OTC ¹²⁷	OTC	OTC	Rx	Rx	1993 ¹²⁸	1992 ¹²⁹
Fenticonazole (topical)	2001	N.R.		N.R.	OTC ¹³⁰	1996	Rx	Rx		Rx		Rx	N.R.	2001 ¹³¹
Haloprogin (topical)	N.R.	N.R.	N.R.	N.R.	N.R.	1978	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Isoconazole (topical)	2001	OTC	N.R.	N.R.	1983 ¹³²	1983 ¹³³	Rx	OTC ¹³⁴	Rx	N.R.	Rx	N.R.	N.R.	OTC ¹³⁵
Ketoconazole (topical)	OTC ¹³⁶	OTC ¹³⁷	1989	1992 ¹³⁸	1998 ¹³⁹	1992	Rx	OTC ¹⁴⁰	OTC ¹⁴¹	OTC ¹⁴²	2002	2007 ¹⁴³	OTC	1995 ¹⁴⁴
Miconazole (topical)	OTC	OTC	1989	1991 ¹⁴⁵	1983	OTC ¹⁴⁶	Rx	OTC	OTC ¹⁴⁷	OTC	1997	1999 ¹⁴⁸	1983	OTC ¹⁴⁹

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Miconazole & Hydrocortisone (topical)	N.R.	OTC	Rx	1992	N.R.	N.R.	Rx	OTC	N.R.	Rx	Rx	Rx	1992	1998 ¹⁵⁰
Naftifine (topical)	OTC	N.R.	N.R.	N.R.	N.R.	1990	Rx	Rx	Rx	N.R.	N.R.	Rx	N.R.	N.R.
Natamycin (topical)	N.R.	N.R.	N.R.	<1965 ¹⁵¹	N.R.	1978	N.R.	Rx	Rx	Rx	Rx	Rx	N.R.	N.R.
Nystatin	Rx	OTC ¹⁵²	Rx	Rx	Rx	OTC ¹⁵³	Rx	OTC ¹⁵⁴	Rx	Rx	1997	Rx	Rx	Rx
Oxiconazole	OTC ¹⁵⁵	N.R.	N.R.	N.R.	Rx	1989 ¹⁵⁶	N.R.	Rx	N.R.	Rx	1997	Rx	N.R.	N.R.
Selenium sulphide	OTC ¹⁵⁷	OTC	N.R.	OTC	OTC	1992	OTC	OTC	N.R.	OTC	OTC	1982 ¹⁵⁸	OTC	OTC
Sulconazole nitrate (topical)	N.R.	Rx	N.R.	N.R.	Rx	N.R.	N.R.	OTC	N.R.	Rx	N.R.	N.R.	N.R.	OTC ¹⁵⁹
Terbinafine	Rx	2004 ¹⁶⁰	1994 ¹⁶¹	OTC ¹⁶²	2002 ¹⁶³	2000 ¹⁶⁴	2005 ¹⁶⁵	2002 ¹⁶⁶	Rx	Rx	Rx	2007 ¹⁶⁷	1994	2001 ¹⁶⁸
Tioconazole	OTC ¹⁶⁹	N.R.	N.R.	1992 ¹⁷⁰	Rx	1992 ¹⁷¹	Rx	OTC ¹⁷²	OTC ¹⁷³	N.R.	1995	1999 ¹⁷⁴	N.R.	1994 ¹⁷⁵
Tolnaftate	OTC ¹⁷⁶	N.R.	N.R.	N.R.	OTC	OTC	Rx	OTC	1992	Rx	OTC ¹⁷⁷	1992 ¹⁷⁸	N.R.	OTC
D03 Treatment of wounds and ulcers														
Hyaluronic acid (topical)	Rx ¹⁷⁹	N.R.	N.R.	N.R.	OTC ¹⁸⁰	OTC	Rx	Rx	OTC	N.R.	Rx	Rx	N.R.	OTC
D06 Antibiotics and Chemotherapeutics for dermatological use														
Aciclovir (topical)	OTC ¹⁸¹	OTC	1993 ¹⁸²	1992 ¹⁸³	1997 ¹⁸⁴	1992 ¹⁸⁵	Rx	OTC ¹⁸⁶	2007	1996	Rx	2000 ¹⁸⁷	2002	1993 ¹⁸⁸
Chlortetracycline (topical)	Rx	OTC	N.R.	Rx	1983	Rx	N.R.	Rx	Rx	N.R.	Rx	Rx	N.R.	Rx
Docosanol (topical)	N.R.	OTC	N.R.	OTC	OTC	N.R.	N.R.	N.R.		2008	N.R.	Rx	Rx.	N.R.
Idoxuridine (topical)	N.R.	Rx	Rx	N.R.	N.R.	Rx	N.R.	OTC ¹⁸⁹	Rx	N.R.	Rx	Rx	N.R.	Rx
Lysozyme HCl	N.R.	OTC	N.R.	N.R.	OTC	OTC	N.R.	N.R.	OTC ¹⁹⁰	N.R.	OTC	1994 ¹⁹¹	N.R.	N.R.
Mupirocin (topical)	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx

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Penciclovir (topical)	OTC ¹⁹²	OTC	1999 ¹⁹³	1998 ¹⁹⁴	2000 ¹⁹⁵	2005 ¹⁹⁶	2005 ¹⁹⁷	Rx	2008	1999	Rx	2006 ¹⁹⁸	OTC ¹⁹⁹	2006 ²⁰⁰
Podofilox (Podophyllotoxin)	Rx	N.R.	N.R.	N.R.	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	OTC ²⁰¹	N.R.	N.R.
Silver sulfadiazine 1%	Rx	OTC	Rx	Rx	OTC	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	N.R.	Rx
Tetracycline	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
D07 Corticosteroids, dermatological preparations														
Alclometasone (topical)	N.R.	N.R.	Rx	N.R.	N.R.	Rx	Rx	Rx		N.R.		N.R.	N.R.	2009 ²⁰²
Clobetasone butyrate (topical)	Rx	Rx	Rx	Rx	Rx ²⁰³	Rx	Rx	Rx		N.R.	Rx	Rx	Rx	2001 ²⁰⁴
Hydrocortisone (topical)	Rx	OTC ²⁰⁵	1989 ²⁰⁶	<1965 ²⁰⁷	1996 ²⁰⁸	1996 ²⁰⁹	Rx	OTC ²¹⁰	1983 ²¹¹	Rx	OTC	1992 ²¹²	1983	1987 ²¹³
Prednisolone	Rx	Rx	Rx	<1965 ²¹⁴	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Triamcinolone (topical)	Rx	OTC	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx ²¹⁵	OTC ²¹⁶
D08 Antiseptics and Disinfectants														
Benzalkonium chloride	OTC	OTC	Rx ²¹⁷	N.R.	OTC	OTC	N.R.	N.R.	OTC	N.R.	OTC	1982 ²¹⁸	Rx ²¹⁹	OTC ²²⁰
Povidone iodine	OTC	OTC	N.R.	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC	1982 ²²¹	OTC	OTC
Triclosan	N.R.	N.R.	N.R.	1980 ²²²	N.R.	OTC	Rx	OTC	OTC	N.R.	N.R. ²²³	1992 ²²⁴	N.R.	OTC
D10 Antiacne preparations														
Benzoyl peroxide	2002 ²²⁵	OTC	OTC	1990 ²²⁶	2007 ²²⁷	OTC	Rx	OTC	OTC ²²⁸	OTC	OTC	1982 ²²⁹	OTC	OTC ²³⁰
Clindamycin	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Erythromycin (topical)	Rx	OTC	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	N.R.	Rx
Tretinoin	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx

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D11 Other dermatological preparations														
Minoxidil	OTC ²³¹	OTC	1993	2002 ²³²	1998 ²³³	OTC ²³⁴	OTC	1996 ²³⁵	OTC ²³⁶	OTC	Rx	1995 ²³⁷	1997 ²³⁸	1994 ²³⁹
G. GENITO-URINARY SYSTEM AND SEX HORMONES														
G01 Gynecological antiinfectives and antiseptics														
Amphotericin (<i>topical</i>)	Rx	N.R.	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Butoconazole	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	N.R.
Clotrimazole (<i>vaginal</i>)	2003 ²⁴⁰	OTC	1996	1994 ²⁴¹	N.R.	1994	Rx	OTC ²⁴²	Rx	Rx	1995	Rx	1994	1992 ²⁴³
Miconazole (<i>vaginal</i>)	2004 ²⁴⁴	OTC	Rx	1993 ²⁴⁵	OTC	1996 ²⁴⁶	Rx	1996 ²⁴⁷	Rx	Rx	1997	Rx	N.R.	1992 ²⁴⁸
Propionate Ca+Na (<i>vaginal</i>)	N.R.	N.R.	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Terconazole (<i>vaginal</i>)	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	Rx	N.R.	N.R.	N.R.
G03 Sex hormones and Modulators in the genital system														
Estriol (<i>vaginal</i>)	Rx	Rx	1999	1992 ²⁴⁹	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	1992	Rx
Levonorgestrel	Rx	2001 ²⁵⁰	Rx	2002 ²⁵¹	1999 ²⁵²	Rx ²⁵³	Rx	Rx	Rx	2005	Rx	2009 ²⁵⁴	2001 ²⁵⁵	2001 ²⁵⁶
G04 Urologicals														
Phenazopyridine	Rx	OTC	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.
Tamsulosin														2009 ²⁵⁷
J. ANTIINFECTIVES FOR SYSTEMIC USE														
J01 Antibacterials for systemic use														
Azithromycin				Rx	Rx	Rx	Rx	Rx		Rx		Rx		2008 ²⁵⁸
Methenamine	Rx	OTC ²⁵⁹	OTC	Rx	OTC	OTC	Rx	N.R.	N.R.	Rx	N.R.	N.R.	Rx	OTC

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J02 Antimycotics for systemic use														
Itraconazole	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
M. MUSCOLO-SKELETAL SYSTEM														
M01 Antiinflammatory and Antirheumatic products														
Benzydamine	OTC ²⁶⁰	N.R.	1989 ²⁶¹	N.R.	Rx	Rx	OTC	OTC ²⁶²	OTC	OTC	OTC	1995 ²⁶³	Rx	OTC
Bufexamac (topical)	OTC ²⁶⁴	OTC	N.R.	N.R.	Rx	OTC	N.R.	OTC ²⁶⁵	OTC	OTC	OTC	N.R.	N.R.	N.R.
Diclofenac	Rx	Rx	Rx	Rx	Rx	2004 ²⁶⁶	Rx	Rx	1983 ²⁶⁷	1998	Rx	2002 ²⁶⁸	OTC ²⁶⁹	Rx
Diclofenac (topical)	OTC ²⁷⁰	OTC	OTC	2001 ²⁷¹	1996 ²⁷²	1999 ²⁷³	2001 ²⁷⁴	2002 ²⁷⁵	1994	N.R. ²⁷⁶	2002	2000 ²⁷⁷	OTC ²⁷⁸	OTC ²⁷⁹
Etofenamate (topical)	OTC ²⁸⁰	OTC	N.R.	N.R.	N.R.	1994	2004	Rx	OTC ²⁸¹	N.R.	Rx	2007 ²⁸²	N.R.	N.R.
Felbinac (topical)	OTC ²⁸³	OTC	N.R.	N.R.	Rx	1995	N.R.	OTC ²⁸⁴	OTC ²⁸⁵	N.R.	Rx	1996 ²⁸⁶	N.R.	1994 ²⁸⁷
Flurbiprofen (lozenges)	Rx	Rx	Rx	N.R.	2005 ²⁸⁸	2004 ²⁸⁹	N.R.	2002 ²⁹⁰		N.R.		Rx	N.R.	2001 ²⁹¹
Glucosamine	OTC	Rx	OTC	Rx	OTC	OTC ²⁹²	Rx	OTC ²⁹³		OTC ²⁹⁴		Rx	2004 ²⁹⁵	OTC
Ibuprofen (oral)	OTC ²⁹⁶	OTC ²⁹⁷	1989 ²⁹⁸	1986 ²⁹⁹	1992 ³⁰⁰	1989 ³⁰¹	OTC ³⁰²	OTC ³⁰³	1984	OTC ³⁰⁴	OTC ³⁰⁵	1986 ³⁰⁶	1988	1983 ³⁰⁷
Ibuprofen (topical)	OTC ³⁰⁸	OTC ³⁰⁹	N.R.	N.R.	1996 ³¹⁰	1989 ³¹¹	Rx	OTC ³¹²	1994	N.R. ³¹³	1996	1996 ³¹⁴	2001	1983 ³¹⁵
Indomet(h)acin (topical)	OTC ³¹⁶	OTC	Rx	Rx	Rx	1996 ³¹⁷	Rx	Rx	OTC ³¹⁸	N.R.	Rx	Rx	N.R.	N.R.
Ketoprofen			Rx	OTC ³¹⁹	1997 ³²⁰			OTC ³²¹	OTC ³²²	1996 ³²³	Rx	Rx	Rx	Rx
Ketoprofen (topical)	OTC ³²⁴	OTC ³²⁵	OTC ³²⁶	1992 ³²⁷	Rx	1998 ³²⁸	Rx	OTC ³²⁹	OTC ³³⁰		1995 ³³¹	2007 ³³²	OTC	1993 ³³³
Meclofenamic acid	N.R.	N.R.	N.R.	Rx	N.R.	Rx ³³⁴	Rx	Rx	Rx	N.R.	Rx	Rx	N.R.	N.R.
Naproxen	2000 ³³⁵	OTC ³³⁶	Rx	Rx	2007 ³³⁷	2001 ³³⁸	Rx	OTC ³³⁹	1994 ³⁴⁰	1997 ³⁴¹	Rx	1996 ³⁴²	OTCZ	2007 ³⁴³
Niflumic acid (topical)	Rx	OTC	N.R.	N.R.	1998 ³⁴⁴	Rx	Rx	N.R.	OTC	N.R.	Rx	Rx	N.R.	N.R.

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Piroxicam (topical)	OTC ³⁴⁵	OTC	1989	OTC ³⁴⁶	Rx	1994	Rx	OTC ³⁴⁷	OTC ³⁴⁸	Rx	Rx	1998 ³⁴⁹	N.R.	1994 ³⁵⁰
Tolmetin	OTC ³⁵¹	N.R.	Rx	N.R.	N.R.	Rx	Rx	Rx	N.R.	Rx	OTC	Rx	N.R.	Rx
M03 Muscle relaxants														
Chlorzoxazone	Rx	N.R.	Rx	Rx	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	N.R.
Idrocilamide	N.R.	OTC	N.R.	N.R.	1990 ³⁵²	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Methocarbamol	N.R.	N.R.	N.R.	Rx	1962 ³⁵³	Rx	N.R.	Rx	N.R.	N.R.	N.R.	Rx	N.R.	Rx
Orphenadrine	Rx	N.R.	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	N.R.	Rx	Rx
N. NERVOUS SYSTEM														
N01 Anaesthetics														
Benzocaine	OTC ³⁵⁴	OTC ³⁵⁵	OTC	OTC ³⁵⁶	OTC	OTC	Rx	OTC ³⁵⁷	OTC	N.R.	OTC	1982 ³⁵⁸	OTC	OTC ³⁵⁹
Butyl aminobenzoate	Rx	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	OTC ³⁶⁰		N.R.	N.R.	1987 ³⁶¹	N.R.	N.R.
Cinchocaine (topical)	Rx	OTC ³⁶²	Rx	OTC ³⁶³	Rx	Rx	Rx	OTC ³⁶⁴	OTC	Rx	N.R.	1995 ³⁶⁵	Rx ³⁶⁶	OTC ³⁶⁷
Dyclonine (oral)	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Lidocaine (topical/oral topical)	OTC ³⁶⁸	OTC	1988	OTC ³⁶⁹	1958 ³⁷⁰	OTC ³⁷¹	Rx	OTC ³⁷²	OTC	OTC ³⁷³	OTC	1982 ³⁷⁴	1987	OTC ³⁷⁵
Oxetacaine	Rx	OTC ³⁷⁶	N.R.	N.R.	OTC ³⁷⁷	Rx	Rx	OTC ³⁷⁸	OTC	N.R.	OTC	Rx	N.R.	1994 ³⁷⁹
Oxybuprocaine	Rx	Rx	N.R.	N.R.	Rx	Rx	N.R.	OTC ³⁸⁰	Rx	Rx	OTC	Rx	Rx	OTC ³⁸¹
Pramocaine	N.R.	OTC ³⁸²	N.R.	N.R.	OTC ³⁸³	OTC	N.R.	OTC	OTC	OTC	N.R.	1986 ³⁸⁴	N.R.	OTC
Prilocaine	Rx	Rx	OTC ³⁸⁵	OTC ³⁸⁶	Rx	OTC	N.R.	OTC ³⁸⁷	Rx	Rx	Rx	Rx	OTC ³⁸⁸	Rx ³⁸⁹

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
N02 Analgesics														
Acetylsalicylic acid	OTC ³⁹⁰	OTC	1984	<1965	OTC ³⁹¹	OTC ³⁹²	OTC ³⁹³	OTC ³⁹⁴	OTC ³⁹⁵	OTC ³⁹⁶	OTC ³⁹⁷	1982 ³⁹⁸	OTC ³⁹⁹	OTC ⁴⁰⁰
Diflunisal	Rx	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	OTC ⁴⁰¹	Rx	Rx	Rx	N.R.	Rx
Dihydrocodeine	Rx	Rx	N.R.	Rx ⁴⁰²	Rx	Rx	Rx	OTC ⁴⁰³	Rx	N.R.	Rx	Rx	N.R.	1992 ⁴⁰⁴
Naratriptan	Rx	Rx	Rx	Rx	Rx	2006 ⁴⁰⁵	Rx	Rx		Rx		Rx	Rx	Rx
Paracetamol	OTC ⁴⁰⁶	OTC ⁴⁰⁷	1984	<1965 ⁴⁰⁸	OTC ⁴⁰⁹	OTC ⁴¹⁰	OTC ⁴¹¹	OTC ⁴¹²	1990 ⁴¹³	OTC	OTC	1982 ⁴¹⁴	OTC	OTC ⁴¹⁵
Paracetamol + dihydrocodeine	Rx	Rx ⁴¹⁶	N.R.	N.R.	N.R.	Rx	N.R.	OTC	N.R.	N.R.	N.R. ⁴¹⁷	Rx	N.R.	1992 ⁴¹⁸
Sumatriptan	Rx	Rx	Rx	Rx	Rx	Rx ⁴¹⁹	Rx	Rx	Rx	Rx	Rx	Rx	Rx	2006 ⁴²⁰
Zolmitriptan	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx		Rx		Rx	Rx	Rx ⁴²¹
N05 Psycholeptics														
Chlorproethazine (<i>topical</i>)	N.R.	N.R.	N.R.	N.R.	N.R.	Rx ⁴²²	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Hydroxyzine	Rx	OTC	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	1995 ⁴²³
Prochlorperazine	N.R.	N.R.	Rx	Rx	N.R.	Rx	N.R.	Rx	Rx	Rx	N.R.	N.R.	Rx	2001 ⁴²⁴
N06 Psychoanaleptics														
Pyritinol	Rx	N.R.	N.R.	N.R.	N.R.	OTC	N.R.	Rx	N.R.	N.R.	OTC	Rx	N.R.	N.R.
N07 Other nervous system drugs														
Nicotine (<i>gum</i>)	OTC	OTC	1989	1988	1997 ⁴²⁵	1994 ⁴²⁶	OTC	OTC	OTC	1992 ⁴²⁷	1995	1995 ⁴²⁸	1990	1991 ⁴²⁹
Nicotine (<i>nasal spray</i>)	2005	Rx	1999	Rx	N.R.	Rx	Rx	Rx	N.R.	2000	Rx	Rx	Rx	2000
Nicotine (<i>oral inhaler</i>)	OTC	OTC	1996 ⁴³⁰	1998	1999 ⁴³¹	2002 ⁴³²	Rx	OTC	OTC ⁴³³	1999	Rx	N.R.	1996	OTC

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Nicotine (<i>patch</i>)	OTC	OTC	1993	1993	1999 ⁴³⁴	1994	OTC	1996	1993	1995	Rx	1996 ⁴³⁵	1993	OTC ⁴³⁶
Nicotine (<i>sublingual</i>)	OTC	OTC	OTC	N.R.	1999 ⁴³⁷	2000	N.R.	OTC		2000	Rx	2002 ⁴³⁸	OTC	2001
P. ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLANTS														
P01 Antiprotozoals														
Carnidazole	N.R.	N.R.	N.R.	N.R.	N.R.	N.R. ⁴³⁹	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Quinfamide	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.		N.R.	Rx	N.R.	N.R.	N.R.
P02 Anthelmintics														
Flubendazole	Rx	N.R.	N.R.	N.R.	1987 ⁴⁴⁰	Rx	N.R.	N.R.	N.R.	N.R.	Rx	Rx	N.R. ⁴⁴¹	N.R.
Mebendazole	Rx	OTC ⁴⁴²	Rx	N.R.	Rx	Rx	Rx	OTC	Rx	OTC	OTC ⁴⁴³	Rx	Rx ⁴⁴⁴	1989 ⁴⁴⁵
Pyrantel	Rx	N.R.	N.R.	1974 ⁴⁴⁶	OTC ⁴⁴⁷	Rx ⁴⁴⁸	Rx	Rx	Rx	N.R.	OTC ⁴⁴⁹	1999 ⁴⁵⁰	N.R. ⁴⁵¹	N.R. ⁴⁵²
P03 Ectoparasiticides														
Benzyl benzoate (<i>topical</i>)	Rx ⁴⁵³	OTC	N.R.	1990	OTC	OTC	Rx	OTC	Rx	N.R.	OTC	1982	OTC	OTC
Lindane (<i>topical</i>)	Rx	N.R.	N.R.	N.R.	OTC	Rx ⁴⁵⁴	N.R.	OTC	N.R.	N.R.	OTC	Rx ⁴⁵⁵	N.R.	N.R. ⁴⁵⁶
R. RESPIRATORY SYSTEM														
R01 Nasal preparations														
Azelastine	2003 ⁴⁵⁷	OTC	1996	Rx	2005 ⁴⁵⁸	1997 ⁴⁵⁹	Rx	1999 ⁴⁶⁰	Rx	Rx	Rx	2000 ⁴⁶¹	OTC	1996 ⁴⁶²
Beclometasone (<i>nasal</i>)	Rx	2008	2001	1996 ⁴⁶³	2002 ⁴⁶⁴	1997 ⁴⁶⁵	Rx	1999 ⁴⁶⁶	Rx	Rx	Rx	2002 ⁴⁶⁷	1999	1994 ⁴⁶⁸
Budesonide (<i>nasal</i>)	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	1999	1995 ⁴⁶⁹
Cromoglicic acid	OTC ⁴⁷⁰	Rx	N.R.	1993	1998 ⁴⁷¹	OTC	Rx	OTC ⁴⁷²	N.R.	OTC ⁴⁷³	OTC	1995 ⁴⁷⁴	1993 ⁴⁷⁵	OTC ⁴⁷⁶
Ephedrine (<i>topical</i>)	OTC ⁴⁷⁷	OTC	Rx	N.R.	1985 ⁴⁷⁸	OTC	N.R.	OTC	OTC	N.R.	OTC	1982 ⁴⁷⁹	N.R.	OTC ⁴⁸⁰
Epinephrine (<i>not for asthma</i>) (adrenaline)	Rx	Rx	N.R.	Rx	N.R.	Rx	N.R.	OTC ⁴⁸¹	N.R.	Rx	Rx	Rx	Rx ⁴⁸²	Rx

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Epinephrine (asthma)	Rx	OTC ⁴⁸³	N.R.	Rx	Rx	Rx	Rx	Rx	N.R.	N.R.	Rx	Rx	Rx	Rx
Flunisolide (nasal)	Rx	Rx	Rx	N.R.	Rx	Rx	N.R.	1999 ⁴⁸⁴	Rx	Rx	Rx	N.R.	N.R.	1994 ⁴⁸⁵
Fluticasone	Rx	Rx	Rx	2004 ⁴⁸⁶	Rx	Rx	Rx	2002 ⁴⁸⁷		Rx	Rx	Rx	Rx	2002 ⁴⁸⁸
Levocabastine	Rx	OTC	1994 ⁴⁸⁹	Rx ⁴⁹⁰	2009 ⁴⁹¹	1998	Rx	Rx	2001	Rx		2004 ⁴⁹²	1997 ⁴⁹³	1998 ⁴⁹⁴
Mometasone (nasal)	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx		Rx		Rx	2004 ⁴⁹⁵	Rx
Naphazoline	OTC ⁴⁹⁶	OTC	1993 ⁴⁹⁷	Rx	Rx ⁴⁹⁸	OTC	OTC	OTC ⁴⁹⁹	OTC	Rx	OTC	1982 ⁵⁰⁰	Rx	OTC ⁵⁰¹
Oxymetazoline	OTC ⁵⁰²	OTC	1989	1986 ⁵⁰³	Rx	OTC	1998	OTC	OTC	OTC	OTC	1982 ⁵⁰⁴	OTC	OTC ⁵⁰⁵
Phenylephrine	OTC ⁵⁰⁶	OTC	Rx	OTC ⁵⁰⁷	OTC ⁵⁰⁸	OTC ⁵⁰⁹	Rx	OTC ⁵¹⁰	OTC	Rx ⁵¹¹	OTC	1982 ⁵¹²	Rx	OTC ⁵¹³
Pseudoephedrine	OTC ⁵¹⁴	OTC	Rx	Rx	OTC ⁵¹⁵	OTC	N.R.	OTC ⁵¹⁶	OTC	N.R.	OTC	1982 ⁵¹⁷	Rx	1994 ⁵¹⁸
Tetrahydrozoline	N.R.	N.R.	N.R.	OTC	Rx ⁵¹⁹	OTC	N.R.	N.R.		N.R.	OTC	1982 ⁵²⁰	N.R.	N.R.
Tramazoline	2002 ⁵²¹	OTC	N.R.	N.R.	N.R.	OTC	N.R.	Rx		OTC	OTC	1982 ⁵²²	N.R.	N.R.
Xylometazoline (nasal)	OTC ⁵²³	OTC	1989	1990 ⁵²⁴	N.R.	OTC	2001 ⁵²⁵	OTC	OTC	OTC	OTC	1982 ⁵²⁶	1989	OTC ⁵²⁷
R02 Throat preparations														
Bacitracin (topical)	Rx	OTC	N.R.	OTC ⁵²⁸	N.R.	OTC	Rx	Rx	OTC	Rx	OTC	1994 ⁵²⁹	N.R.	Rx
Tyrothricin	OTC	OTC	N.R.	N.R.	N.R.	OTC	Rx	OTC ⁵³⁰	OTC	N.R.	OTC	1992 ⁵³¹	N.R.	OTC ⁵³²
R03 Drugs for obstructive airway diseases														
Fenoterol	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Orciprenaline	Rx	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	Rx	Rx	Rx	N.R.	Rx	N.R.	Rx
Salbutamol	Rx	Rx	Rx	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Theophylline	Rx	OTC ⁵³³	Rx	Rx	OTC ⁵³⁴	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	OTC
R05 Cough and Cold preparations														
Acetylcysteine	OTC ⁵³⁵	OTC	OTC	1987 ⁵³⁶	OTC	1994	OTC ⁵³⁷	OTC ⁵³⁸	OTC ⁵³⁹	OTC	Rx	1996 ⁵⁴⁰	Rx	Rx

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Ambroxol	OTC ⁵⁴¹	OTC	N.R.	N.R.	1998 ⁵⁴²	1984	Rx	N.R.	OTC	2004	Rx	2002 ⁵⁴³	Rx.	N.R.
Benproperine	N.R.	N.R.	N.R.	N.R.	N.R.	1988	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Benzonatate	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	OTC ⁵⁴⁴	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.
Bromhexine	OTC	OTC	OTC	1992 ⁵⁴⁵	OTC	OTC	OTC	OTC	OTC ⁵⁴⁶	OTC	OTC	1994 ⁵⁴⁷	OTC	N.R.
Carbocisteine	N.R.	OTC	N.R.	1990 ⁵⁴⁸	OTC	Rx	Rx	OTC ⁵⁴⁹	OTC ⁵⁵⁰	OTC	1995	1995 ⁵⁵¹	N.R.	Rx
Chlorphendianol	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.
Codeine	Rx	OTC ⁵⁵²	1984 ⁵⁵³	N.R.	1984 ⁵⁵⁴	Rx	Rx	OTC ⁵⁵⁵	Rx	OTC ⁵⁵⁶	Rx	Rx	Rx	OTC ⁵⁵⁷
Dextromethorphan	OTC ⁵⁵⁸	OTC	1993 ⁵⁵⁹	1983 ⁵⁶⁰	1996 ⁵⁶¹	OTC	Rx	OTC ⁵⁶²	OTC	OTC ⁵⁶³	OTC	1982 ⁵⁶⁴	N.R.	1989 ⁵⁶⁵
Dimemorfan	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	OTC ⁵⁶⁶	N.R.	N.R.	Rx	N.R.	N.R.
Noscapine	Rx	OTC	OTC	<1965 ⁵⁶⁷	1957 ⁵⁶⁸	Rx	N.R.	Rx	OTC ⁵⁶⁹	OTC	N.R.	Rx	OTC	N.R.
R06 Antihistamines for systemic use														
Acrivastine	Rx	N.R.	1992	1994 ⁵⁷⁰	N.R.	Rx	N.R.	Rx	Rx	Rx	Rx	N.R.	Rx	1993 ⁵⁷¹
Azatadine	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	Rx	N.R.	N.R.	Rx	Rx	N.R.	N.R.
Brompheniramine	N.R.	N.R.	N.R.	N.R.	1968 ⁵⁷²	OTC	Rx	OTC	N.R.	N.R.	OTC	1982 ⁵⁷³	N.R.	OTC
Carbinoxamine	Rx	OTC ⁵⁷⁴	N.R.	Rx	N.R.	OTC	N.R.	N.R.	OTC	N.R.	N.R.	1995 ⁵⁷⁵	N.R.	N.R.
Cetirizine	2001 ⁵⁷⁶	2000 ⁵⁷⁷	1985	1994 ⁵⁷⁸	1998 ⁵⁷⁹	1995 ⁵⁸⁰	Rx	OTC ⁵⁸¹	OTC ⁵⁸²	OTC	Rx	2002 ⁵⁸³	1999 ⁵⁸⁴	1993 ⁵⁸⁵
Chlorpheniramine	OTC ⁵⁸⁶	OTC	OTC	N.R.	OTC	OTC	Rx	OTC	1991	N.R.	OTC	1982 ⁵⁸⁷	N.R.	OTC
Clemastine	OTC ⁵⁸⁸	N.R.	OTC	N.R.	N.R.	OTC	N.R.	OTC	OTC	Rx	OTC	Rx	Rx	OTC
Cyproheptadine	Rx	OTC	OTC	N.R.	OTC	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	OTC
Dexbrompheniramine	OTC ⁵⁸⁹	N.R.	N.R.	Rx	N.R.	OTC	Rx	N.R.	N.R.	N.R.	OTC	1994 ⁵⁹⁰	Rx	N.R.
Dexchlorpheniramine			OTC	N.R.	OTC			N.R.		Rx		2004 ⁵⁹¹	Rx	Rx
Dimetindene	OTC	OTC	N.R.	N.R.	OTC.	OTC	OTC ⁵⁹²	N.R.	OTC	Rx	OTC ⁵⁹³	1992 ⁵⁹⁴	N.R.	N.R.
Diphenhydramine	OTC	OTC	OTC ⁵⁹⁵	Rx	OTC	OTC ⁵⁹⁶	OTC	OTC	OTC	Rx	OTC	1982 ⁵⁹⁷	Rx	OTC ⁵⁹⁸

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Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Diphenylpyraline	OTC ⁵⁹⁹	N.R.	N.R.	N.R.	N.R.	1979	N.R.	N.R.	N.R.	N.R.	N.R.	1995 ⁶⁰⁰	N.R.	OTC
Doxylamine succinate	Rx	OTC ⁶⁰¹	N.R.	N.R.	OTC	OTC	N.R.	OTC ⁶⁰²	OTC ⁶⁰³	N.R.	Rx ⁶⁰⁴	1982 ⁶⁰⁵	N.R.	OTC
Ebastine	Rx	Rx	OTC	2001 ⁶⁰⁶	Rx	Rx	Rx	N.R.		Rx		Rx	2002 ⁶⁰⁷	N.R.
Fexofenadine	2009 ⁶⁰⁸	2008	Rx	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Ketotifen	Rx	Rx	OTC	Rx	Rx	Rx	Rx	Rx		Rx		Rx	OTC	Rx
Levocetirizine			Rx	2004 ⁶⁰⁹	Rx			Rx				Rx	OTC ⁶¹⁰	Rx
Loratadine	OTC ⁶¹¹	OTC ⁶¹²	1990	1999 ⁶¹³	2006 ⁶¹⁴	1994	Rx	OTC ⁶¹⁵	2004 ⁶¹⁶	1996	Rx	2007 ⁶¹⁷	1992 ⁶¹⁸	1993 ⁶¹⁹
Meclozine	Rx	OTC	OTC	1966	OTC	Rx	Rx	N.R.		OTC ⁶²⁰	2002	1982 ⁶²¹	Rx	OTC
Mepyramine maleate	OTC ⁶²²	OTC ⁶²³	OTC ⁶²⁴	N.R.	OTC	OTC	N.R.	OTC	OTC ⁶²⁵	N.R.	OTC	1995 ⁶²⁶	N.R.	OTC ⁶²⁷
Mequitazine	N.R.	N.R.	N.R.	N.R.	OTC	Rx	N.R.	Rx	Rx	N.R.	Rx	Rx	N.R.	N.R.
Oxatomide	Rx	N.R.	N.R.	N.R.	Rx	Rx	Rx	Rx	1999 ⁶²⁸	Rx	Rx	Rx	N.R.	N.R.
Promethazine	N.R.	N.R.	OTC ⁶²⁹	N.R.	OTC	Rx	Rx	OTC	OTC ⁶³⁰	Rx	Rx	1995 ⁶³¹	Rx	OTC
Tripeleminamine	OTC ⁶³²	N.R.	N.R.	1986 ⁶³³	N.R.	OTC	N.R.	N.R.	OTC	OTC	N.R.	1987 ⁶³⁴	N.R.	N.R.
Trip(r)olidine	OTC ⁶³⁵	Rx	N.R.	N.R.	OTC	OTC	N.R.	OTC ⁶³⁶	OTC	N.R.	Rx	1987 ⁶³⁷	N.R.	OTC
S. SENSORY ORGANS														
S01 Ophthalmologicals														
Sulfacetamide (<i>topical</i>)	Rx	OTC	N.R.	N.R.	N.R.	Rx	N.R.	Rx	Rx	N.R.	Rx ⁶³⁸	Rx	N.R.	N.R.
S03 Other ophthalmological and otological preparations														
Chloramphenicol	Rx	OTC	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	OTC	Rx	Rx	2005 ⁶³⁹
Polymyxin B (<i>topical</i>)	Rx	OTC	Rx	Rx	Rx	Rx	Rx	Rx	OTC ⁶⁴⁰	Rx	OTC	Rx	Rx	Rx
NON-CLASSIFIED														
Bronopol	N.R.	N.R.	N.R.	N.R.	N.R.	OTC ⁶⁴¹	N.R.	N.R.	N.R.	N.R.	N.R.	1992 ⁶⁴²	N.R.	N.R.

Legal classification status of selected ingredients in the European Union (15 countries) (last major update: 19 December 2008)

(Data for **New-EU / Non-EU European countries** and data for **selected countries Worldwide** are available in separate tables)

Ingredient	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherl.	Portugal	Spain	Sweden	UK
Cilastatin	Rx	Rx	Rx	N.R.	Rx	1990	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Decaline	N.R.	N.R.	N.R.	N.R.	N.R.	OTC ⁶⁴³	N.R.	N.R.	N.R.	N.R.	N.R.	1992 ⁶⁴⁴	N.R.	N.R.
Potassium nitrate (toothpaste)	N.R.	N.R.	N.R.	N.R.	N.R. ⁶⁴⁵	N.R. ⁶⁴⁶	N.R.	OTC	N.R.	N.R.	N.R. ⁶⁴⁷	N.R. ⁶⁴⁸	N.R.	OTC ⁶⁴⁹
Strontium chloride (toothpaste)	OTC ⁶⁵⁰	N.R.	N.R.	N.R.	N.R.	N.R. ⁶⁵¹	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.

Endnotes:

- 1 For caries prophylaxis in toothpaste in doses of up to an equivalent of 1mg/day.
- 2 Maximum daily dose of 2mg is OTC. Gel for topical use in dentistry is OTC.
- 3 GSL in 2001 with a maximum strength of 0.05% and mouthwashes for other than daily use with a maximum strength of 0.2%. Pharmacy only in dentifrices with a maximum strength of 0.33%. Other preparations for the use in prevention of dental caries in the form of: (1) tablets or drops 2.2mg maximum daily dose; (2) mouth rinses other than those for daily use, maximum strength 0.2%; (3) mouth rinses for daily use, maximum strength 0.05%.
- 4 Antiseptic for the mouth (maximum strength: 0.1%) and, since 1994, for sore throat (liquid: maximum strength: 0.1%). Spray: maximum strength: 0.2%).
- 5 For the treatment of recurring mouth ulcers.
- 6 Switched in July 2003 for the treatment of recurring mouth ulcers (aphthous stomatitis).
- 7 Triamcinolone acetonide available as a pharmacy-only medicine with a maximum strength of 0.1% in packages containing not more 5g of medicinal product. For the treatment of common mouth ulcers. Maximum treatment period 5 days. Check age and duration of treatment for children.
- 8 In combination with lidocaine.
- 9 In combination.
- 10 In combinations.
- 11 Up to 2% for topical use and for local treatment of cold sores and mouth ulcers.
- 12 Pellet: maximum dose 5mg and maximum daily dose 25mg. Gel: maximum strength 2%.
- 13 (Sodium). Pellet maximum dose 5mg; maximum daily dose 25mg (No product on UK market). Gel maximum strength 2%. Granules for mouthwash in adults and children over 12 years, maximum dose 20mg; maximum daily dose 80mg and maximum strength 1% and container or package containing maximum 560mg carbenoxolone sodium (No OTC product yet available on UK market).
- 14 Up to 200mg for gastro oesophageal reflux and short term treatment only.
- 15 Oral form with maximum dose of 200mg and maximum 2g per pack. Can be advertised to consumers.
- 16 Authorised with a maximum dose of 200mg (no public advertising allowed).
- 17 Maximum dose 200mg. Maximum daily dose 400mg. Only for adults over 16. Can be advertised to consumers. No combination product. Maximum treatment period: one week.
- 18 Cimetidine SmithKline Beecham 200mg tablets OTC, but not marketed, Tagamet effervescent tablets 200mg OTC, but not marketed, Tagamet tablets 100mg OTC, but not marketed.
- 19 For short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity and for the prophylaxis of meal-induced heartburn, maximum dose 200mg, 800mg maximum daily dose, for a maximum period of 14 days. For the prophylactic management of nocturnal heartburn by a single dose taken at night, 100mg maximum dose to be taken as a single dose at night, for a maximum period of 14 days.
- 20 Oral use only.
- 21 Limit per pack 120mg (10mg per unit).

- 22 Launched OTC in May 1996 as 12 x 10mg tablets (= maximum dose per pack). Can be advertised to consumers.
- 23 Dosage 10mg. For heartburn and reflux, with a maximum duration of two weeks.
- 24 For the short term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperactivity and the prevention of these symptoms when associated with food and drink, including nocturnal symptoms. Maximum dose 10mg; maximum daily dose 20mg. Maximum treatment period 14 days. For use in adults and children not less than 16.
- 25 Switched to OTC status in 2004 for heartburn and reflux in a dosage of 10mg. P.A. famotidine 10mg + magnesium 165mg + calcium 800mg.
- 26 Only combinations with antacids for neutralisation, with neutralisation capability not over 50 milliequivalents. Maximum dose of famotidine alone and in combination: 10mg. Maximum daily dose 20mg. Only for adults over 16. Can be advertised to consumers. Maximum treatment period: one week.
- 27 Tablets of 10mg in packages of 6, 12 or 24.
- 28 For short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms. Maximum dose 10mg and maximum daily dose 20mg. For a maximum period of 14 days. General sale since 2000 when 10mg (maximum 12 tablets per pack), maximum daily dose 20mg, and only used for the short-term symptomatic relief of heartburn, indigestion, acid indigestion and hyperacidity.
- 29 Lanzoprazole 15mg tablets and effervescent tablets switched to non-prescription status in 2004 in packs of 14.
- 30 OTC for the prevention of heartburn, indigestion and excess acid in adults and children not under 16. Maximum dose 75mg, maximum daily dose 150mg, maximum pack size 8, maximum period of treatment 14 days.
- 31 For the prevention and treatment of the symptoms of food-related heartburn, and meal-induced indigestion. For use in adults and children over 16. Maximum dose 75mg; maximum daily dose 150mg. For a maximum period of 14 days. No OTC product marketed yet.
- 32 Omeprazole 20mg-oral formulations for heartburn and acid reflux – switch to be discussed in January 2009. Could become effective 1 October 2009.
- 33 OTC status applies to treatment of symptoms of gastro-oesophageal reflux disease (e.g. heartburn, regurgitation) and for short-term treatment of up to 14 days. Dosage 10mg. Losec Mups enterotablets in packs of 7 or 14 units are OTC, other presentations are Rx.
- 34 From 2004, omeprazole may be supplied as a pharmacy-only medicine for the relief of reflux-like symptoms such as heartburn in adults aged 18 years and over. Maximum treatment period: 4 weeks. Maximum strength: 10mg; maximum dose: 20mg; maximum daily dose: 20mg; maximum pack size: 28 tablets.
- 35 Pantoprazole 20 mg was switched to non-prescription status in the entire European Union through a Decision of the European Commission under the centralised procedure.
- 36 Oral up to 75mg maximum dose (not yet marketed).
- 37 Only 75mg tablets.
- 38 Limit per pack 1.5 g (300mg per unit).
- 39 Switched in March 1997; maximum dose 75mg; maximum pack size 900mg.
- 40 Dosage 75mg. For heartburn and reflux, with a maximum duration of two weeks.
- 41 OTC for the prevention of heartburn, indigestion and excess acid in adults and children not under 16. Maximum dose 75mg, maximum daily dose 150mg; maximum period of treatment 14 days.

42 Dosage 75mg.

43 Maximum dose 75mg, maximum daily dose 150mg, and maximum treatment period one week. For adults over 16 years of age. Status is“EFP”. No combination product.

44 Effervescent tablets of 150mg. Packs of 6, 10, 12, 20 or 24 tablets.

45 For short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity or for the prevention of these symptoms when associated with consuming food and drink. Maximum dose 75mg. Maximum daily dose 300mg. For a maximum period of 14 days. General sale pack sizes are restricted to maximum pack size of 12 tablets for symptomatic relief of heartburn, dyspepsia, indigestion, and hyperacidity with a maximum strength of 75mg and maximum daily dose of 150mg

46 Patients with restricted kidney function, especially patients submitted to dialysis, with Morbus Alzheimer or forms of dementia have to avoid a long term and higher dose treatment.

47 OTC only in combination with ketoprofen.

48 Maximum dose 10mg; maximum daily dose 60mg. Liquid preparations intended for infants are Rx only.

49 In associations.

50 Maximum dose 10mg. Maximum daily dose 60mg.

51 Tablets, sachets and suppositories for adult are OTC. Other suppositories and oral solutions are Rx.

52 Oral solid dosage forms only.

53 5mg x 20 sachets are OTC.

54 Restricted to pharmacy-only distribution as from 1 March 2009.

55 For relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn, maximum dose 10mg and maximum daily dose 40mg. Pack/container size containing maximum 200mg.

56 Depending on the indication: Irritable Bowel Syndrome relief – GSL status; Other indications – 20 and 24 packs have non-prescription status; 56 tablets have Rx status.

57 Suspensions are Rx.

58 Internal use only.

59 For symptomatic relief of irritable bowel syndrome; maximum dose 135mg; maximum daily dose 405mg. For use other than the symptomatic relief of irritable bowel syndrome; maximum dose 100mg; maximum daily dose 300mg.

60 Only suppositories for adults (6 x 20mg) and some tablets are OTC. Other forms and some tablets are Rx.

61 OTC for topical use only (hyperhydrosis).

62 Propantheline bromide.

63 (Bromide). Maximum dose 15mg and maximum daily dose 45mg.

64 (Bromide). Maximum dose 15mg. Maximum daily dose 45mg. However there is no marketed OTC product.

65 OTC maximum strength 0.15%. Internal and external use are OTC except ophthalmic use which is Rx.

66 Hyoscine hydrobromide: maximum dose 300 micrograms. Maximum daily dose 900 micrograms. External (except ophthalmic) / internal (otherwise than by inhaler) routes. Hyoscine patches became available as a pharmacy-only product in 2004 for the prevention of travel sickness symptoms. For use in adults and children aged 10 years or over. Maximum strength: 1.5mg per patch; maximum pack size: 2 patches. Other preparations for internal use: maximum strength: 0.15%.

67 Oral, up to 0.4g per unit, 12g per pack.

68 Without prescription (public advertising not allowed).

69 Maximum dose 10mg for general sale to adults and children over 10 years (maximum 40 tablets).

70 For symptomatic treatment of constipation.

71 As a laxative.

72 General sale if for adults and children over 10 years; maximum strength 0.1%; maximum dose 15mg; maximum daily dose 15mg. In 2004, the conditions for GSL supply were extended to include liquid-filled capsules with a maximum strength of 2.5mg. Maximum pack size: 24 capsules.

73 Oral up to 2mg per dose and 12mg per day.

74 Suspensions are Rx.

75 Tablets only. Syrups are classified as Rx.

76 Limit per pack 32mg (2mg per unit).

77 2mg/dose and 24mg per pack.

78 Maximum daily dose for OTC use 12mg, restricted to treatment of acute diarrhoea. Without prescription only for adults and children >12 years.

79 Treatment of acute diarrhoea is OTC.

80 Not for use in children under 12 years. Maximum dose: 2mg. Maximum daily dose: 16mg. Maximum treatment period: 2 days.

81 For treatment of acute diarrhoea. General sale for the symptomatic treatment of acute diarrhoea, in adults and children over 12 years, maximum strength 2mg; maximum dose 4mg; maximum daily dose 12mg; maximum pack size containing up to 6 x 2mg.

82 Antiseptic for intestinal use in acute diarrhoea presumed of bacterial origin, maximum oral dose 200mg; maximum pack size 2.4g.

83 Orlistat 60 mg was switched to non-prescription status in the entire European Union through a Decision of the European Commission under the centralised procedure.

84 In the list Dnro 1452/01/2000 it is mentioned that insulin can be delivered only on prescription. Insulin is a special reimbursable medicine and, therefore, in practice it is always delivered on prescription. OTC status remains in case of emergency.

85 External use and internal up to 5000 i.E per day. (Pregnant women, women capable of bearing children without secure contraceptive measures and breast feeding women may not exceed a daily dose of 5000 I.U. of retinol to prevent infant deformation.)

86 In combinations only.

87 Maximum dose for OTC status is 50 000 I.U.

88 Please note that the oral form of vitamin A is available as food supplement with a maximum daily dosage of 1200 RE.

89 OTC. Topical use. Nasal protector since 1995. Epithelium use since 1999.

90 OTC in combination with other vitamins.

- 91 As a single ingredient.
- 92 Maximum dose for OTC status is 50 micrograms.
- 93 Rx or food supplements.
- 94 OTC in 500mg tablets.
- 95 Consultation in 2008 on switch to non-prescription status of tranexamic acid 500mg tablets for the reduction of heavy menstrual bleeding (menorrhagia).
- 96 OTC provided maximum daily dose of folic acid is not greater than 500 micrograms
- 97 Rx or food supplements.
- 98 OTC when in vitamin products (not for anaemia).
- 99 Maximum daily dose of folic acid is 500 micrograms. This dosage became general sale in 1995.
- 100 In combinations.
- 101 OTC only when use other than for treatment (symptomatic) of paroxysmal AV-junctional tachycardies (which remains Rx).
- 102 Only available as injection solutions.
- 103 Hospital use only.
- 104 OTC in combinations but only as a vitamin factor.
- 105 Only available as injection solutions.
- 106 For oral administration at a maximum daily dose of 750 micrograms. Product should not be taken for longer than 12 weeks without medical advice; not for children under 14 years of age.
- 107 Dosage is 50mg. Without prescription (no consumer advertising allowed).
- 108 Classified as a “cardiotonic”.
- 109 Simvastatin 10mg switched to pharmacy status in 2004 under the name *Zocor Heart-Pro*[®] used in conjunction with necessary lifestyle changes to reduce the risk of a first major coronary event in people likely to be at a moderate risk (approximately 10-15% 10-year risk of a first major event) of coronary heart disease (CHD). Maximum strength: 10mg; maximum daily dose: 10mg; maximum pack size: 28 tablets.
- 110 Amorolfine hydrochloride nail lacquer was switched to pharmacy (P) status on 15 September 2006 for the treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails. Dosage: a once-weekly administration. Maximum strength: 5% amorolfine (as the base). Maximum pack size: 3ml (equivalent to approximately 3 months’ treatment).
- 111 External use only.
- 112 Topical form with 1% concentration is OTC.
- 113 Ciclopiroxolamine is not registered in Denmark but ciclopirox is Rx.
- 114 Only in topical forms; maximum strength 1%; maximum pack size 500mg.
- 115 Only in topical form.
- 116 Maximum strength 1% for topical use.

- 117 Cream, powder and solutions are OTC.
- 118 Ointment 1% only.
- 119 Only OTC for athlete's foot. Maximum strength 1%.
- 120 Maximum strength 1%. For external use for prevention of (2001) or as an adjunct to the treatment of tinea pedis. Maximum 500mg in an individual container or package (General sale in 1995).
- 121 OTC for external use only.
- 122 For topical treatment against mycosis of the skin and nails.
- 123 External use only. Only some creams, powders and sprays are OTC.
- 124 Vaginal forms are Rx. All topical forms are OTC.
- 125 OTC for topical use only. Vaginal use is Rx.
- 126 External use is OTC.
- 127 External use including vaginal use for vaginal candidiasis.
- 128 External and vaginal use.
- 129 External use but in the case of vaginal use only external use for the treatment of vaginal candidiasis.
- 130 Cream, concentration up to 2%. Maximum dose per tube: 15g; 600mg maximum per boxe.
- 131 2001: for external use (but in the case of vaginal use, only for the treatment of vaginal candidiasis).
- 132 Cream, concentration 2%. Maximum dose per tube: 30g. 300mg per unit dose (ovules for vaginal use)
- 133 Only external use is OTC.
- 134 Also OTC for vaginal use for the treatment of vaginal candidiasis.
- 135 Isoconazole nitrate. External use but in case of vaginal use, only external use for the treatment of vaginal candidiasis.
- 136 Shampoo and up to 2% for topical use (the latter switched in 1997).
- 137 All topical forms are OTC (shampoo and cream).
- 138 Up to 2% for external use.
- 139 For topical use in a maximum concentration of 1% and a maximum pack size of 1g.
- 140 Also OTC for vaginal use for the treatment of vaginal candidiasis.
- 141 Ointment 2% and shampoo 1%.
- 142 Not registered but marketed as a health product under cosmetics' regulation (the Medicines Evaluation Board did not want to grant a marketing authorisation to the shampoo, because they did not regard dandruff as a medical indication).
- 143 Maximum strength 1% (dandruff shampoo)..
- 144 Maximum strength 2%. Shampoo: for prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp. Cream only: treatment of tinea pedis, tinea cruris and candidal intertrigo; maximum frequency of application of once every three days; maximum pack/container size 120ml containing maximum of 2.4g ketoconazole.

- 145 Up to 2% for external use.
- 146 Indications for non-prescription use extended on 1 July 2005 to the treatment of fungal infections in the mouth.
- 147 Combination “miconazole + benzoyl peroxide” is Rx.
- 148 Up to 2% for external use. OTC just for the indication athlete’s foot.
- 149 Miconazole nitrate. Maximum strength 2% for cream or powder (in case of spray powders 2% w/w excluding any propellants). For external use for treatment of tinea pedis only (general sale). For fungal and associated bacterial infections of skin including nappy rash (Pharmacy only).
- 150 For the treatment of athlete’s foot and candidal intertrigo. Maximum strength hydrocortisone 1%. Maximum pack/container size 15g. Also see CSM Guidelines
- 151 For external use.
- 152 Only external use is OTC.
- 153 Oral, vaginal and external uses are OTC.
- 154 Rx for vaginal use.
- 155 External use only.
- 156 Except vaginal use which remains Rx.
- 157 For treatment of the scalp, up to 3%.
- 158 For the treatment of scalp.
- 159 External use (except vaginal use). However there is no marketed OTC product yet.
- 160 Only topical use is OTC.
- 161 Topical use only.
- 162 Limit per pack 150mg, maximum dose 1% for topical use. Since 2002, 1% liquid is available for self-medication in 15mg/ml packs for the treatment of tinea pedis and fungal intertrigo infections. Since 2002, 1% gel is available for self-medication in packs of 15g.
- 163 Cream, concentration 1%. Maximum dose per pack: 0.1g. Maximum 7-day treatment.
- 164 1% formulations for topical treatment of fungal infections.
- 165 Cream for external use 1%.
- 166 For external use in products other than sprays. For the treatment of jock itch and athletes foot. Maximum strength 1%, maximum pack size 15g and maximum period of treatment 14 days. For use in adults and children not under 16 years.
- 167 Maximum strength 1%. Only for athlete’s foot.
- 168 In 2001, the 1% spray formulation was allowed for sale without a prescription for the treatment of tinea pedis, tinea cruris, and tinea corporis. Maximum strength 1%; maximum pack size 30ml. In 2001, the 1% gel formulation was allowed for the same indications in a maximum pack size of 30g. As from 2004, a cream preparation may be supplied as a GSL medicine for the treatment of tinea pedis and tinea cruris. As from November 2009, an 1% cutaneous solution, to be administered as a single application, may be supplied on general sale for the treatment of tinea pedis in persons aged 18 years and older.
- 169 Up to 1% for topical use.

170 Maximum strength 1% for topical use and pessary 100mg x 3.
171 Only external use is OTC.
172 External use including vaginal use for vaginal candidiasis.
173 Public advertising not allowed.
174 Only topical use (athlete's foot), maximum 1%.
175 External (except vaginal). Vaginal for treatment of vaginal candidiasis. However there is no marketed OTC product yet. Maximum strength 2%.
176 Topical forms. Not marketed.
177 Topical use.
178 Only the topical form at a maximum strength of 1% is OTC for the indication athlete's foot.
179 Not marketed.
180 If used as a topical cream, hyaluronic acid is a cosmetic. If used as a perfusion, the product is either a medical device or a listed medicine.
181 Up to 5% for topical use in the treatment of cold sores.
182 Maximal strength 5%.
183 Limit per pack 100mg. Up to 5% in ointments for the treatment of herpes of the lips.
184 Can be advertised to consumers. Different name to the prescription version. Maximum strength 5%. Up to 100mg per pack.
185 Pack size 2g maximum.
186 Maximum strength 5.0% and maximum pack size 2g (for cold sores).
187 For the treatment of *herpes labialis*. Maximum strength 5%.
188 Maximum strength 5%. For treatment of herpes simplex virus infections of the lips and face (*herpes labialis*). Maximum pack/container size 2g. From 2004, 5% cream may be supplied on general sale for the treatment of cold sores.
189 Maximum strength 0.1% (cold sores).
190 OTC in combination with thonzylamine and phenolpropamine.
191 Maximum dose: 4mg.
192 Up to 5% for topical use in the treatment of cold sores.
193 1% cream.
194 Up to 1% in ointments for the treatment of herpes of the lips.
195 1% cream; maximum pack size 20mg.
196 Switched to non-prescription status on 1 January 2005 for herpes labialis in packs of up to 2 g and concentrations of up to 20mg.
197 For external use. 1%, in a 2g tube. Effective 2005 under the tradename Fenivir®.
198 Up to 1% for topical use in the treatment of herpes simplex virus infections of the lips.
199 1% cream.

- 200 For external use. Switched to pharmacy status on 15 September 2006 for the treatment of herpes simplex virus infections of the lips and face (herpes labialis) in adults and children aged 12 years or more. Maximum strength: 1%. Maximum pack size: 2g.
- 201 Only OTC (without advertising to the general public) as a laxative (oral forms). Not allowed for topical use (antimycotic) in EFP medicines.
- 202 Alclometasone dipropionate 0.05% w/w cream may from November 2009 be supplied without a prescription for the short-term treatment and control of patches of eczema and dermatitis including atopic eczema and primary irritant and allergic dermatitis in adults and children aged 12 years and older.
- 203 = Clobetazol.
- 204 For the short-term symptomatic treatment and control of patches of eczema and dermatitis (excluding seborrhoeic dermatitis) in adults and in children aged 12 years and over. Maximum strength 0.05%. Maximum pack size 15 grams.
- 205 Some creams are Rx.
- 206 Maximum strength 1%.
- 207 Limit per pack for tablets 150mg as first aid for snakebites and wasp and other insect stings. For external use both in suppositories and rectal ointments.
- 208 In concentrations of up to 0.5% and maximum pack size of 75mg. Can be advertised to consumers.
- 209 Effective July 1996 (the first switch of its category in Germany). Hydrocortisone or hydrocortisone acetate up to 0.25% for all indications, for adults and children over 6 years of age, Pack size 50g. Hydrocortisone or hydrocortisone acetate from 0.25% up to 0.5% for the short-time treatment (max. 2 weeks) of phlogistic or allergic skin diseases and pruritus, for adults and children over 6 years of age, Pack size 30g.
- 210 For irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema in adults and children not under 10 years. Maximum strength 1%, maximum pack size 15g. Also OTC in suppository form (maximum strength 10mg, maximum pack size 12) and as an ointment (maximum strength 1%, maximum pack size 15g) in combination with certain specified ingredients for use in haemorrhoids in adults and children not under 10 years.
- 211 Only 0.5% ointment for topical use is OTC.
- 212 a) For itches. Maximum strength: 1%. b) For relief of haemorrhoids. Not for use in children under 12 years. Maximum strength: 0.5%. c) As an anti-inflammatory in the mouth: Not for use in children under 12. Maximum dose: 2.5mg, Maximum daily dose: 10mg. Not for oral ulcers, injuries or gingival infections.
- 213 Maximum strength 1%. For use as a cream, ointment or spray either alone or in conjunction with crotamiton in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and either in combination with clotrimazole or miconazole nitrate for athlete's foot and candidal intertrigo or in combination with lidocaine for anal and perianal itch associated with haemorrhoids. For use in adults and children 10 years or over. Maximum strength 0.5% for use in combination with nystatin of maximum strength 3% for intertrigo. Also see CSM Guidelines. Container or package containing not more than 15g of medicinal product (cream or ointment) or 30ml (spray). .
A spray containing hydrocortisone 0.2% and lidocaine hydrochloride 1.0% may be supplied on general sale for the symptomatic relief of anal and perianal itch, irritation and pain associated with external haemorrhoids. Maximum pack size 30ml.
- 214 Limit per pack 500mg, maximum strength 5mg/g in preparations for topical use / Maximum strength 1.5mg/g in rectal preparations.
- 215 Mouthpaste is OTC.

- 216 Triamcinolone acetonide non-pressurised nasal spray switched to pharmacy-only status in 2000 to treat symptoms of seasonal allergic rhinitis in those aged 18 years and over, for no longer than three months in containers of not more than 3.575mg labelled with a maximum daily dose of 110 micrograms per nostril.
- 217 Only marketed in combination with triamcinolone and salicylic acid.
- 218 Topical use: sore throat (since 1994); topical antiseptic (since 1982); spermicide (since 1992).
- 219 In combination with triamcinolone and salicylic acid.
- 220 Whether external or internal (e.g. pastilles, lozenges, throat tablets), maximum strength for general sale is 600 micrograms.
- 221 Antiseptic for topical use. (a) For dermatological use: maximum strength 10%. (b) For sore throat: maximum strength 1%. (c) For vaginal use: maximum strength of the solution: 0.3%).
- 222 In combination products.
- 223 Triclosan is not registered as a medicinal product but as a cosmetic product.
- 224 Antiseptic for topical use. Maximum strength 2%.
- 225 OTC for external use up to 10% only.
- 226 Limit per pack 2.5g. Up to 5% for external use.
- 227 Benzoyl peroxide 5%/5g switched to non-prescription status in July 2007.
- 228 Combination “miconazole + benzoyl peroxide” is Rx.
- 229 Topical use (against acne).
- 230 Maximum strength for general sale 2.5% for treatment of spots or pimples on the face. Maximum strength 10% (P status).
- 231 Topical solution 2%.
- 232 Switched to self-medication in May 2002 in doses of 20mg/ml and 50mg/ml for male pattern baldness.
- 233 Topical solution 2%; maximum 3.6g per pack.
- 234 Non-prescription strength for the treatment of androgenetic alopecia upped to 5% on 1 July 2005.
- 235 Topical solution 2% for application to the scalp. Also 5% solution for the treatment of alopecia androgenetica in persons aged 18 to 65 years.
- 236 External use 2%, no public advertising.
- 237 Maximum strength: 2% (for the treatment of alopecia).
- 238 Since 1997, solutions of 20mg/ml, 60mg/ml and 3 x 60ml is OTC. Since 2000, also solutions 50mg/ml in packs of 1 x 60ml or 3 x 60ml.
- 239 Maximum strength 2% for the treatment of alopecia androgenetica in men and women. Maximum 5% in men aged 18–65 years (but not in women).
- 240 Up to 0.5g per dose.
- 241 Maximum strength 2% for vaginal cream and pessary.
- 242 Vaginal candidiasis only.
- 243 External use for treatment of vaginal candidiasis. As from 2004, a combination pack of a 500mg pessary and 2% cream may be supplied on general sale for the treatment of candidal vulvovaginitis (thrush).

- 244 In doses up to 0.1g.
- 245 Up to 400mg x 3 units in pessaries for external use.
- 246 Vaginal mycosis (a three day treatment)
- 247 Vaginal candidiasis only.
- 248 External use only for the treatment of vaginal candidiasis.
- 249 Only 0.5mg pessary and 1mg/g vaginal ointment.
- 250 Switched to OTC as emergency contraceptive: 2 tablets of 0.75mg.
- 251 2 x 0.75mg tablets switched to self-medication in January 2002. Rx for persons under 15.
- 252 This was the first non-prescription emergency contraceptive in the European Union to use levonorgestrel as a single ingredient (June 1999). Maximum dose 1,5mg (since 2004); maximum pack size 1.5mg per pack; maximum treatment period: one day (since 2004). Since December 2000: free and anonymous supply to women under 18.
- 253 Scheduled to be switched to OTC status in January 2004 (pending): 2 tablets of 0.75mg.
- 254 OTC since 2009 for use as an emergency contraceptive. Maximum strength 0.75mg.
- 255 Since 2001 as an emergency hormonal contraceptive: two tablets of 0.75mg.
- 256 Since 2001 as an emergency hormonal contraceptive. Specific delivery: only women aged 16 years and over. Otherwise it can be prescribed for any age group.
- 257 The United Kingdom became the first country in the world in December 2009 to switch the ingredient tamsulosin to non-prescription (pharmacy-only) status for short-term use in men aged 45 to 75 to treat the symptoms of benign prostatic hyperplasia (BPH) following a consultation with a pharmacist. Patients will need to obtain a GP diagnosis prior to longer-term use and annual check-ups are recommended thereafter. Tamsulosin will also continue to be available on prescription.
- 258 Azithromycin 500mg tablets switched to non-prescription status to treat chlamydia for persons 16 years and over if they have tested positive for the infection and have no symptoms, and for their sexual partners. A Nucleic Acid Amplification Technique (NAAT) test – a urine test – detects the nucleic acid of the Chlamydia trachomatis bacterium.
- 259 OTC only in combination and low dosage.
- 260 OTC for external use against pain and swellings after blunt traumata, muscle tensions and lumbago, and OTC for use in the oral cavity.
- 261 Cream 5%.
- 262 Topical use: maximum strength 3.0%. Throat spray: maximum strength 0.15% and maximum pack size 30ml.
- 263 Topical use: maximum strength 5%. For mouth and throat pains: Solution: maximum strength 0.15%. Solution for oral pulverisation: maximum strength 2.04mg/pulsation and 6.12 mg per day. Oral forms: maximum 3mg/dose.
- 264 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago.
- 265 Maximum strength 5%.
- 266 Oral form switched to OTC status in January 2004; maximum single dose is 25mg; maximum daily dose is 75mg.
- 267 Oral use: 25mg/tablet OTC; 50mg/tablet Rx.
- 268 Since 2002: tablets are OTC for adults and children over 14 in a maximum dose of 25mg; maximum daily dose 75mg.

- 269 Tablets 25mg, maximum 20 units/package.
- 270 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago”.
- 271 Cutaneous spray gel 4% with indications: inflammation associated with trauma of the muscles, joints and ligaments (for example, sprains, strains and bruises). Gel 11.6mg/g with indications: sprains, strains and sport injuries. Should not be used for more than 14 days. Not for children under 12 years.
- 272 For topical use; maximum concentration 1%; maximum pack size 60g. Eye drops remain Rx (List II).
- 273 Topical diclofenac has been OTC since 1999 with a maximum concentration of 5% (in rheumatic and muscular pain).
- 274 Maximum strength 1%.
- 275 External use for local symptomatic relief of pain and inflammation in muscles, joints etc and in localised soft tissue rheumatism. Maximum strength 1%, maximum pack size 30g, and maximum period of treatment 7 days. Not for use in children under 12.
- 276 Not registered but marketed as a “health product” under cosmetics regulation.
- 277 For external use, cream or gel maximum 1% for adults and children over 12.
- 278 Currently not on the market..
- 279 External form (as diethylammonium and sodium) with maximum strength of 1.16%. For local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of soft-tissue rheumatism in adults and children over 12 years, for maximum 7 days. Maximum pack/container size increased from 30g to 50g. Indication for diclofenac diethylammonium: for the relief of the pain of non-serious arthritic conditions. Diclofenac sodium is available OTC for the relief of pain and inflammation associated with sprains and strains, for maximum 7 days. Maximum dose: 40mg; maximum daily dose: 120mg; maximum strength: 4%; maximum pack size: 25g of product.
- Diclofenac 1% topical gel may be supplied on general sale for the symptomatic relief of pain and inflammation associated with trauma of the muscles, joints and ligaments (for example, sprains, strains and bruises), and with localised forms of soft tissue rheumatism.
- In 2004 diclofenac 4% spray gel for the local symptomatic relief for mild to moderate pain and inflammation following acute blunt trauma of small and medium sized joints and peri-articular structures e.g. sprains and strains. For use in adults, elderly and children over 15 years of age. Maximum daily dose 15 pump strokes (3g of spray containing 120mg of diclofenac sodium). Treatment period must not exceed 7 days without review. Maximum pack size 30 mL (25g).
- 280 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago.
- 281 Public advertising not allowed.
- 282 Maximum strength 5%..
- 283 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago”.
- 284 External use for local symptomatic relief of pain and inflammation in muscles, joints etc. and in localised soft tissue rheumatism. Maximum strength 3.17%, maximum pack size 30g, and maximum period of treatment 7 days. Not for use in children under 12.
- 285 Public advertising not allowed.
- 286 3% felbinac as a topical analgesic. Can be advertised to consumers.
- 287 Maximum pack size increased to 50g from 30g.

288 Lozenges. Limit per unit 8.75mg, limit per pack 140mg.

289 Lozenges switched to OTC status on 1 July 2004 for the short-term symptomatic treatment of painful inflammations of the throat.

290 Throat lozenges. Maximum strength 8.75mg; maximum daily dose 43.75mg (i.e. 5 lozenges) and maximum pack size 140mg (i.e. 16 lozenges). For use in adults and children not under 12 years.

291 Throat lozenges: maximum strength: 8.75mg; maximum daily dose: 43.75mg; maximum pack size: 140mg.

292 Oral form.

293 Available OTC as a food supplement. One presentation is registered as a prescription medicine.

294 Not registered as a medicinal product but available in food supplements.

295 Glucosamine 400mg tablets switched to non-prescription status in 2004 in packs of 90 for the symptomatic treatment of arthritis.

296 OTC status for internal use up to 400mg per dose and 1200mg per day. For children under the age of 12: prescription-only.

297 Ibuprofen immediate release tablets 200mg and 400 mg are OTC for adults and children over three months of age. For the same dosage, some products are Rx or OTC e.g. Malafène® 100ml: 100mg/5ml is Rx and Junifen® 100ml: 100mg/5ml is OTC.

298 Maximum strength 200mg.

299 Maximum pack size 30 tablets of 400mg (2007).

300 Solid oral forms: maximum dose 400mg (March 2007) and maximum pack size 6g. Liquid forms (switched in 2000): maximum concentration 2g/100ml and maximum pack size 4g. Maximum treatment period for both presentations: 5 days.

301 In 1996 also authorised in liquid form as an analgesic. From July 1998, the allowed maximum dose was raised to 400mg (instead of 200mg) and the maximum daily dose to 1200mg (instead of 800mg). As from 1 July 2005, ibuprofen became available without a prescription for the treatment of migraine headaches with and without aura.

302 OTC oral form maximum strength 200mg.

303 In all cases, maximum dose 400mg, maximum daily dose 1200mg. Maximum strength 400mg with maximum pack size of 25 for use in adults and children not under 12 years in muscular pain, backache, dental pain and dysmenorrhoea. Maximum strength 200mg with maximum pack size of 50 with no age restrictions for a wider range of indications including fever, headache, neuralgia and migraine.

304 Maximum dose 400mg. Liquid forms in maximum concentrations of 20mg/ml.

305 Maximum dose 200mg and maximum pack size 60 tablets for OTC use. Higher dosage is Rx.

306 Solid forms: Adults: maximum 400mg/dose. Maximum daily dose: 1200mg; Children: 5-10mg/Kg/dose. Maximum daily dose 20mg /Kg.

307 Maximum dose 400mg. Controlled release maximum dose 600mg. Maximum daily dose 1200mg. For use in rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, and symptoms of colds and influenza. In 1995, 200mg ibuprofen became GSL in pack size of 12 or under, in 1999 it was increased to pack size of 16 or under for all above indications except arthritic pain. Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza. In 2002, liquid ibuprofen became available GSL with a maximum strength of 2% for internal use. In 2002, ibuprofen tablets for children under 12 years of age with a maximum dose of

- 200mg and a maximum daily dose of 800mg became available GSL. In 2002, ibuprofen lysine tablets became available GSL for adults and children over 12 with a maximum strength of 200mg, a maximum daily dose of 400mg and a maximum pack size of 1200mg.
- 308 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago.
- 309 OTC up to 50mg.
- 310 Topical forms: maximum concentration 5% and maximum pack size 60g.
- 311 OTC maximum strength 5% and maximum quantity of product 60g. Suppositories switched to OTC in 2001 for light to moderate pain and fever.
- 312 External use for local relief of pain and inflammation in muscles, joints etc. and in localised soft tissue rheumatism. Maximum strength 5% and maximum pack size 30g and maximum period of treatment 7 days. For use in adults and children not under 12 years.
- 313 Not registered but marketed as a “health product” under cosmetics regulation.
- 314 5% ibuprofen as a topical analgesic. Can be advertised to consumers.
- 315 In 1996, maximum dose 125mg, maximum daily dose 500mg; maximum pack size 2.5g for rheumatic pain, muscular aches and pains, swellings such as sprains, strains, and sports injuries for use by adults and children over 12 years (general sale). In 2000 – for external use, maximum strength: 10%; maximum dose: 125mg; maximum daily dose: 500mg; maximum pack size: 50g (Pharmacy sale).
- 316 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago.
- 317 1% topical solution switched in 1996.
- 318 Public advertising not allowed.
- 319 Tablets with a dosage up to 25mg.
- 320 Non-prescription status for oral forms with a maximum dose of 25mg and a maximum pack size of 500mg.
- 321 OTC for external use for local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.
- 322 Switched OTC in 1990. Switched back to Rx in December 1994. In 1999, oral form OTC up to 25mg.
- 323 Oral form with a dosage of 25mg.
- 324 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago.
- 325 Topical use only.
- 326 Topical use only.
- 327 Maximum unit dose 25mg; maximum pack size 375mg; maximum strength 2,5% for topical use.
- 328 Switched for external use in analgesic and antirheumatic treatment in July 1998.
- 329 External use for local symptomatic relief of pain and inflammation in muscles, joints etc and in localised soft tissue rheumatism. Maximum strength 2.5%, maximum pack size 30g, and maximum period of treatment 7 days. Not for use in children under 12.
- 330 Switched OTC in 1990. Switched back to Rx in December 1994. In 1999, topical form OTC with concentration 1-15%.
- 331 Topical use is OTC but oral use remains Rx.

- 332 External use. Only cream forms. Maximum 2.5% p/p.
- 333 Topical use only: Only external form with maximum strength of 2.5%. For rheumatic and muscular pain in adults and children over 12 years, for a maximum of 7 days. Maximum pack/container size 30g.
- 334 Switched to OTC for veterinary use in horses in July 2002.
- 335 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago. For internal use as analgesic up to 200mg per dose and 600mg per day. For children under 12 years on medical prescription only.
- 336 Naproxen 220mg is OTC for adults and children over 12 years of age. Maximum daily dose = 660mg. Only one OTC product marketed: Aleve 220mg tablets.
- 337 Naproxen sodium 220 mg switched to OTC status in 2007 in pack sizes of 15 tablets.
- 338 OTC in 2001 for light to moderate pain and fever. In 2002, single dose increased to 250mg; maximum daily dose to 750mg; maximum pack size to 7500mg.
- 339 External use for local symptomatic relief of pain and inflammation in muscles, joints etc and in localised soft tissue rheumatism. Maximum strength 5%, maximum pack size 30g, and maximum period of treatment 7 days. Not for use in children under 12.
- 340 For topical use; maximum concentration 10%; maximum pack size 50g. No consumer advertising allowed.
- 341 Aleve (220 mg naproxen-sodium) was switched to non-prescription status in 1997. In 2007, the 550 mg version, Aleve Intense, was switched from Rx to OTC.
- 342 As oral analgesic, naproxen 200mg was switched in 1996 (consumer advertising allowed). Maximum daily dose 600mg. For adults and children over 16 only. Topical form (maximum strength 10%) switched in 2004. For adults and children over 12. Combinations are not allowed.
- 343 Naproxen 250mg switched to non-prescription status in 2008 for the treatment of primary dysmenorrhoea for women aged between 15 and 50 years.
- 344 Concentrations with a penetrating excipient up to 2.5%; with a non-penetrating excipient up to 3%.
- 345 For topical use against pain and swelling after blunt injuries, cramped muscle and lumbago.
- 346 Pack size 25g (0.5% gel) is OTC.
- 347 External use for local symptomatic relief of pain and inflammation in muscles, joints etc and in localised soft tissue rheumatism. Maximum strength 0.5%, maximum pack size 30g, maximum period of treatment 7 days. Not for use in children under 12.
- 348 Without prescription (public advertising not allowed).
- 349 For topical use, maximum strength 0.5%.
- 350 Maximum strength 0.5%. For relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains, and sports injuries in adults and children over 12 years, for a maximum of 7 days. Maximum pack/container size 30g.
- 351 For topical use against swelling and pain after blunt injuries, sprains, effusions, sport injuries, lumbago, stiff neck and cramped muscle". Product registered but not marketed.
- 352 Cream, concentration: 5%; maximum pack size: 3g.
- 353 Cream, concentration: 10%; maximum pack size: 4g.
- 354 External use and for external anal area.
- 355 Topical use only and only in combination.

- 356 Limit per unit 10mg. For topical use in the treatment of mouth and throat. Up to 5% for dental drops and up to 10% for external use.
- 357 Any use except local ophthalmic use.
- 358 Topical use (sore throat and for the relief of haemorrhoids).
- 359 General sale if maximum strength is 3%. For use in adults and in children aged 12 years and over, except ophthalmic use. A spray formulation containing 1% benzocaine and 0.5% mepyramine maleate may be supplied on general sale for the treatment of insect bites and stings, nettle stings and jellyfish stings in adults and children aged 2 years and over. Maximum pack size 30ml.
- 360 OTC sale only under the supervision of a pharmacist.
- 361 Maximum strength: 1%.
- 362 In combinations only.
- 363 For rectal preparations, maximum strength 1.2% for ear drops.
- 364 Any use except local ophthalmic use subject to a maximum strength of 3%.
- 365 Dosage 1% as topical anti-haemorrhoid.
- 366 Only available in combinations.
- 367 Maximum strength is equivalent to 3% cinchocaine in non-ophthalmic preparations.
- 368 Only in lozenges.
- 369 Limit per pack is 1g for rectal preparations / Limit per pack is 0.05 g as mixtures in patches. Since 2001, maximum dose is 5g in self-medication.
- 370 Oral/topical form is OTC only for adults and children over 6 years. Topical form is OTC for benign post-traumatic pain or as an anti-haemorrhoidal. Topical form is also OTC in association with a local skin disinfectant.
- 371 Ophthalmic use is Rx. Eardrops recommended for re-switch to Rx status as of 1 January 2005.
- 372 Any use except local ophthalmic use.
- 373 Depending on the presentation form.
- 374 a) Sore throat: Solid forms: maximum daily dose for adults: 16mg; maximum daily dose for children over 6 years: 8mg / Liquid forms: maximum daily dose for adults: 16mg; maximum dose daily for children over 12 years: 8mg
b) Relief of haemorrhoids: maximum strength 2%.
- 375 Lidocaine preparations: For external use except ophthalmic use (which is pharmacy-only). Maximum strength is 2% for use in adults and children aged 12 years and over and in any type of preparation except spray. Product for internal use is available on general sale in a maximum strength of 0.7%. The temporary relief of pain caused by recurrent mouth ulcers and denture irritation is a suitable GSL indication for lidocaine hydrochloride 2% gel.
A spray containing hydrocortisone 0.2% and lidocaine hydrochloride 1.0% may be supplied on general sale for the symptomatic relief of anal and perianal itch, irritation and pain associated with external haemorrhoids. Maximum pack size 30ml.
- 376 Only in association.
- 377 Ophthalmic use is prescription only.

378 For internal use and only as a constituent in antacids.
379 Maximum dose 10mg; maximum daily dose 30mg. Pack size containing maximum 400mg. No OTC product marketed yet.
380 Any use except local ophthalmic use.
381 Ophthalmic use is Rx. No OTC product marketed yet.
382 Topical use only and only in combination.
383 For topical use in anti-haemorrhoidal cream.
384 Topical use OTC since 1992: maximum strength 1%; for the relief of haemorrhoids since 1986.
385 Topical use only.
386 Limit per pack is 0.05g as mixture in patches. Since 2001, available in maximum dose of 5g for self-medication.
387 Any use except local ophthalmic use.
388 In combination with lidocaine.
389 Ophthalmic use is Rx. No OTC product marketed yet.
390 Up to 1g per dose and 3g per day. Children under 12 years of age only with medical prescription.
391 Dosage of 1g authorised.
392 Dosages of 1g are not authorised.
393 As antipyretic-analgesic for short term use in a dose of 1g; maximum daily dose: 3g; children under 3 years: Rx.
394 Maximum dose 650mg. Maximum daily dose 4g. Not for use in children under 12 years of age.
395 OTC status only for adults; maximum dose 500mg/tablet, only as analgesic.
396 Dosages up to 1g are authorised.
397 100mg is Rx for some specific therapeutic indications.
398 Do not use in persons under 16 years old.
399 Tablets of 250mg and 500mg, effervescent tablets of 320mg and 500mg.
400 In 2002, dose of acetylsalicylic acid for general sale was set at 75mg in packs of up to 28 tablets. Pharmacy only: Pharmacists can sell individual packs of 32; multiple packs up to a total quantity of 100 capsules or tablets in justifiable circumstances.
401 OTC status for 250mg (20 tablets). Rx status for 500mg (30 tablets).
402 Narcotic substance.
403 Maximum dose 10mg and maximum strength 1.5%.
404 In undivided preparations or in single dose preparations, maximum strength is 1.5% (calculated as base) and maximum dose is 10mg (calculated as base). Advertising to public possible through all media. Combination with paracetamol possible with these restrictions.
405 Naratriptan tablets switched to non-prescription status on 1 April 2006 in a single dose of up to 2.5mg and a maximum pack size of 5mg.

- 406 OTC status up to 650mg per dose and 2g per day, with the statement “Not longer than 10 days running without medical order. With longer treatment or excessive dose (more than 2g per day) liver and kidney defects cannot be excluded. Children under 3 years of age, only with medical prescription.”
- 407 OTC status for immediate release tablets, syrups and suppositories for adults and children of all ages. Limited packs sizes. Extended release tablets to become prescription-only.
- 408 Limit per pack for tablets 6g (500mg per unit). Limit per pack for oral solutions is 1.5 g. Limit per pack for suppositories is 1.5 g (250mg per unit).
- 409 In 2000, maximum daily dose 4 g (for adults and children over 50kg) in case of “more intense pain”.
- 410 OTC status up to 1g.
- 411 In a dose of 1g; maximum daily dose: 3g; solution for children under 3 years Rx; solid forms for children under 12 years: Rx.
- 412 Maximum dose 1g; maximum daily dose 4g. Medicinal Products (Control of Paracetamol) Regulations, 2001 restricts pack sizes as follows: Pharmacy packs- maximum 24 x 500mg (or equivalent), maximum 140ml paediatric/junior formulations (not more than 120mg per ml), maximum 70 ml liquid forms containing 120-250mg per ml paracetamol. Pharmacists may sell a maximum of 50 tablets at one time. Packs for sale in non-pharmacy outlets - single ingredient only, maximum 12 x 500mg (or equivalent), maximum 60ml paediatric/junior formulations.
- 413 OTC status for 500mg x 10 tablets.
- 414 OTC status up to 1g.
- 415 In 1998 – non-effervescent tablets and capsules: maximum strength (adults): 500mg, maximum strength (child under 12): 120mg; maximum pack size: 32; maximum quantity: 100 tablets or capsules all other preparations. 500mg: may be sold to the public provided packs contain no more than 32 capsules or tablets; pharmacists can sell multiple packs up to a total quantity of 100 capsules or tablets in justifiable circumstances. In 2000 – maximum strength replaces 120mg with 250mg. In 2001, liquid paracetamol became available GSL in 5% strength for use in children aged 6 to 12; maximum unit dose 5ml; maximum pack size 10 unit doses. 2005: Orodispersible tablets containing 250mg paracetamol may be supplied GSL for use in adults and children aged 6 years and over. Liquid preparations of paracetamol with a strength of 2.4% or less may be supplied GSL in multidose containers of not more than 100ml.
- 416 Associations of analgesics with codeine were back-switched to Rx on 1 March 2002.
- 417 Only the oral combination “paracetamol + codeine” is registered and is Rx.
- 418 Dihydrocodeine: maximum dose 10mg (calculated as base). Maximum strength 1.5%(calculated as base) .
- 419 2 x 50mg sumatriptan oral tablets switch in acute migraine attacks with or without aura in adults aged 18-65 years to be discussed in January 2009. Effective date could be 1 October 2009.
- 420 Sumatriptan 50mg tablets switched to non-prescription status on 19 May 2006. For the acute relief of migraine attacks.
- 421 Zolmitriptan 2.5mg tablets proposed for switch to non-prescription status in August 2005. For the acute treatment of migraine with or without aura.
- 422 No product listed.
- 423 Only for dermatological indication. Maximum dose 25mg per tablet; maximum daily dose 75mg for adults and 50mg in children aged 6-12 years. Maximum pack size 750mg. However, there is no marketed OTC product yet.

- 424 For the treatment of nausea and vomiting in previously diagnosed migraine only, in those aged 18 years and over. Maximum strength 3mg; maximum dose 12mg; maximum pack size 8 tablets.
- 425 4mg gums are OTC and can be advertised to consumers. Up to 420mg per pack (2005).
- 426 On 1 July 2004, all oral forms of nicotine and its salts gained non-prescription status for a single dose of 10mg and a maximum daily dose of 64mg.
- 427 In 1995, the 4mg dosage received OTC approval.
- 428 Maximum strength 4mg per gum.
- 429 Maximum strength 4mg per gum. As from November 2009, a combination pack containing nicotine patches releasing 15mg over 16 hours of continuous application together with nicotine 2mg gum may be supplied on general sale as an aid to smoking cessation.
- 430 Put on the market straight away as an OTC.
- 431 Maximum strength 10mg; maximum pack size 420mg.
- 432 Maximum strength 10mg; maximum daily dose 64mg.
- 433 Launched as OTC product.
- 434 Maximum strength 15mg/16 hours or 21mg/24 hours.
- 435 Maximum release: 1mg/hour.
- 436 As from November 2009, a combination pack containing nicotine patches releasing 15mg over 16 hours of continuous application together with nicotine 2mg gum may be supplied on general sale as an aid to smoking cessation.
- 437 4mg gums and 4mg sublingual tablets are OTC and can be advertised to consumers. Up to 420mg per pack (2001).
- 438 Lozenges: maximum dose 1.5mg. Compressed lozenges: maximum dose 4mg.
- 439 Only registered for veterinary use!
- 440 Maximum dose 100mg, up to 600mg per pack (i.e. 2%).
- 441 Veterinary use OTC (Flubenol Vet).
- 442 OTC up to 100mg.
- 443 100mg is OTC.
- 444 Veterinary use is OTC (Telmin Vet).
- 445 For oral use in the treatment of enterobiasis in adults and in children over 2 years. Maximum dose 100mg. Container or package containing not more than 800mg of medicinal product.
- 446 For veterinary use.
- 447 Pyrantel embonate.
- 448 Pyrantel embonate.
- 449 Pyrantel pamoate.

450 Pyrantel embonate. Anthelmintic against threadworms (*enterobius vermicularis*). Combination products not allowed. Not for use in children under 2 years. Unique dosage:
10mg/Kg. Maximum dose: 1g.

451 Veterinary use is OTC (Banminth Vet).

452 Product discontinued.

453 Only veterinary products are available.

454 Switched back from OTC to Rx in 1996.

455 OTC between 1982 and 2004. Switched back to Rx status in 2004.

456 Product discontinued.

457 In nasal applications up to 0.1%.

458 Nasal spray. Up to 0.1%.

459 Switch of anti-allergic nasal sprays containing azelastine approved in January 1997. Switch of eye drops approved at the end of 2002.

460 For nasal use in a non-aerosol aqueous form for the treatment of seasonal allergic rhinitis in adults and children not less than 12. Maximum dose 140 micrograms per
nostril, maximum daily dose 280 micrograms per nostril, and maximum pack size 5040 micrograms of azelastine hydrochloride.

461 Drops maximum 0.14mg/U.D. or spray 0.56mg/day for adults and children over 12 (EFP = non-Rx with public advertising). In 2007, antihistamine eye drops: maximum
0.05% p/p.

462 Azelastine hydrochloride. For nasal administration in aqueous form (other than by aerosol) for the treatment of seasonal allergic rhinitis in adults and children aged 12 and
over. Since 2000, also for perennial allergic rhinitis in those over five years of age. Maximum dose 140 micrograms per nostril. Maximum daily dose 280 micrograms per
nostril. Pack/container size containing maximum 5040 micrograms. In 2002, eye drops containing 0.05% azelastine became available for the treatment of seasonal and
perennial allergic conjunctivitis.

463 Limit per pack 100mg for nasal sprays.

464 Nasal spray switched to OTC in 2002; maximum unit dose 100µg; maximum pack size 5mg.

465 For intranasal short-term use in seasonal rhinitis. Maximum pack size 5.5mg. For adults and children over 12.

466 For use as a nasal spray in the prevention and treatment of seasonal allergic rhinitis in persons aged 18 and over. Maximum dose 100 micrograms per nostril, maximum
daily dose 200 micrograms per nostril, maximum pack size 9000 micrograms of beclometasone, maximum period of treatment 3 months.

467 Maximum dose 100µg; maximum daily dose 400µg. Combinations are not allowed. Only for people over 18. Maximum treatment period: one week.

468 As dipropionate, for nasal administration (other than by aerosol) for the prevention and treatment of allergic rhinitis in adults over 18 years. Maximum dose 100
micrograms per nostril. Maximum daily dose 200 micrograms per nostril. Maximum period of treatment 3 months. Pack/container size containing maximum 20000
micrograms.

469 For nasal administration in aqueous form (other than by aerosol) for the prevention and treatment of seasonal allergic rhinitis in adults over 18 years. Maximum dose 200
micrograms per nostril. Maximum daily dose 200 micrograms per nostril. Maximum period of treatment 3 months. Pack/container size containing maximum 10mg.

470 For the treatment of the nasal mucous membrane. June 2003: for use in eye drops up to 2%.

471 Eye drops; maximum strength 2%; maximum pack size 200mg. January 2007: nasal spray maximum strength 2%. Maximum pack size 300mg.
472 When intended for administration through the nose or as eye drops.
473 OTC for the prophylaxis of hayfever; Rx for the prophylaxis of asthma.
474 Anti-allergic agent for topical nasal and ophthalmic use. Maximum strength 2%. No combination products.
475 2000: maximum dose 40mg/ml; maximum pack size 60 units.
476 For nasal use. Eye drops for treatment of acute seasonal or perennial allergic conjunctivitis in maximum strength 2%. Maximum pack size 10ml. (Ointment no longer on UK market).
477 OTC for nasal ointments, nasal oils and for topical use up to 3%.
478 Non-prescription for oral and auricular use. Maximum 1g per pack (5%). Cannot be available directly over the counter.
479 a) Nasal use. Not for children under 6 years. Maximum strength 0.5%. b) Relief of haemorrhoids (vasoconstrictor).
480 Nasal sprays or nasal drops of ephedrine hydrochloride are OTC with maximum strength equivalent of 2% ephedrine. Only 0.5 and 1% ephedrine hydrochloride nasal drops available on UK market. There are non-proprietary ephedrine nasal drops available for sale through pharmacies. As from 1 April 2008, nasal decongestants containing more than 720mg pseudoephedrine and 180mg ephedrine per pack were switched back to prescription-only status.
481 OTC for external use only.
482 Bronchitis, whooping cough and cough in connection with respiratory tract infections.
483 One infusion for anaphylactic shock is non-prescription on the Belgian market.
484 In the form of a non-pressurised nasal spray for the prevention and treatment of seasonal allergic rhinitis (including hay fever) in persons aged 18 and over. Maximum strength 0.025%, maximum dose 50 micrograms per nostril, maximum daily dose 100 micrograms per nostril, maximum pack size 6000 micrograms of flunisolide, maximum period of treatment 3 months.
485 Maximum strength 0.025%. For nasal administration in non-pressurised nasal spray for the prevention and treatment of seasonal allergic rhinitis including hay fever, in adults over 18 years. Maximum dose 50 micrograms per nostril. Maximum daily dose 100 micrograms per nostril. Maximum period of treatment 3 months. Pack/container size containing maximum 6000 micrograms.
486 9/2004: Fluticasone propionate 50 mikrog/dose, 60 doses for the prophylaxis and treatment of allergic rhinitis in children and adults. Maximum daily dose 2 sprays into each nostril twice a day.
487 Nasal spray for the prevention and treatment of allergic rhinitis, including hay fever. Maximum dose 100mcg per nostril, maximum daily dose 200mcg per nostril, maximum pack size 3000mcg and maximum period of treatment 6 months. For use in adults and children not under 12 years.
488 Fluticasone propionate 0.05% for the prophylaxis and treatment of allergic rhinitis in those aged 18 years and over. Maximum pack size 60 metered sprays; maximum daily dose 2 sprays into each nostril twice a day. Should not be used for more than 3 months without consulting the doctor.
489 In eye drops and nose spray.
490 Nasal spray 0.5mg/ml for allergic rhinitis.
491 Levocabastine in eye drops in a maximum concentration of 0.05% w/w was switched to non-prescription status on 15 December 2009. Maximum pack size 2.5 mg.

492 As a nasal and ocular antihistamine: maximum strength 0.05%.

493 Nasal spray 50 µg/dose, 15 ml and eye drops 0.5mg/ml in bottles of 4 ml.

494 Maximum strength: 0.05%. For adults and children over 12 years. Maximum treatment period 4 weeks. Nasal spray: For the symptomatic treatment of seasonal allergic rhinitis; maximum pack size 10mL. Aqueous eye drops: For the symptomatic treatment of seasonal allergic conjunctivitis; maximum pack size 4mL.

495 Mometasone furoate nose spray, suspension 50µg/dose, 140 doses, switched to non-prescription status in 2004.

496 OTC for nasal use up to 0.1% and for external use in the eye up to 0.1% only.

497 In eye drops.

498 All products are associations.

499 OTC as eye drops (maximum strength 0.015%) and as nasal drops or spray not containing liquid paraffin as a vehicle (maximum strength 0.05%).

500 Decongestant agent for topical nasal use (not for children under 6 years). Strengths: 0.05% or 0.025%). For ophthalmic use: strengths from 0.01% to 0.03%.

501 OTC as eye drops (maximum strength 0.015%) and as nasal drops or spray not containing liquid paraffin as a vehicle (maximum strength 0.05%). No OTC product marketed yet.

502 OTC for treatment of the nasal mucous membrane.

503 Up to 0.05% for nasal drops and sprays.

504 Decongestant agent for topical nasal use (since 1982). Not for children under 6 years. Strengths: 0.05% and 0.025%. For ophthalmic use (since 1992): maximum strength 0.025%.

505 If non-oily nasal sprays and nasal drops, maximum strength 0.05%.

506 OTC for the treatment of nasal mucous membrane and for topical use up to 0.5%.

507 Maximum strength 0.5% for topical use and nasal sprays.

508 Nasal preparations are Rx. Cannot be available over the counter.

509 Maximum dose for OTC status 2.5%.

510 For internal use, maximum dose 10mg; maximum daily dose 40mg.

511 For the eyes.

512 Topical use: (a) Decongestant for topical nasal use (not for children under 6 years; strengths: 0.5%, 0.25% and 0.125%) or for ophthalmic use (strengths from 0.08% to 0.2%). (b) Relief of haemorrhoids (vasoconstrictor).

513 (As hydrochloride). General sale if internal (all preparations except nasal drops, nasal sprays, and nasal inhalations equivalent to maximum dose 10mg phenylephrine).

514 OTC for nasal ointments, nasal oils and for topical use up to 3% and up to 60mg per dose with the statement “Do not use long term or in higher doses or rather concentrations than recommended without medical prescription”.

515 Cannot be available directly over the counter.

516 OTC for internal use. All prolonged release products – maximum dose 120mg, maximum daily dose 240mg. Any other products – maximum dose 60mg, maximum daily dose 240mg. Since 2008: not indicated for children under 2.

517 Maximum daily dose 360mg. In several doses.
518 In 1995, the maximum daily dose was increased from 180mg to 240mg. In 1997, increase in maximum dose in sustained release form to 120mg (from the previous 90mg).
As from 1 April 2008, nasal decongestants containing more than 720mg pseudoephedrine and 180mg ephedrine per pack were switched back to prescription-only status.
519 Tetryzoline.
520 Topical use: (a) Decongestant for topical nasal use. Not for children under 6 years. (b) Ophthalmic use: Strengths from 0.01% to 0.05%.
521 For nasal use up to 0.1%.
522 For nasal use. Not for children under 6 years old.
523 OTC for the treatment of nasal mucous membrane.
524 Limit per pack 10mg. Up to 0.1% for nasal drops and sprays.
525 Up to 0.1% for nasal drops and sprays.
526 Decongestant agent for topical nasal use. Only for people over 6 years. Strengths: 0.1% and 0.05%.
527 (as hydrochloride) general sale if non-oily nasal sprays and nasal drops maximum strength 0.1%.
528 For external use in multi-ingredient products
529 OTC. For sore throat. Unit dose 200 UI. Maximum daily dose: Adults: 1600 UI; children 6-15 years: 800 UI.
530 Throat lozenges and throat pastilles only.
531 OTC. For sore throat. Not for use in children under 6 years. Maximum dose: 1mg per tablet.
532 Pastilles and lozenges only.
533 Theophylline is OTC in Belgium but if it is prescribed the product is reimbursed.
534 For inhalation.
535 For oral use.
536 Limit per pack 6 g (200mg per unit).
537 OTC: 100mg/sachet & 200mg/sachet: Rx: 600mg/sachet.
538 Any use except ophthalmic.
539 Without prescription (public advertising not allowed).
540 Since 2001: in children from 6-12 maximum dose 100mg; maximum daily dose 300mg. In children from 12-18: maximum dose 200mg; maximum daily dose 600mg. In adults:
maximum unit and daily dose 600mg.
541 For oral use up to 75mg.
542 Ambroxol chlorhydrate, oral form, 60mg per dose (0.6%). Maximum pack size 2g.
543 Maximum dose 60mg; maximum daily dose 120mg. Not for children under 12 years.
544 OTC for internal use.
545 Limit per pack 240mg (8mg per unit). For cough medicines.

546 Syrups, suppositories, tablets and sachets are OTC. Ampoules are Rx.

547 Mucolytic. Children from 6 to 12 years: maximum dose 4mg, maximum daily dose 12mg. Over 12 years: maximum dose 16mg; maximum daily dose 48mg.

548 Maximum pack size 10 g (750mg per unit). For cough medicines.

549 OTC for internal use.

550 5% syrup is OTC (consumer advertising allowed); all other forms are non-prescription but no consumer advertising allowed.

551 Mucolytic. Not for use in children under 12 years. Maximum dose 750mg. Maximum daily dose: 2.25 g.

552 Associations of analgesics with codeine were back-switched to Rx on 1 March 2002.

553 In combination with acetylsalicylic acid.

554 Limit per pack 300mg,; maximum strength 0,1%; maximum dose 20mg per unit; limit 150mg in syrup. Advertising to public is prohibited. Combination with acetylsalicylic acid and paracetamol possible under these restrictions.

555 Maximum strength 1.5%, maximum dose 20mg. Advertising to the public is prohibited. Combination with acetylsalicylic acid possible under these restrictions.

556 Maximum pack size 300mg (15mg per unit of 15mg/ml of cough syrup). Public advertising allowed in all media..

557 In undivided preparations or in single dose preparations, maximum strength is 1.5% (calculated as base) and maximum dose is 20mg (calculated as base). Advertising to public possible through all media. Combination possible with acetylsalicylic acid or paracetamol under these restrictions.

558 Up to 15mg dextromethorphan per dose and in combination with substances which are not centrally effective antitussive and narcotic analgesics.

559 Tablets and liquids.

560 Limit per pack 600mg (30mg per unit). For liquid cough medicines, if there is enough of an abuse-preventing substance such as sorbitol in the composition.

561 For the treatment of dry coughs and irritation of the throat in adults of 15 years and over and children of 6 years (or 20kg) and over. Maximum dose 30mg per unit; maximum strength 0.3%; maximum daily dose 120mg; maximum pack size 400mg.

562 OTC for internal use. For controlled release preparations, maximum dose 30mg; maximum daily dose 75mg. In any other case, maximum dose 15mg; maximum daily dose 75mg.

563 Restricted to pharmacy-only distribution as from 1 March 2009.

564 For cough. Maximum daily dose 120mg. In several doses.

565 (Hydrobromide) In case of a prolonged-release preparation, equivalent of maximum dose 30mg; maximum daily dose 75mg. In any other case, equivalent of: maximum dose 15mg; maximum daily dose 75mg.

566 Without prescription. No consumer advertising allowed.

567 Limit per pack 600mg (50mg per unit).

568 Maximum dose 40mg; up to 800mg per pack.

569 In association with guaiphenesin or propyphenazone.

570 Limit per pack 96mg (8mg per unit).

- 571 Maximum daily dose 24mg. Pack/container size containing maximum 240mg. 8mg capsules may be supplied GSL for the symptomatic relief of allergic rhinitis, including hayfever, and chronic idiopathic urticaria, in adults and children aged 12 to 65 years.
- 572 Oral form: maximum dose 12mg; maximum pack size 240mg (0.05%). Suppositories: maximum dose 6mg; maximum pack size 60mg.
- 573 In combination for common colds. Only adults. Maximum daily dose: 24mg. In several doses.
- 574 In combinations only.
- 575 In combination for common colds: maximum of 16mg/day (Children over twelve: 8mg/day). In several doses.
- 576 Oral forms of up to 10mg per dose and day.
- 577 Tablet form only.
- 578 Limit per pack 70mg (10mg per tablet). 10 mg/ml (drops)
- 579 Oral form, 10mg per tablet, 70mg per pack.
- 580 No limitation, e.g. in dosage, package size or indication.
- 581 Maximum daily dose 10mg, maximum strength 10mg and maximum pack size 10.
- 582 In combination.
- 583 Unit dose in children of 6-12 years: 5mg; in adults and children over 12: 10mg.
- 584 Dose 10mg, for allergy in nose and eyes.
- 585 Maximum daily dose 10mg; maximum pack size 100mg. In 2002, the pack/container size limit of maximum 100mg was removed for pharmacy-only products. In 2002, this formulation became available GSL in packs of maximum 7 tablets. As from 2004, the conditions for general sale supply were extended to include liquid preparations, for use in adults and children aged six years and over.
- 586 Only external use.
- 587 For nasal use: only persons over 6 years. Maximum strength: 0.5%. In combination for common colds: Adults: maximum daily dose 24mg. In several doses. Children between 6-12 years: maximum daily dose 8mg.
- 588 Up to 0.1% for topical use.
- 589 Only external use.
- 590 In combination for common colds. Only for adults. Maximum daily dose: 12mg. Doses of 2mg every 4-6 hours. Retard forms: 6mg every 12 hours; maximum daily dose 12mg.
- 591 a) Topical antihistamine (since 1995): Maximum strength 0.2%. Not for sun burns.
b) Oral forms (since 2004): For children from 6 to 12: maximum daily dose 6mg; for people over 12, maximum daily dose 12mg.
- 592 Only topical use.
- 593 Topical use.
- 594 For oral and topical use. Oral use (allergy relief). Maximum single dose: 1mg. Maximum daily dose: Adults: 5mg; Children: 2.5mg.
- 595 Not registered as an antihistamine but as an antitussive in combination with other ingredients, this product is classified as OTC.
- 596 Diphenhydramine injectable returned to Rx 2002.

- 597 For nasal, topical and oral use.
Oral use:
- a) Allergy relief. Maximum single dose: 50mg. Maximum daily dose: Adults: 300mg; Children over 6 years: 150mg
 - b) In combination for common colds. Only for adults. Maximum daily dose: 300mg. In several doses.
 - c) Relief of temporary sleeplessness. Not for use in children under 12 years. Maximum daily dose: 50mg.
 - d) Citrate: Relief of temporary sleeplessness. Not for use in children under 12 years. Maximum daily dose: 76mg.
- Nasal use: not for use in children under 6 years. Maximum strength: 0.1%.
- 598 Rx if liquid filled capsules.
- 599 Up to 0.5% for topical use.
- 600 In combination for common colds: maximum of 10mg / day. Only for adults. In several doses.
- 601 In combinations only.
- 602 Maximum dose 10mg and maximum daily dose 40mg.
- 603 In association.
- 604 Registered as anti-emetic.
- 605 Oral use. In combination for common colds. Only for adults. Maximum daily dose: 75mg. Relief of temporary sleeplessness.
- 606 10mg tablets in packs of 10.
- 607 10mg tablets in packs of 10, for temporary allergic symptoms such as red running and itching eyes, nasal congestion and sneezing.
- 608 Fexofenadine 120 mg to treat the symptoms of allergic rhinitis was recommended for non-prescription status on 15 December 2009.
- 609 5mg.
- 610 Currently not marketed..
- 611 Only in the case of allergic rhinitis and chronic urticaria.
- 612 Syrups are Rx.
- 613 Limit per pack 100mg, limit per tablet 10mg, maximum pack size 10 tablets.
- 614 Loratadine 10mg tablets switched in November 2006. Maximum pack size 70mg.
- 615 Maximum daily dose 10mg, maximum strength 10mg and maximum pack size 10.
- 616 Switched to non-advertisable non-prescription status in 2004. Maximum strength 10mg; maximum pack size 7 tablets.
- 617 Children from 6 to 12 years, maximum daily dose: 5mg. Over 12 years, maximum daily dose: 10mg.
- 618 2001: maximum OTC pack size increased from 14 to 28 10mg tablets. 2004: maximum OTC pack size increased from 28 to 30 10mg tablets.
- 619 Maximum daily dose 10mg. In 2002, this formulation became available GSL in a maximum pack size of 7 tablets. In November 2009, the maximum pack size available on general sale was increased from seven to 14 tablets. Limit on pack/container size containing maximum 100mg was removed for sales under supervision of a pharmacist in 2002.

620 There is a product against travel sickness containing 12.5mg meclizine hydrochloride per tablet.
621 As an anti-emetic agent..
622 For topical use only.
623 In combinations only.
624 Topical use only.
625 Syrup (0.1g) and tablets 0.025g.
626 In combination for common colds: maximum of 75mg/day. Only for adults. In several doses.
627 For topical use. General sale if maximum strength = 2% and if sold for symptomatic relief of insect stings and bites and nettle stings, in adults and children aged 2 years and over. A spray formulation containing 1% benzocaine and 0.5% mepyramine maleate may be supplied on general sale for the treatment of insect bites and stings, nettle stings and jellyfish stings in adults and children aged 2 years and over. Maximum pack size 30ml.
628 External use only. Public advertising not allowed.
629 Oral use only.
630 Cream for topical use is OTC (oral is Rx).
631 In 1995, promethazine maximum 2% was given OTC status as a topical antihistamine. Not for sunburns.
632 For topical use.
633 Maximum strength 2% for topical use for insect bites.
634 EFP as a topical antihistamine.
635 OTC for external use only.
636 OTC sale only under the supervision of a pharmacist.
637 In combination for common colds.
638 Only registered as eye drops.
639 Chloramphenicol 0.5% eye drops were switched to pharmacy-only (P) status in June 2005, in a pack size of not more than 10ml. The product - a broad spectrum antibiotic active against a wide range of bacteria - can be used for the treatment of acute bacterial conjunctivitis in children aged 2 years and over, adults and the elderly. The approved dosage is 1 drop every 2 hours for the first 48 hours and 4 hourly thereafter. The course of treatment is 5 days. Chloramphenicol eye ointment 1% switched to Pharmacy status in 2007 for the treatment of acute bacterial conjunctivitis.
640 Rx when used in combination with hydrocortisone.
641 Classified as a preservative.
642 Antiseptic for topical use.
643 Classified as an antiseptic.
644 Topical use: antiseptic and sore throat. Pills or tablets: maximum dose 0.25mg. Liquid: maximum dose: 5mg/ml (5%). Spray: maximum dose 0.3mg/ml (0.03%).
645 Cosmetic.

- 646 Cosmetic.
- 647 Potassium nitrate is not registered as a medicinal but as a cosmetic product.
- 648 Cosmetic.
- 649 Maximum dose for general sale is 100mg.
- 650 Up to a concentration of 10%.
- 651 Cosmetic.