

Legal classification status of selected ingredients worldwide

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 However, because of the rapidly changing situation, some information may be outdated.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 WSMI national associations in **December 2008**.

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Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
A. ALIMENTARY TRACK AND METABOLISM												
A01 Stomatological preparations												
Fluoride (sodium)	OTC	OTC ¹	OTC	Rx	N.R.	Rx	OTC	OTC	OTC	OTC ²	OTC ³	OTC ⁴
Hexetidine	OTC	N.R.	OTC	OTC	N.R.	N.R.	Rx	OTC	OTC ⁵	OTC ⁶	OTC	
Triamcinolone (<i>buccal</i>)	Rx	1996 ⁷	Rx	Rx	Rx	2006	OTC	N.R.	OTC ⁸	Rx	2002 ⁹	Rx
A02 Drugs for acid-related disorders												
Aluminium hydroxide	OTC	OTC ¹⁰	OTC	OTC	OTC	OTC	OTC	OTC	OTC ¹¹	OTC ¹²	N.R.	Rx
Calcium carbonate	OTC	OTC	OTC	Rx	2005	OTC	OTC	OTC	OTC	OTC ¹³	OTC	OTC
Carbenoxolone	N.R.	OTC ¹⁴	Rx	N.R.	Rx	N.R.	OTC	N.R.	OTC ¹⁵	Rx	OTC	
Cetraxate	N.R.	N.R.	N.R.	N.R.	N.R.	1987	Rx	N.R.	N.R.	N.R.	N.R.	
Cimetidine	OTC	1995 ¹⁶	OTC ¹⁷	Rx	OTC ¹⁸	1997	OTC	OTC	1994	Rx	1995 ¹⁹	1995 ²⁰
Famotidine	2005	1995 ²¹	1996 ²²	Rx	OTC ²³	1997	OTC	OTC	OTC	Rx	2000 ²⁴	1995 ²⁵
Lansoprazole	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	N.R.	Rx	N.R.	2009 ²⁶
Nizatidine	N.R.	1996 ²⁷	1998 ²⁸	Rx	Rx	2005	Rx	1998	OTC	Rx	Rx	1996 ²⁹
Omeprazole	2005	Rx	Rx	Rx	2004	Rx	Rx	OTC	Rx	Rx	Rx	2003 ³⁰
Pantoprazole	Rx	2008 ³¹	Rx	Rx	Rx	N.R.	Rx	OTC	Rx	Rx	Rx	Rx
Ranitidine	1997	1995 ³²	1997 ³³	Rx	OTC ³⁴	1997	OTC	OTC	OTC	OTC ³⁵	2000 ³⁶	1995 ³⁷
Sucralfate	Rx	OTC ³⁸	Rx	Rx	OTC	1987	OTC	1998	OTC	N.R.	OTC	Rx
A03 Drugs for functional gastrointestinal disorders												
Dicyclomine (Dicycloverine)	Rx	Rx ³⁹	OTC	Rx	N.R.	OTC	Rx	Rx	OTC	Rx	OTC	Rx
Dimeticone	N.R.	OTC ⁴⁰	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC ⁴¹	OTC	OTC

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Domperidone	Rx	Rx	Rx	OTC	OTC ⁴²	Rx	OTC	Rx	Rx	Rx	2000 ⁴³	Rx
Hyoscine butylbromide	OTC	199 ⁴⁴	OTC ⁴⁵	Rx		OTC	1979	2006	OTC	2000	Rx	
Mebeverine	Rx	Rx	N.R.	Rx	Rx	N.R.	OTC	Rx	Rx	Rx	OTC	
Metoclopramide	N.R.	2000 ⁴⁶	Rx	Rx	Rx	Rx	OTC	Rx	OTC ⁴⁷	Rx	Rx	Rx
Propantheline	N.R.	Rx ⁴⁸	OTC	N.R.	OTC	Rx	OTC	N.R.	OTC	N.R.	OTC	Rx
A04 Antiemetics and Antinauseants												
Dimenhydrinate (diphenhydramine and chlorotheophylline)	N.R.		OTC	Rx	OTC ⁴⁹	OTC	OTC	N.R.	OTC ⁵⁰	Rx	OTC	Rx
Hyoscine (Scopolamine)	2003	OTC ⁵¹	OTC	Rx	OTC ⁵²	1987 ⁵³	Rx	1998	OTC	Rx	OTC	Rx
A05 Bile and liver therapy												
Hymecromone	N.R.	N.R.	N.R.	N.R.	Rx	Rx	OTC	N.R.	N.R.	N.R.	N.R.	Rx
A06 Laxatives												
Bisacodyl	OTC	OTC ⁵⁴	OTC	Rx	OTC	OTC	OTC	1998	OTC	OTC ⁵⁵	OTC	OTC
Lactitol	Rx	N.R.	N.R.	N.R.	Rx	Rx	Rx	N.R.	N.R.	N.R.	N.R.	
Lactulose	OTC	OTC ⁵⁶	OTC	Rx	OTC ⁵⁷	Rx	Rx	Rx	OTC	Rx	OTC	Rx
Picosulfate (sodium)	OTC	OTC ⁵⁸	OTC	Rx	N.R.	1983	OTC	OTC	OTC	N.R.	N.R.	N.R.
A07 Antidiarrheals												
Loperamide	OTC	1987 ⁵⁹	1986	Rx	Rx	1989	OTC	Rx	OTC	OTC ⁶⁰	OTC	1988 ⁶¹
Nifuroxazide	N.R.		N.R.	Rx	N.R.	N.R.	OTC	OTC	N.R.	Rx	Rx	
A08 Antiobesity preparations												
Orlistat	Rx	2004 ⁶²	Rx	Rx	2005	N.R.	Rx	Rx	2005 ⁶³	2005	2005 ⁶⁴	2007

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Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
A10 Drugs used in diabetes												
Insulin	Rx	OTC ⁶⁵	OTC	Rx	Rx	Rx	Rx	Rx	Rx	Rx	OTC	OTC
A11 Vitamins												
Vitamin A (Retinol)	OTC	OTC ⁶⁶	OTC	Rx	OTC	OTC	OTC	OTC	OTC	OTC ⁶⁷	OTC	Rx
A12 Mineral supplements												
Selenium	OTC	OTC ⁶⁸	OTC	Rx	OTC	N.R.	OTC	OTC	OTC	OTC	OTC	OTC ⁶⁹
B. BLOOD AND BLOOD FORMING ORGANS												
B02 Antihemorrhagics												
Tranexamic acid		Rx	Rx		Rx	Rx		N.R.				
Iron and folic acid preparations	OTC	OTC ⁷⁰	OTC	Rx	OTC	OTC	OTC	OTC	OTC	Rx	OTC	OTC ⁷¹
C. CARDIOVASCULAR SYSTEM												
C01 Cardiac therapy												
Adenosine	Rx	Rx ⁷²	Rx	Rx	Rx	Rx ⁷³	OTC	Rx	Rx	Rx	Rx	Rx
Nitro-glycerine	Rx	OTC ⁷⁴	OTC	Rx	Rx	Rx	Rx	Rx	Rx	Rx	2000 ⁷⁵	Rx
Ubidecarenone	N.R.	OTC	OTC	Rx	Rx	1990	Rx	N.R.	N.R.	Rx	N.R.	
C10 Lipid modifying agents												
Colestyramine	N.R.	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	N.R.	N.R.	Rx	Rx
Lovastatin	N.R.	N.R.	Rx	Rx	Rx	N.R.	Rx	Rx	N.R.	Rx	Rx	Rx
Pravastatin	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Simvastatin	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx

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D. DERMATOLOGICAL												
D01 Antifungals for dermatological use												
Amorolfine (topical)	N.R.	OTC ⁷⁶	N.R.	Rx	Rx	2002 ⁷⁷	Rx	Rx	N.R.	Rx	Rx	
Bifonazole	OTC	1997 ⁷⁸	Rx	Rx	OTC ⁷⁹	1993	OTC	1998 ⁸⁰	OTC ⁸¹	N.R.	N.R.	Rx
Butenafine	N.R.	N.R.	OTC	Rx	2005 ⁸²	2002 ⁸³	OTC	N.R.	N.R.	Rx	N.R.	Rx
Ciclopirox olamine	Rx	2002 ⁸⁴	Rx	Rx	OTC	1987	OTC	Rx	OTC ⁸⁵	OTC	N.R.	Rx
Clotrimazole (topical)	1998	OTC ⁸⁶	1994	Rx	OTC	1980	OTC	OTC	OTC ⁸⁷	Rx	2000 ⁸⁸	1989 ⁸⁹
Croconazole	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	OTC	N.R.	N.R.	N.R.	N.R.	
Econazole	1999	1994 ⁹⁰	Rx	Rx	OTC ⁹¹	1988	OTC	1998 ⁹²	OTC ⁹³	Rx	1995/ 2000 ⁹⁴	Rx
Fenticonazole			N.R.		N.R.	N.R.		Rx	N.R.			
Fluconazole			2009 ⁹⁵									
Haloprogin (topical)	N.R.	N.R.	OTC	N.R.	N.R.	OTC	OTC	N.R.	OTC	N.R.	N.R.	1982 ⁹⁶
Isoconazole (topical)	OTC	OTC ⁹⁷	N.R.	Rx	N.R.	Rx	OTC	1998	OTC ⁹⁸	Rx	1995 ⁹⁹	Rx
Ketoconazole (topical)	OTC	OTC ¹⁰⁰	1994	Rx	OTC ¹⁰¹	Rx	OTC	OTC	OTC ¹⁰²	OTC ¹⁰³	2002 ¹⁰⁴	1997 ¹⁰⁵
Miconazole (topical)	OTC	OTC ¹⁰⁶	1994	Rx	OTC ¹⁰⁷	1987	OTC	OTC	OTC ¹⁰⁸	OTC ¹⁰⁹	2000 ¹¹⁰	1982 ¹¹¹
Miconazole & Hydrocortisone (topical)	Rx	OTC ¹¹²	Rx	Rx	N.R.	N.R.	OTC	1998	OTC	N.R.	OTC	N.R.
Naftifine (topical)	N.R.	N.R.	OTC	N.R.	2004 ¹¹³	N.R.	OTC	N.R.	N.R.	N.R.	OTC	Rx
Natamycin (topical)	Rx	Rx	N.R.	N.R.	Rx	Rx	OTC	Rx	Rx	N.R.	Rx	Rx ¹¹⁴
Neticonazole (topical)	N.R.		N.R.	N.R.	N.R.	2002 ¹¹⁵	OTC	N.R.	N.R.	N.R.	N.R.	
Nystatin	Rx	OTC ¹¹⁶	OTC	Rx	OTC	Rx	OTC	OTC ¹¹⁷	OTC ¹¹⁸	Rx	Rx	Rx
Oxiconazole	Rx	2006 ¹¹⁹	Rx	Rx	N.R.	1993	OTC	1998 ¹²⁰	OTC ¹²¹	N.R.	N.R.	Rx

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Selenium sulfide	OTC	OTC ¹²²	OTC	N.R.	OTC	OTC	OTC	OTC	OTC	OTC	2000 ¹²³	OTC
Sulconazole nitrate (topical)	Rx	N.R.	Rx	Rx	N.R.	1993	OTC	Rx	OTC	N.R.	N.R.	Rx
Terbinafine	OTC	1996 ¹²⁴	Rx	Rx	OTC	2002 ¹²⁵	OTC	1998	OTC ¹²⁶	OTC	2000 ¹²⁷	1999 ¹²⁸
Tioconazole	Rx	1987 ¹²⁹	1995 ¹³⁰	Rx	N.R.	1991	OTC	Rx	OTC ¹³¹	OTC ¹³²	1995 ¹³³	1997 ¹³⁴
Tolnaftate	OTC	OTC ¹³⁵	OTC	OTC	N.R.	OTC	OTC	OTC	OTC ¹³⁶	OTC ¹³⁷	2003 ¹³⁸	OTC
D03 Treatment of wounds and ulcers												
Hyaluronic acid (topical)	OTC	OTC ¹³⁹	OTC	Rx	Rx.	Rx	N.R.	N.R.	OTC	N.R.	OTC	N.R. ¹⁴⁰
D06 Antibiotics and Chemotherapeutics for dermatological use												
Aciclovir (topical)	2002	1996 ¹⁴¹	Rx	Rx	OTC	2007 ¹⁴²	OTC	OTC	1992 ¹⁴³	Rx	2000 ¹⁴⁴	Rx
Chlortetracycline	N.R.	Rx	Rx	N.R.	OTC ¹⁴⁵	OTC ¹⁴⁶	OTC	N.R.	Rx	N.R.	Rx	OTC ¹⁴⁷
Docosanol (topical)	N.R.	N.R.	2002 ¹⁴⁸	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	2000 ¹⁴⁹
Idoxuridine (topical)	N.R.	1996 ¹⁵⁰	Rx	Rx	Rx	Rx	OTC	Rx	OTC	N.R.	Rx ¹⁵¹	Rx
Lysozyme HCl	Rx	N.R.	N.R.	Rx	OTC	OTC	OTC	N.R.	N.R.	N.R.	OTC	
Mupirocin (topical)	Rx	Rx	Rx	Rx	OTC	Rx	OTC	1998	Rx ¹⁵²	Rx	2002	Rx
Penciclovir	OTC	1998 ¹⁵³	Rx	Rx	Rx	N.R.	Rx	N.R.	OTC	N.R.	N.R.	Rx
Podofilox (Podophyllotoxin)	N.R.	OTC ¹⁵⁴	Rx	Rx	Rx	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	Rx
Silver sulfadiazine 1%	Rx	Rx	Rx	Rx	OTC	Rx	OTC	Rx	OTC ¹⁵⁵	Rx	Rx	Rx
Tetracycline	Rx	Rx	Rx	Rx	Rx	Rx	OTC	Rx	Rx	Rx	Rx	OTC ¹⁵⁶
D07 Corticosteroids, dermatological preparations												
Alclomethasone (topical)	N.R.	OTC ¹⁵⁷	N.R.	Rx	N.R.	Rx	OTC	N.R.	N.R.	N.R.	N.R.	
Clobetasone butyrate	N.R.	2002 ¹⁵⁸	2006 ¹⁵⁹	Rx	N.R.	Rx	Rx	N.R.	N.R.	N.R.	2002 ¹⁶⁰	Rx
Hydrocortisone (topical)	Rx	OTC ¹⁶¹	1986 ¹⁶²	Rx	OTC	1990	OTC	OTC	OTC	OTC ¹⁶³	OTC	1979 ¹⁶⁴

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Prednisolone	N.R.	Rx	Rx	Rx	Rx	1992 ¹⁶⁵	OTC	Rx	Rx	Rx	Rx	Rx
Triamcinolone (topical)	Rx		Rx		OTC	2006		OTC	OTC ¹⁶⁶			
D08 Antiseptics and Disinfectants												
Benzalkonium chloride	OTC	OTC ¹⁶⁷	OTC	OTC	OTC ¹⁶⁸	OTC	OTC	OTC	OTC	OTC ¹⁶⁹	OTC	OTC
Povidone iodine	OTC	OTC ¹⁷⁰	OTC	OTC	OTC	OTC	OTC	OTC	OTC	OTC ¹⁷¹	OTC	OTC ¹⁷²
Triclosan	OTC	OTC ¹⁷³	OTC	OTC	Rx	N.R. ¹⁷⁴	OTC	OTC	OTC ¹⁷⁵	OTC	OTC	OTC
D10 Antiacne preparations												
Benzoyl peroxide	OTC	OTC ¹⁷⁶	1981 ¹⁷⁷	Rx	OTC ¹⁷⁸	N.R.	OTC	OTC	OTC ¹⁷⁹	OTC ¹⁸⁰	OTC	OTC
Clindamycin	Rx	Rx	Rx	Rx	OTC ¹⁸¹	Rx	Rx	Rx	OTC ¹⁸²	Rx	Rx	Rx
Erythromycin (topical)	Rx	Rx	Rx	Rx	OTC ¹⁸³	Rx	OTC	1998	Rx	Rx	Rx	Rx
Tretinoin	Rx	Rx	Rx	Rx	OTC	Rx	OTC	Rx	Rx	OTC ¹⁸⁴	Rx	Rx
D11 Other dermatological preparations												
Minoxidil (topical)	OTC	1998 ¹⁸⁵	2000 ¹⁸⁶	Rx	2004 ¹⁸⁷	1999 ¹⁸⁸	OTC	OTC	OTC	Rx	2002 ¹⁸⁹	1996 ¹⁹⁰
G. GENITO-URINARY SYSTEM AND SEX HORMONES												
G01 Gynecological antiinfectives and antiseptics												
Amphotericin (topical)	N.R.	Rx	Rx	N.R.	Rx	Rx ¹⁹¹	Rx	N.R.	OTC ¹⁹²	Rx	Rx	Rx
Butoconazole	Rx	2007 ¹⁹³	Rx	Rx	N.R.	N.R.	OTC	1998 ¹⁹⁴	Rx ¹⁹⁵	N.R.	N.R.	1995 ¹⁹⁶
Clotrimazole (vaginal)	2004	OTC ¹⁹⁷	1994	Rx	OTC	Rx	OTC	OTC	OTC	OTC ¹⁹⁸	1995 ¹⁹⁹	1990 ²⁰⁰
Miconazole (vaginal)	Rx	1994 ²⁰¹	1994	Rx	OTC	Rx	OTC	OTC	OTC	OTC ²⁰²	1995 ²⁰³	1991 ²⁰⁴
Propionate Ca+Na (vaginal)	N.R.	N.R.	OTC	OTC	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	
Terconazole	N.R.	N.R.	Rx	Rx	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	Rx

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G03 Sex hormones and Modulators in the genital system												
Estriol (vaginal)	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Levonorgestrel	Rx	2004 ²⁰⁵	2005 ²⁰⁶	Rx	OTC	Rx	OTC	1999 ²⁰⁷	OTC ²⁰⁸	Rx	Rx	2006 ²⁰⁹
G04 Urologicals												
Phenazopyridine	Rx	Rx	Rx	Rx	Rx	N.R.	Rx	1998	OTC	Rx	OTC	Rx
Tamsulosin												
J. ANTIINFECTIVES FOR SYSTEMIC USE												
J01 Antibacterials for systemic use												
Azithromycin		Rx	Rx		Rx	Rx		Rx				
Methenamine	N.R.	OTC ²¹⁰	OTC	Rx	OTC ²¹¹	Rx	Rx	1998	N.R.	Rx	N.R.	Rx
J02 Antimycotics for systemic use												
Itraconazole	Rx	Rx	Rx	Rx	Rx	Rx	OTC	Rx	Rx	Rx	Rx	Rx
M. MUSCOLO-SKELETAL SYSTEM												
M01 Antiinflammatory and Antirheumatic products												
Benzydamine	Rx	1987 ²¹²	Rx	Rx	Rx	N.R.	OTC	OTC	OTC	Rx	OTC	
Bufexamac (topical)	OTC	OTC ²¹³	OTC	OTC	OTC	1980	Rx	N.R.	OTC	N.R.	NR	
Diclofenac	OTC	1997 ²¹⁴	Rx	Rx	OTC	Rx	OTC	OTC	OTC ²¹⁵	Rx	Rx	Rx
Diclofenac (topical)	2002	OTC	2008 ²¹⁶	OTC	OTC	Rx	OTC	OTC	OTC ²¹⁷	Rx ²¹⁸	1998 ²¹⁹	Rx
Etofenamate (topical)	2000	N.R.	N.R.	OTC	Rx	N.R.	OTC	1998	OTC	Rx	N.R.	N.R.
Felbinac (topical)	N.R.	N.R.	N.R.	OTC	Rx	1995	Rx	N.R.	OTC	OTC ²²⁰	N.R.	N.R.
Flurbiprofen (lozenges)	N.R.	2003 ²²¹	Rx	Rx	Rx	Rx	Rx	Rx	OTC ²²²	N.R.	Rx	Rx ²²³
Glucosamine	OTC	OTC	OTC	Rx	OTC	N.R. ²²⁴	OTC	OTC	OTC	OTC ²²⁵	N.R.	N.R. ²²⁶

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Ibuprofen (oral)	2002 ²²⁷	1989 ²²⁸	1989 ²²⁹	OTC	OTC ²³⁰	1985	OTC	OTC ²³¹	1985 ²³²	OTC ²³³	2002 ²³⁴	1984 ²³⁵
Ibuprofen (topical)	OTC	OTC ²³⁶	1989	OTC	OTC ²³⁷	1990 ²³⁸	OTC	N.R.	OTC	OTC	1998 ²³⁹	N.R.
Indomet(h)acin (topical)	Rx	1992 ²⁴⁰	Rx	Rx	OTC ²⁴¹	1985	OTC	N.R.	OTC	Rx	N.R.	Rx ²⁴²
Ketoprofen	Rx	Rx	Rx	Rx	OTC	Rx	OTC ²⁴³	1998	OTC	Rx	Rx	1995 ²⁴⁴
Ketoprofen (topical)	OTC	2000 ²⁴⁵	N.R.	OTC	OTC	1994	OTC	Rx	OTC	Rx	1998 ²⁴⁶	N.R.
Mefenamic acid	N.R.	OTC ²⁴⁷	Rx	Rx	Rx	Rx	OTC	Rx	OTC	OTC ²⁴⁸	Rx	Rx
Naproxen	OTC	1990 ²⁴⁹	Rx	OTC	OTC	Rx	OTC	OTC	OTC ²⁵⁰	N.R.	2003 ²⁵¹	1994 ²⁵²
Niflumic acid (topical)	Rx	N.R.	N.R.	Rx	Rx	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	
Piroxicam (topical)	OTC	1998 ²⁵³	Rx	OTC	OTC ²⁵⁴	1994	OTC	1998	OTC	OTC ²⁵⁵	2000 ²⁵⁶	Rx
Tolmetin	N.R.	Rx	Rx	Rx	Rx	Rx	N.R.	1998 ²⁵⁷	Rx	N.R.	N.R.	Rx
M03 Muscle relaxants												
Chlorzoxazone	N.R.	Rx	OTC	Rx	OTC	Rx	Rx	Rx	Rx	Rx	N.R.	Rx
Idrocilamide	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	N.R.
Methocarbamol	N.R.	Rx	OTC	N.R.	Rx	OTC	Rx	OTC	Rx	N.R.	Rx	Rx
Orphenadrine	N.R.	Rx	OTC	Rx	N.R.	N.R.	Rx	Rx	Rx	Rx	Rx	Rx
N. NERVOUS SYSTEM												
N01 Anaesthetics												
Benzocaine	OTC	OTC ²⁵⁸	OTC	OTC	OTC	OTC	OTC	OTC	OTC ²⁵⁹	OTC ²⁶⁰	OTC	OTC
Butyl aminobenzoate	N.R.	2002 ²⁶¹	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	
Cinchocaine (topical)	Rx	OTC ²⁶²	OTC	N.R.	N.R.	OTC	N.R.	OTC	OTC	Rx	OTC	
Dyclonine (oral)	N.R.	N.R.	OTC	OTC	OTC	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	1982 ²⁶³
Lidocaine (topical/oral topical)	OTC	OTC ²⁶⁴	OTC	Rx	OTC ²⁶⁵	OTC	Rx	OTC	OTC ²⁶⁶	Rx	OTC	OTC

Legal classification status of selected ingredients worldwide (last major update: 19 December 2008)

(Data for the European Union of 15 and new EU and non-EU European countries are available in separate tables)

Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
Oxetacaine	Rx	OTC ²⁶⁷	OTC	Rx	N.R.	1995 ²⁶⁸	Rx	N.R.	OTC ²⁶⁹	OTC	OTC	
Oxybuprocaine	Rx	Rx	OTC	Rx	Rx	Rx	Rx	Rx	Rx	N.R.	OTC	Rx
Pramocaine	Rx	N.R.	OTC	N.R.	N.R.	N.R.	OTC	N.R.	Rx	Rx	N.R.	OTC
Prilocaine	N.R.	1993 ²⁷⁰	OTC	Rx	Rx	Rx	OTC	OTC	OTC ²⁷¹	N.R.	OTC	Rx
N02 Analgesics												
Acetylsalicylic acid	2003 ²⁷²	OTC ²⁷³	OTC	OTC	OTC ²⁷⁴	OTC	OTC	OTC	OTC ²⁷⁵	OTC ²⁷⁶	OTC	1988
Diflunisal	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	N.R.	Rx	Rx
Dihydrocodeine	Rx	OTC ²⁷⁷	Rx	Rx	Rx	OTC	Rx	N.R.	Rx	N.R.	N.R.	Rx
Naratriptan	N.R.	Rx	Rx	Rx	N.R.	Rx	Rx	N.R.	Rx	N.R.	Rx	Rx
Paracetamol	OTC	OTC ²⁷⁸	OTC	OTC	OTC	OTC	OTC	OTC	OTC ²⁷⁹	OTC ²⁸⁰	OTC	1955
Paracetamol + dihydrocodeine	Rx	OTC ²⁸¹	Rx	N.R.	Rx	N.R. ²⁸²	Rx	N.R.	Rx	N.R.	N.R.	Rx
Sumatriptan	Rx	Rx	Rx	Rx	Rx	Rx	Rx	OTC	Rx	Rx	Rx	Rx
Zolmitriptan	N.R.	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
N05 Psycholeptics												
Chlorproethazine (topical)	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	
Hydroxyzine	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx	Rx
Prochlorperazine	N.R.	2000 ²⁸³	Rx	Rx	N.R.	Rx	OTC	N.R.	OTC ²⁸⁴	N.R.	Rx	Rx
N06 Psychoanaleptics												
Pyritinol	N.R.	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	
N07 Other nervous system drugs												
Nicotine (gum)	OTC	1988 ²⁸⁵	1992 ²⁸⁶	Rx	2008	2001	OTC	OTC	OTC ²⁸⁷	N.R.	2002 ²⁸⁸	1996 ²⁸⁹
Nicotine (nasal spray)	N.R.	OTC ²⁹⁰	2003	N.R.	N.R.	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	Rx

Legal classification status of selected ingredients worldwide (last major update: 19 December 2008)

(Data for the European Union of 15 and new EU and non-EU European countries are available in separate tables)

Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
Nicotine (<i>oral inhaler</i>)	N.R.	OTC ²⁹¹	2003 ²⁹²	N.R.	N.R.	N.R.	N.R.	2002	OTC	N.R.	2002 ²⁹³	Rx ²⁹⁴
Nicotine (<i>patch</i>)	OTC	1997 ²⁹⁵	1998 ²⁹⁶	Rx	2008	2008	OTC	1998	OTC	N.R.	1999	1996 ²⁹⁷
Nicotine (<i>sublingual</i>)	N.R.	OTC ²⁹⁸	2006 ²⁹⁹	N.R.	Rx	N.R.	N.R.	N.R.	OTC ³⁰⁰	Rx	2002 ³⁰¹	2002
P. ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLANTS												
P01 Antiprotozoals												
Carnidazole	N.R.	Rx	OTC	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	
Quinfamide	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	N.R.	2002 ³⁰²	N.R.	N.R.	N.R.	
P02 Anthelmintics												
Flubendazole	Rx	N.R.	N.R.	Rx	N.R.	N.R.	OTC	N.R.	N.R.	N.R.	N.R.	
Mebendazole	Rx	OTC ³⁰³	Rx	Rx	OTC ³⁰⁴	Rx	N.R.	OTC	OTC	OTC ³⁰⁵	OTC	Rx
Pyrantel	Rx	OTC ³⁰⁶	OTC ³⁰⁷	Rx	OTC ³⁰⁸	Rx ³⁰⁹	OTC ³¹⁰	OTC ³¹¹	OTC ³¹²	OTC ³¹³	2000 ³¹⁴	1986 ³¹⁵
P03 Ectoparasiticides												
Benzyl benzoate (<i>topical</i>)	OTC	OTC ³¹⁶	OTC	N.R.	OTC	N.R. ³¹⁷	OTC	OTC	OTC ³¹⁸	OTC ³¹⁹	OTC	Rx
Lindane (<i>topical</i>)	N.R.	OTC ³²⁰	OTC	OTC	Rx	N.R.	OTC	OTC	OTC	OTC	N.R.	Rx
R. RESPIRATORY SYSTEM												
R01 Nasal preparations												
Azelastine	Rx	OTC ³²¹	N.R.	Rx	Rx	2006	N.R.	Rx	OTC ³²²	Rx	Rx	Rx
Beclometasone (<i>nasal</i>)	Rx	1999 ³²³	Rx	Rx	OTC ³²⁴	Rx	OTC	Rx	OTC ³²⁵	Rx	2000 ³²⁶	Rx
Budesonide (<i>nasal</i>)	Rx	1999 ³²⁷	Rx	Rx	2005 ³²⁸	Rx ³²⁹	Rx	Rx	OTC ³³⁰	Rx	2000 ³³¹	Rx
Cromoglicic acid	OTC	1990 ³³²	1998 ³³³	Rx	OTC	1997 ³³⁴	OTC	1998 ³³⁵	OTC	N.R.	1995 ³³⁶	1997 ³³⁷
Ephedrine (<i>topical</i>)	OTC	Rx	Rx	N.R.	OTC ³³⁸	OTC	OTC	N.R.	OTC ³³⁹	N.R.	OTC	1980 ³⁴⁰

Legal classification status of selected ingredients worldwide (last major update: 19 December 2008)

(Data for the European Union of 15 and new EU and non-EU European countries are available in separate tables)

Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
Epinephrine (<i>not for asthma</i>) (adrenaline)	N.R.	OTC ³⁴¹	OTC	Rx	Rx	OTC	Rx	Rx	OTC ³⁴²	Rx	Rx	1980 ³⁴³
Epinephrine (<i>asthma</i>)	N.R.	OTC ³⁴⁴	OTC	Rx	Rx	Rx	Rx	N.R.	OTC	Rx	N.R.	OTC
Flunisolide (<i>nasal</i>)	Rx	Rx ³⁴⁵	Rx	Rx	N.R.	N.R.	OTC	N.R.	Rx	N.R.	N.R.	Rx
Fluticasone	Rx	OTC ³⁴⁶	Rx	Rx	OTC	Rx	Rx	Rx	OTC	Rx	Rx	Rx
Levocabastine	Rx	OTC ³⁴⁷	Rx	Rx	Rx	Rx	Rx	Rx	OTC ³⁴⁸	N.R.	N.R.	Rx ³⁴⁹
Mometasone (<i>nasal</i>)	Rx	2003 ³⁵⁰	Rx	Rx	Rx	Rx	Rx	Rx	OTC ³⁵¹	Rx	Rx	Rx
Naphazoline	OTC	OTC ³⁵²	OTC	OTC	OTC	OTC	OTC	OTC	OTC	Rx	OTC	Rx
Oxymetazoline	OTC	OTC ³⁵³	OTC	OTC	OTC ³⁵⁴	Rx	OTC	OTC	OTC	OTC ³⁵⁵	OTC	1976 ³⁵⁶
Phenylephrine	OTC	OTC ³⁵⁷	OTC	Rx	Rx	OTC	OTC	OTC	OTC ³⁵⁸	OTC ³⁵⁹	OTC	1980 ³⁶⁰
Pseudoephedrine	2003 ³⁶¹	OTC ³⁶²	OTC	Rx	OTC	2002 ³⁶³	OTC	N.R.	OTC ³⁶⁴	OTC ³⁶⁵	OTC	1976 ³⁶⁶
Tetrahydrozoline	N.R.	OTC ³⁶⁷	OTC	N.R.	N.R.	OTC	N.R.	OTC	OTC	OTC ³⁶⁸	OTC	Rx
Tramazoline	N.R.	OTC ³⁶⁹	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	OTC	N.R.	N.R.	OTC
Xylometazoline (<i>nasal</i>)	2003	OTC ³⁷⁰	OTC	Rx	OTC	N.R.	OTC	N.R.	OTC	OTC ³⁷¹	OTC	1976 ³⁷²
R02 Throat preparations												
Bacitracin (<i>topical</i>)	Rx	Rx	OTC	Rx	Rx	OTC	OTC	1998	Rx	Rx	Rx ³⁷³³⁷⁴	OTC
Tyrothricin	OTC	N.R.	OTC	OTC	OTC ³⁷⁵	N.R.	OTC	N.R.	N.R.	N.R.	1997	
R03 Drugs for obstructive airway diseases												
Fenoterol	Rx.	Rx	Rx	Rx	N.R.	Rx	OTC	Rx ³⁷⁶	Rx	Rx	Rx	
Orciprenaline	N.R.	Rx	Rx	Rx	N.R.	Rx	Rx	Rx	Rx	Rx	OTC	Rx
Salbutamol	Rx	OTC ³⁷⁷	Rx	Rx	Rx	Rx	OTC	2008	OTC ³⁷⁸	Rx	OTC ³⁷⁹	Rx
Theophylline	Rx	OTC ³⁸⁰	Rx	Rx	Rx	OTC ³⁸¹	OTC	Rx	OTC ³⁸²	Rx	Rx	Rx

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(Data for the European Union of 15 and new EU and non-EU European countries are available in separate tables)

Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
R05 Cough and Cold preparations												
Acetylcysteine	OTC	OTC ³⁸³	OTC	Rx	OTC	Rx	OTC	Rx	OTC	Rx	OTC	Rx
Ambroxol	OTC	N.R.	N.R.	OTC	OTC	2007	OTC	1998	N.R.	OTC ³⁸⁴	2002 ³⁸⁵	
Benproperine	N.R.	N.R.	N.R.	Rx	OTC	Rx	OTC	N.R.	N.R.	N.R.	N.R.	N.R.
Benzonatate	N.R.	N.R.	OTC	Rx	N.R.	N.R.	Rx	OTC	N.R.	N.R.	N.R.	Rx
Bromhexine	OTC	OTC ³⁸⁶	N.R.	OTC	OTC	1987	OTC	OTC	OTC	OTC ³⁸⁷	2002 ³⁸⁸	N.R.
Carbocisteine	Rx	2001 ³⁸⁹	Rx	OTC	OTC	1988	OTC	Rx	OTC	OTC ³⁹⁰	OTC	
Chlophendianol	Rx	N.R.	OTC	N.R.	N.R.	N.R.	Rx	N.R.	OTC	N.R.	N.R.	1987 ³⁹¹
Dextromethorphan	Rx	OTC ³⁹²	OTC	Rx	OTC	OTC	OTC	OTC	OTC ³⁹³	OTC ³⁹⁴	OTC	1982 ³⁹⁵
Dimemorfan	N.R.	N.R.	N.R.	N.R.	N.R.	1985	Rx	N.R.	N.R.	N.R.	N.R.	
Noscapine	Rx	OTC ³⁹⁶	OTC	OTC	OTC	OTC	OTC	N.R.	OTC	N.R.	N.R.	OTC
R06 Antihistamines for systemic use												
Acrivastine	N.R.	N.R.	N.R.	Rx	Rx	N.R.	OTC	N.R.	Rx	Rx	1997	Rx
Azatadine	N.R.	1988 ³⁹⁷	Rx	Rx	N.R.	N.R.	Rx	Rx	OTC	N.R.	OTC	Rx
Brompheniramine	Rx	OTC ³⁹⁸	OTC	Rx	OTC ³⁹⁹	N.R.	OTC	OTC	OTC ⁴⁰⁰	OTC ⁴⁰¹	OTC	1976 ⁴⁰²
Carbinoxamine	Rx	N.R.	OTC	Rx	N.R.	OTC ⁴⁰³	N.R.	Rx	N.R.	N.R.	OTC	Rx
Cetirizine	Rx	1997 ⁴⁰⁴	1995	Rx	2008	Rx	OTC	OTC	OTC	OTC	1997	2007 ⁴⁰⁵
Chlorpheniramine	OTC	OTC ⁴⁰⁶	OTC	Rx	OTC	OTC	OTC	OTC	OTC ⁴⁰⁷	OTC ⁴⁰⁸	OTC	1976 ⁴⁰⁹
Clemastine	N.R.	Rx ⁴¹⁰	OTC	Rx	OTC	1979	OTC	OTC	N.R.	OTC ⁴¹¹	N.R.	1992 ⁴¹²
Cyproheptadine	Rx	OTC ⁴¹³	OTC	Rx	OTC	Rx	OTC	Rx	OTC	N.R.	OTC	Rx
Dexbrompheniramine	N.R.	N.R.	OTC	Rx	N.R.	N.R.	Rx	Rx	N.R.	N.R.	OTC	1982 ⁴¹⁴
Dexchlorpheniramine	Rx	OTC ⁴¹⁵	OTC	Rx	N.R.	OTC	OTC	OTC	OTC ⁴¹⁶	N.R.	OTC	1976 ⁴¹⁷

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Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
Dimetindene	Rx	N.R.	N.R.	N.R.	N.R.	N.R.	Rx	Rx	N.R.	N.R.	N.R.	
Diphenhydramine	OTC ⁴¹⁸	OTC ⁴¹⁹	OTC	Rx	OTC ⁴²⁰	OTC	OTC	OTC	OTC ⁴²¹	OTC ⁴²²	OTC	1981 ⁴²³
Diphenylpyraline	Rx	Rx ⁴²⁴	OTC	Rx	N.R.	OTC	OTC	Rx	OTC ⁴²⁵	N.R.	N.R.	Rx
Doxylamine succinate	N.R.	OTC ⁴²⁶	OTC	Rx	N.R.	N.R.	OTC	N.R.	OTC ⁴²⁷	Rx	N.R.	OTC
Ebastine	N.R.	N.R.	N.R.	Rx	Rx	Rx	Rx	N.R.	N.R.	Rx	Rx	
Fexofenadine	Rx	OTC ⁴²⁸	OTC ⁴²⁹	Rx	Rx	Rx	Rx	Rx	OTC	Rx	N.R.	Rx ⁴³⁰
Ketotifen	N.R.	Rx	Rx	Rx	OTC	2005.	Rx	Rx	OTC ⁴³¹	Rx	Rx	Rx
Levocetirizine	Rx		N.R.		Rx	N.R.		Rx	OTC ⁴³²			
Loratadine	2003	OTC ⁴³³	1988 ⁴³⁴	Rx	2005 ⁴³⁵	Rx	Rx	1998	OTC	OTC ⁴³⁶	1995	2002 ⁴³⁷
Meclozine	N.R.	2005 ⁴³⁸	2000 ⁴³⁹	Rx	N.R.	N.R.	N.R.	Rx	OTC ⁴⁴⁰	OTC ⁴⁴¹	OTC	
Mepyramine maleate	Rx	OTC ⁴⁴²	OTC	Rx	N.R.	N.R.	N.R.	Rx	OTC	N.R.	N.R.	
Mequitazine	N.R.	N.R.	N.R.	Rx	N.R.	1990	Rx	N.R.	OTC	Rx	N.R.	
Oxatomide	Rx	N.R.	N.R.	Rx	N.R.	Rx	Rx	1998 ⁴⁴³	N.R.	N.R.	N.R.	
Promethazine	Rx	OTC ⁴⁴⁴	OTC	N.R.	OTC ⁴⁴⁵	OTC	OTC	Rx	OTC ⁴⁴⁶	Rx	OTC	Rx
Tripelennamine	Rx	Rx	OTC	Rx	Rx	OTC	OTC	N.R.	N.R.	N.R.	N.R.	Rx
Trip(r)olidine	Rx	OTC ⁴⁴⁷	OTC	Rx	2008	OTC	OTC	N.R.	OTC ⁴⁴⁸	N.R.	OTC	1982 ⁴⁴⁹
S. SENSORY ORGANS												
S01 Ophthalmologicals												
Sulfacetamide (topical)	OTC	1996 ⁴⁵⁰	Rx	N.R.	OTC ⁴⁵¹	N.R.	OTC	1998	OTC	Rx	Rx	Rx
S03 Other ophthalmological and otological preparations												
Chloramphenicol	N.R.	2009	Rx	Rx	Rx	OTC ⁴⁵²	OTC ⁴⁵³	Rx	Rx	Rx	Rx	Rx

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Ingredient	Argentina	Australia	Canada	Chile	China	Japan	Korea	Mexico	New Zealand	Philippines	Singapore	USA
Polymyxin B (topical)	Rx	Rx	OTC	Rx	Rx	Rx	OTC	1998	Rx	OTC ⁴⁵⁴	Rx	OTC
NON-CLASSIFIED												
Bronopol	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	Rx	N.R.	N.R.	N.R.	N.R.	N.R.
Cilastatin	Rx ⁴⁵⁵		Rx		Rx	N.R.		Rx	Rx			
Decaline	N.R.	N.R.	N.R.	OTC	N.R.	N.R.	Rx	N.R.	N.R.	OTC ⁴⁵⁶	N.R.	
Potassium nitrate (toothpaste)	OTC	OTC ⁴⁵⁷	OTC	N.R.	N.R.	OTC ⁴⁵⁸	OTC	OTC	OTC	N.R.	N.R.	OTC
Strontium chloride (toothpaste)	N.R.	N.R. ⁴⁵⁹	OTC	OTC	N.R.	N.R.	OTC	OTC	OTC ⁴⁶⁰	N.R.	N.R.	N.R.

Endnotes:

¹ For Australia, the following classification applies according to the “Standard for Uniform Scheduling of Drugs and Poisons” (SUSDP):

GSL	Unscheduled medicine
S2	Pharmacy Medicine
S3	Pharmacist Only Medicine
S4	Prescription Medicine
S5	Caution
S6	Poison
S7	Dangerous Poison
S8	Controlled Drug
Appendix H	S3 substances that may be advertised to the public

Fluoride is GSL in pastes, powders or gels containing 1000mg/kg or less of fluoride ion or in other preparations for topical use containing 15mg/kg or less of fluoride ion
S2 - Effective 1 September 2007: Fluorides for human use (except in preparations containing 15 mg/kg or 15 mg/L or less of fluoride ion):

(a) as sodium fluoride, in preparations for ingestion containing 2.2 mg or less of sodium fluoride per dosage unit; or (b) in preparations for topical use containing 2.5 per cent or less of fluoride ion except: (i) when included in Schedule 3; (ii) dental hygiene, whitening or bleaching products that are pastes, powders or gels for use on teeth, containing 1000 mg/kg or less of fluoride ion; (iii) other dental hygiene, whitening or bleaching products that are therapeutic goods, containing 220 mg/kg or 220 mg/L or less of fluoride ion, in packs containing not more than 120 mg total fluoride, fitted with a child-resistant closure, when compliant with the requirements of the Required Advisory Statements for Medicine Labels; or (iv) other dental hygiene, whitening or bleaching products that are not therapeutic goods, containing 220 mg/kg or 220 mg/L or less of fluoride ion, in packs containing not more than 120 mg total fluoride, fitted with a child-resistant closure and labelled with warnings to the following effect: (A) Do not swallow; and (B) Do not use [this product/name of product] in children six years of age or less.

S3 – Fluorides in dental hygiene, whitening or bleaching products that are pastes, powders or gels for use on teeth, containing more than 1000 mg/kg of fluoride ion.

S4 – Fluorides in preparations for human use except: (a) when included in Schedule 2 or 3; (b) dental hygiene, whitening or bleaching products that are pastes, powders or gels for use on teeth, containing 1000 mg/kg or less of fluoride ion; (c) other dental hygiene, whitening or bleaching products that are therapeutic goods, containing 220 mg/kg or 220 mg/L or less of fluoride ion, in packs containing not more than 120 mg total fluoride, fitted with a child-resistant closure, when compliant with the requirements of the Required Advisory Statements for Medicine Labels; (d) other dental hygiene, whitening or bleaching products that are not therapeutic goods, containing 220 mg/kg or 220 mg/L or less of fluoride ion, in packs containing not more than 120 mg total fluoride, fitted with a child-resistant closure and labelled with warnings to the following effect: (i) Do not swallow; and (ii) Do not use [this product/name of product] in children six years of age or less. (e) Other preparations containing 15 mg/kg or 15 mg/L or less of fluoride ion.

² Fluoride in combinations is OTC.

³ Sodium fluoride – Substances containing less than 3% of sodium fluoride as a preservative; dentifrices containing not more than 0.5% of sodium fluoride; mouth wash tablets containing not more than 0.2% of sodium fluoride and liquid mouth washes containing not more than 0.05% thereof; tablets containing not more than 0.016%, weight in weight, of sodium fluoride and intended, when chewed, to prevent tooth decay.

4 Acidulated phosphate fluoride rinse (dental rinse). Dosage is 0.02% fluoride in aqueous solution (topical). Sodium fluoride rinse (dental rinse). Dosage is 0.05% aqueous solution (topical). Stannous fluoride gel (anti-cavities gel). Dosage is 0.4% gel (topical). Stannous fluoride rinse (dental rinse). Dosage is 0.1% aqueous solution (topical).

5 For external use.

6 Solution (mouthwash): 0.10%.

7 Effective 1 September 2004, S3 to S2 switch for aqueous nasal sprays. Preparations for mouth ulcers remain in S3.
S2 entry: Triamcinolone in aqueous nasal sprays delivering 55 micrograms or less of triamcinolone per actuation when the maximum recommended daily dose is no greater than 220 micrograms and when packed in a primary pack containing 120 actuations or less, for prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.
S3 entry: Triamcinolone for the treatment of mouth ulcers, in preparations containing 0.1 per cent or less of triamcinolone in a pack of 5g or less.
Effective 1 September 2006, the limit on actuation removed from S2 entry.

8 Oral forms only.

9 Triamcinolone acetonide (0.1% in orabase) switched to OTC status in August 2002.

10 General sale.

11 General sale.

12 Aluminium hydroxide 600mg/5ml and below (oral suspensions) and 600mg and below (tablets).

13 Capsules: 500mg and below.

14 S2 for topical oral use.

15 General sale. External use only.

16 Switched from S4 to S3 in July 1995 for the relief of symptoms of gastro-oesophageal reflux in a pack containing not more than 14 days supply: Effective 22 June 1997, dosage restriction and divided preparation controls removed (i.e. as the only therapeutically active substance in preparations for oral use for relief of symptoms of gastro oesophageal reflux in a pack containing not more than 14 days supply).
Effective 17 March 2000, ‘as the only therapeutically active substance’ control removed, i.e. for the relief of symptoms of gastro-oesophageal reflux, in a primary pack containing not more than 14 days supply.
Effective 1 January 2006, the indication “for the relief of symptoms of gastro-oesophageal reflux” was deleted from the S3 entry.

17 200mg.

18 For oral preparation, maximum dose is 0.2g per tablet or per pill; for oral emulsions, maximum strength is 1%.

19 Cimetidine oral preparations for a) short-term relief of heartburn, dyspepsia and hyperacidity, and b) prophylactic management of nocturnal heartburn; maximum daily dose of a) 200mg and b) 100mg (as a single night-time dose); maximum supply of 2 weeks.

20 In 1995, cimetidine was approved as acid reducer with a dosage of 200mg up to twice a day.

21 Switched from S4 to S3 in 1995 as the only therapeutically active substance in divided preparations for oral use containing 200mg or less of famotidine per dosage unit, for relief of symptoms of gastro oesophageal reflux in a pack containing not more than 14 days supply.
Effective 22 June 1997, dosage restriction and divided preparation controls removed i.e. as the only therapeutically active substance in preparations for oral use for relief of

symptoms of gastro oesophageal reflux in a pack containing not more than 14 days supply.

Effective 17 March 2000, switched to S2 'as the only therapeutically active substance' control removed, i.e. for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

Effective 1 January 2006, the indication "for the relief of symptoms of gastro-oesophageal reflux" was deleted from the S2 entry.

22 For treatment & prevention of acid-related gastrointestinal symptoms. Dosage is 10mg per tablet, Maximum Daily Dose is 20mg (treatment should not exceed two weeks). 20 & 40mg dosages remain Rx.

23 Maximum dose is 20mg per tablet.

24 Famotidine oral preparations for short-term relief of heartburn, dyspepsia and hyperacidity at a maximum daily dose of 300 mg and a maximum of 2 weeks' supply.

25 In 1995, famotidine received OTC approval as acid reducer with an adult dosage of 10mg up to 20mg per day.

26 In Mazy 2009, Prevacid® 24HR (lansoprazole delayed-release capsules 15 mg – Novartis Consumer Health) was approved for OTC use for frequent heartburn

27 Switched in 1995: S4 until July 1995. As the only therapeutically active substance in divided preparations for oral use containing 200mg or less of nizatidine per dosage unit, for relief of symptoms of gastro oesophageal reflux in a pack containing not more than 14 days supply.

Switched in 1997: effective 22 June 1997, dosage restriction and divided preparation controls removed i.e. as the only therapeutically active substance in preparations for oral use for relief of symptoms of gastro oesophageal reflux in a pack containing not more than 14 days supply

2000: effective 17 March 2000, 'as the only therapeutically active substance' control removed, i.e. for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

Effective 1 January 2006, the indication "for the relief of symptoms of gastro-oesophageal reflux" was deleted from the S2 entry.

28 Nizatidine 75mg, for the symptomatic treatment of heartburn and acid indigestion.

29 In 1996, approval for OTC marketing as an acid reducer, 75 mg up to twice daily.

30 20 mg/day acid reducer to treat frequent heartburn

31 Pantoprazole was switched on 1 May 2008 from prescription-only to S3 status in oral preparations containing 20 mg or less for the relief of heartburn and other symptoms of gastrooesophageal reflux disease, in packs containing not more than 14 days of supply. The product cannot be advertised to the general public.

32 S3 as the only therapeutically active substance in preparations for oral use for the relief of symptoms of gastro-oesophageal reflux in packs containing not more than 14 days supply (Rx to S3 in stages (1995-1997)). Effective 17 March 2000, 'as the only therapeutically active substance' control removed, i.e. for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

Effective 1 January 2006, the indication "for the relief of symptoms of gastro-oesophageal reflux" was deleted from the S2 entry.

33 75mg or less per dosage unit, for symptomatic treatment of heartburn and acid indigestion.

34 Maximum dose is 0.15g per tablet.

35 Tablets: 75mg.

36 Ranitidine oral preparations for short-term relief of heartburn, dyspepsia and hyperacidity at a maximum daily dose of 300 mg and a maximum of 2 weeks' supply.

37 Ranitidine as acid reducer with an adult dosage of 75mg up to twice per day.

38 General sale.

- 39 S2 entry deleted and rescheduled to S4 effective 1 May 2007.
- 40 General sale.
- 41 Dimethicone is OTC in combinations.
- 42 For tablets, maximum dose is 10mg per tablet; for suspensions or drops, maximum strength is 0.1%; for suppository, maximum dose is 30mg per unit.
- 43 Domperidone oral preparations for relief of postprandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn at a maximum dose of 10 mg and a maximum daily dose of 40 mg.
- 44 S2 for 20 mg tablets in packs up to 200 mg.
- 45 Pharmacy-only.
- 46 Switched in 2000: effective 17 March 2000, S3 when compounded with paracetamol in divided preparations, packed and labelled only for the treatment of nausea associated with migraine, in packs containing not more than 10 dosage units.
- 47 In combination with paracetamol.
- 48 Effective 1 May 2005, rescheduled from S2 to S4 status (S2 entry deleted).
- 49 Maximum dose is 50mg per tablet.
- 50 Maximum 10 tablets. Restricted to authorised travel outlets..
- 51 Hyoscine (excluding hyoscine butylbromide): Up to 1 June 2002, preparations containing 0.25 per cent or less of the hyoscine were sold as pharmacy medicines (S2). Effective 1 June 2002, only the following oral preparations are permitted as S2. All others have been rescheduled to S4 (prescription medicines):
- (a) in undivided preparations containing 0.03 per cent or less of total solanaceous alkaloids when labelled with a dose of 0.3 mg or less of total solanaceous alkaloids and a recommended daily dose of 1.2 mg or less of solanaceous alkaloids; or
 - (b) in divided preparations containing 0.3 mg or less of total solanaceous alkaloids per dosage unit, when labelled with a recommended daily dose of 1.2 mg or less of total solanaceous alkaloids.
- Changes:
- lower concentration of hyoscine permitted in S2 (pharmacy medicine) products;
 - maximum content of **total** solanaceous alkaloids in the preparation considered and specified, not just the individual ingredient;
 - recommended daily dose specified;
 - no preparations for external use permitted.
- 52 For pellicle (plaster), maximum dose is 1.5mg per plaster.
- 53 Hyoscine butylbromide.
- 54 General sale.
- 55 Tablets: 5mg; Suppositories: 10mg and below.
- 56 General sale.
- 57 For powders, maximum dose is 20g per pack; for syrup or oral solutions, maximum strength is 50%.
- 58 Effective 1 September 2002, sodium picosulfate switched from GSL to S3 in preparations for oral use for bowel cleansing prior to diagnostic medical and surgical procedures.

- 59 Switched in 1987: S4 until 1987. Rescheduled to S3 in packs of 8 dosage units or less, each dosage unit containing 2mg or less of loperamide. Switched in 2001 (S4 to S2), for oral use in packs of 20 dosage units or less is S2 (previously in packs of 8 dosage units or less, each dosage unit containing 2mg or less).
- 60 Capsules: 2mg.
- 61 Loperamide as antidiarrhoeal. Adult dosage is 4mg then 2mg up to 8mg/day (oral).
- 62 Effective 1 May 2004, S4 to S3 switch for products containing ≤ 120 mg per dosage unit. All other preparations remain S4.
S3 entry: Orlistat in oral preparations for weight-control purposes containing 120 mg or less of orlistat per dosage unit. Effective 1 October 2007: Schedule H entry deleted, meaning consumer advertising no longer allowed.
- 63 Pharmacist only. Consumer advertising permitted.
- 64 Orlistat 120mg capsules reclassified from Prescription Only Medicine (POM) to Pharmacy Only Medicine (P) status with effect from 31 January 2005 to treat people who are obese (BMI ≥ 30).
- 65 Schedule 3 (S3).
- 66 General sale: in preparations for topical use containing 1% or less of vitamin A.
- 67 Vitamin A is OTC in combinations..
- 68 S3 in preparations for oral use with a recommended daily dose of 100mcg or less.
General sales line (i.e. sale not limited to pharmacy only) in preparations for oral use with a recommended daily dose of 26mcg or less (in organic form) or 52mcg or less (in inorganic form) (otherwise Rx).
- 69 This is a dietary supplement, not a medicine.
- 70 - Folic Acid:
General sale: in preparations containing 500 micrograms or less of folic acid per recommended Daily Dose (Otherwise S3).
- Iron compounds (excluding iron oxides when present as an excipient, up to 1 per cent in undivided preparations or up to 10 mg per dosage unit in divided preparations) for human internal use were switched from S2 to general sale effective 1 September 2002 except:
- . when included in Schedule 4; or
 - . when labelled with a recommended daily dose of 24 mg or less of iron
 - (i) in undivided preparations supplied in packs each containing 750 mg or less of iron; or
 - (ii) in divided preparations (A) containing more than 5 mg of iron per dosage unit in packs each containing 750 mg or less of iron; or (B) containing 5 mg or less of iron per dosage unit.
- Rx: in injectable preparations for human use.
- Note: The status of an iron and folic acid preparation would depend on the status of the individual components as shown above.
- September 2003: Clarification of the exemption for iron oxide concentrations when present as an excipient (S2 entry): in divided preparations ≤ 10 mg of total iron oxides per dosage unit; and undivided preparations $\leq 1\%$ of total iron oxide.
- 71 This is a dietary supplement, not a medicine.
- 72 Rx: in preparations for injection (Otherwise N.R.).

73 Adenosine triphosphate.

74 Rx: in preparations for injection or in metered-dose aerosols. S2 in all other forms. Effective 1 January 2008, S2 to S3 switch for preparations for rectal use.

75 Glyceryl trinitrate transdermal preparations.

76 S2 Pharmacy Only for topical use in preparations containing 0.25% or less of amorolfine. Unscheduled GSL for tinea pedis. All other preparations S3 Pharmacist Only.

77 For the treatment of athlete's foot.

78 Switched from S4 to S2 in 1997 for human use in dermal preparations. S2 in preparations for dermal use containing $\leq 1\%$ bifonazole for the treatment of the scalp Effective 1 January 2006, dermal preparations switched from S2 to GSL for the treatment of tinea pedis.

79 Topical form.

80 Topical form.

81 Extended to General Sale for tinea pedis only (July 1999).

82 1% cream and lotion.

83 Topical. For the treatment of athlete's foot.

84 S2: Ciclopirox in preparations for dermal use containing less than 2 per cent of ciclopirox with effect from 1 September 2002. Permission for treatment of nails included in S2 entry from 1 January 2007.
Effective 1 May 2007: GSL for preparations for tinea pedis.

85 Extended to General Sale for tinea pedis only (July 1999).

86 Effective 1 January 2006, switched from S2 to GSL status for dermal preparations in the treatment of tinea pedis. Permission for treatment of nails included in S2 entry from 1 January 2007.

87 Extended to General Sale for tinea pedis only (July 1999).

88 Clotrimazole dermatological preparations 1% were switched from P to GSL in September 2000.

89 Clotrimazole as antifungal, 1% lotion and cream, twice daily.

90 S2 in dermal preparations (Rx to S3 and S2 in stages (1994-1997)).
S3 in preparations for vaginal use (Rx to S3 (1997)) (Otherwise Rx).
Effective 1 January 2006, S2 to GSL switch in dermal preparations for the treatment of tinea pedis.

91 1% cream and lotion.

92 Topical form.

93 Extended to General Sale for tinea pedis only (July 1999).

94 Econazole vaginal preparations were switched from POM to P in November 1995. Econazole dermatological preparations 1% were switched from P to GSL in September 2000.

95 On 19 November 2009, the Canadian Government approved the nonprescription status for 150 mg of fluconazole for oral use in the treatment of vaginal candidiasis.

96 Dosage is 1% as topical antifungal.

97 S2 in dermal preparations (Otherwise Rx). Since June 1999, vaginal use is S3 (Pharmacist only).

98 Vaginal use is also OTC.

- 99 Isoconazole vaginal preparations were switched from POM to P in November 1995.
- 100 Ketoconazole switched from S3 to S2 in September 1999 in preparations for human dermal use. Unscheduled in preparations containing 1% or less for the treatment of the scalp. Effective 1 January 2006, S2 to GSL switch for dermal preparations for the treatment of tinea pedis
- 101 1% and 2% lotion, 2% cream.
- 102 Since 1998, shampoos containing 1% or less of ketoconazole are general sale. Also extended to General Sale for tinea pedis (July 1999).
- 103 Cream and shampoo: 2% and below.
- 104 Ketoconazole topical preparations POM to P Sep 1997; 1% were switched from P to GSL in April 2002.
- 105 Shampoo only (1%).
- 106 Switched in 1994: S4 until December 1994. In topical preparations for vaginal use and when containing 2 per cent or less of miconazole for the treatment of oral candidiasis. Switched in 1999: effective June 1999, concentration limitation removed i.e. miconazole for human use in topical preparations for treatment of oral candidiasis; or for vaginal use. Effective 1 January 2006, S2 to GSL switch for dermal preparations for the treatment of tinea pedis.
- 107 2% cream and lotion.
- 108 Extended to General Sale for tinea pedis only (July 1999).
- 109 Miconazole nitrate, cream: 2%. Also in creams in association with hydrocortisone: 20mg (miconazole) + 10mg (hydrocortisone) / 5g.
- 110 Miconazole dermatological preparations 2% were switched from P to GSL in September 2000.
- 111 Miconazole nitrate. Maximum dosage is 2%.
- 112 S3 (only as hydrocortisone acetate) for topical rectal use when containing 0.5% or less of miconazole as the only other therapeutically active substance.
- 113 1% cream.
- 114 Ophthalmic suspension.
- 115 For the treatment of athlete's foot.
- 116 Switched in 1990: S4 until 1990. Rescheduled to S3 in treatments for topical use for treatment of candidal infections only. In March 1997, rescheduled to S2 as preparations for topical use, except in dermal preparations.
- 117 For vaginal use.
- 118 Extended to General Sale for tinea pedis only (July 1999).
- 119 Effective 1 January 2006, S4 to GSL switch for dermal preparations for the treatment of tinea pedis. Vaginal use S3 from 1 September 2006. All other dermal preparations S2.
- 120 Topical use.
- 121 Extended to General Sale for Tinea pedis only (July 1999).
- 122 General sale in preparations for topical therapeutic use containing 2.5% or less of selenium sulfide. Effective 1 January 2004, S4 to S2 switch for topical preparations for human topical therapeutic use except in preparations containing 3.5% or less of selenium sulfide.. S4 to GSL for preparations > 2.5% and ≤ 3.5% selenium sulphide. Other selenium entries in S3, S4, S6 or S7.

- 123 Selenium sulfide scalp preparations not exceeding 2.5% were switched from P to GSL in September 2000.
- 124 Switched in 1996: S4 until 21 December 1996. S2 in topical preparations containing 1 per cent or less of terbinafine, for treatment of fungal infections of the skin. Switched in 1999: effective June 1999, limit on concentration removed. S2 in preparations for dermal use.
- 125 Topical. For the treatment of athlete's foot.
- 126 Extended to General Sale for Tinea pedis only (July 1999).
- 127 Terbinafine 1% dermatological preparations are OTC.
- 128 Only OTC for topical preparations (1%). Tablets remain Rx.
- 129 S2 in preparations for dermal use (Rx---S3 (1987) and S3---S2 (1999) strength limitation removed in 1999)(Otherwise Rx). S3 in preparations for vaginal use since June 1999. Effective 1 January 2006, S2 to GSL switch for dermal preparations for the treatment of tinea pedis.
- 130 External and vaginal use. Cautionary statements include a warning not to use the medicine for the first time without prior diagnosis by a physician.
- 131 External and vaginal use. Extended to General Sale for Tinea pedis only (July 1999).
- 132 Topical cream: 1%.
- 133 Tioconazole vaginal preparations were switched from POM to P in November 1995.
- 134 Tioconazole as a vaginal ointment. Dosage of 6.5% in one-dose treatment.
- 135 General sale.
- 136 General sale.
- 137 Solutions, creams, ointments and powders: 1%.
- 138 Tolnaftate solutions, creams 1%. were switched from P to GSL in 2003.
- 139 Rx in preparations for injection.
- 140 Inactive ingredient in the USA.
- 141 Switched from S4 to S2 on 21 December 1996 in preparations containing 5 per cent or less of aciclovir for external use for the treatment of herpes labialis in packs containing 10g or less. Effective 1 June 2002, these preparations were switched to general sale (i.e., S2 entry deleted). All other aciclovir preparations are scheduled S4.
- 142 Aciclovir switched to OTC status in mid 2007 for recurrent herpes mouth ulcers. Distribution restricted to pharmacies following an initial doctor consultation.
- 143 Available on general sale maximum 5%, 10g tube.
- 144 Aciclovir topical for the treatment of cold sores. Maximum strength: 5%; maximum pack size: 2g.
- 145 0.5% as eye ointment, 1% as dermatological ointment.
- 146 For topical use.
- 147 Topical use.
- 148 On 22 September 2002, the Nonprescription Drug Scheduling Advisory Committee agreed to support unscheduled (general sale) status for docosanol cream 10% if the products labelling and package insert could be amended to show that the maximum duration of treatment was 10 days.
- 149 10% cream for cold sore / fever blister.
- 150 Switched in 1999: S2 in preparations containing 0.5% or less for dermal use until September 1999. Unscheduled in preparations containing 0.5% or less for dermal use.

- 151 Registered formulation of idoxuridine (topical) in combination with dimethylsulfoxide.
- 152 Rx effective since July 1999 (switched back from OTC status).
- 153 Switched in 1998: S4 until September 1998. S2 in preparations for dermal use containing 1 per cent or less of Penciclovir. All other preparations S4.
Switched in 1999: Higher concentrations S4 until September 1999. S2 in preparations for external use for the treatment of herpes labialis.
- 154 S2 in preparations for external therapeutic use containing 2% or less of podophyllotoxin. S3 in preparations for external therapeutic use containing more than 2% but not more than 4% of podophyllotoxin.
- 155 For external use; pack size 50g or less.
- 156 Topical use.
- 157 S3 Pharmacist Only as the only therapeutically active substance in preparations for dermal use containing 0.05 per cent or less of aclo­methasone (aclo­metasone) in packs containing 30g or less of the preparation.
- 158 Dermal preparations containing less than 0.05% clobetasone 17-butyrate in packs of less than 30g were switched to S3 (Pharmacist only) status effective 1 September 2002. As from 1 September 2003, limitation to single active ingredient formulations for dermal use \leq 0.05% clobetasone in packs of \leq 30 g.
Effective 1 September 2007, Appendix H entry deleted (S3 product can no longer be advertised to consumers).
- 159 Clobetasone butyrate obtained OTC status in 2006 at up to 0.05% concentration.
- 160 Clobetasone butyrate 0.05% was proposed for declassification from Rx to OTC in 2002.
- 161 Effective 1 January 2008: S2 - Hydrocortisone and hydrocortisone acetate, but excluding other salts and derivatives, in preparations containing 0.5% or less hydrocortisone:
(a) for dermal use, in packs containing 30g or less of such preparations containing no other therapeutically active constituent other than an antifungal substance.
(b) for rectal use when combined with a local anaesthetic substance but no other therapeutically active constituent except unscheduled astringents:
- in undivided preparations in packs of 35g or less, or
- in packs containing 12 or less suppositories
S3 - Hydrocortisone and hydrocortisone acetate, but excluding other salts and derivatives, in preparations containing 1% or less pf hydrocortisone:
(a) for dermal use, in packs containing 30g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance or
(b) for rectal use when combined with a local anaesthetic but no other therapeutically active substance except unscheduled astringents:
- in undivided preparations in packs of 35g or less, or
- in packs containing 12 or less suppositories
except when included in Schedule 2
S4 – Hydrocortisone:
(a) for human use except when included in Schedule 2 or 3; or
(b) for the treatment of animals.
- 162 Dosage up to 0.5%.
- 163 Only combination (ointments) “oxytetracycline + hydrocortisone” as “30mg + 5mg (or 10mg)” per g.
- 164 Hydrocortisone or hydrocortisone acetate as antipruritic. Dosages from 0.25 to 0.50%. In 1991, OTC approval for dosages between 0.5% and 1%.

- 165 Topical form only.
- 166 Buccal use: 0.1% or less. Maximum pack size 5g. Aqueous nasal spray: maximum 55µg per actuation.
- 167 General sale (some warning labels applied through the classification system).
- 168 Bromide form only. For external solutions, maximum strength is 10% (should be diluted for use); for plasters, maximum dose is 0.11mg/cm².
- 169 Spray: 0.13g/100ml. Also in association with cetrimide “0.01% + 0.2%” (cream).
- 170 General sale.
- 171 Solutions, creams and ointments: 10% and below; Solutions for mouthwash: 1%.
- 172 In 1987, OTC approval for povidone iodine 10% as antimicrobial with a new sponge dosage form.
- 173 General sale.
- 174 Classified as “quasi drug”.
- 175 General sale.
- 176 S2 in preparations for external therapeutic use containing 5% or less of benzoyl peroxide. S3 in preparations for external therapeutic use containing more than 5% but not more than 10% of benzoyl peroxide. Rx: in preparations for external therapeutic use containing more than 10% of benzoyl peroxide.
- 177 Dosage up to 5%.
- 178 5% cream and gel.
- 179 General sale 5% or less.
- 180 10% and below (lotions and gels).
- 181 1% topical gel and lotion.
- 182 For dermal use.
- 183 0.5% as eye ointment, 1% as dermatological ointment.
- 184 Lotion: 0.05% and below.
- 185 Switched in 1998: S4 until September 1998. S3 in preparations for dermal use containing 2 per cent or less of minoxidil. All other preparations S4. Switched in 2000: effective 17 March 2000, S3 in preparations for dermal use containing 5 per cent or less of minoxidil. All other preparations S4.
- 186 Minoxidil 2% topical solution switch to OTC in February 2000.
- 187 5%.
- 188 Immediate OTC sale in 1999 (no switch from Rx).
- 189 Minoxidil topical. Maximum strength = 5%.
- 190 2% and 5 % topical solution as hair grower.
- 191 Oral form.
- 192 For treatment of oral candidiasis.

- 193 Effective 1 May 2007: S4 to S3 switch for vaginal use.
S3 – Butoconazole in preparations for vaginal use.
S4 – Butoconazole except when included in Schedule 3.
- 194 Topical form.
- 195 Changed to Rx September 2005.
- 196 Butoconazole nitrate as anticandidal, with a dosage of 2.0% cream and applicators. Three-day treatment for vaginal yeast infections (previously seven-day treatment).
- 197 S3 in preparations for vaginal use (Rx to S3 in 1997).
- 198 Vaginal tablets: 100mg%; Solution and cream: 1%.
- 199 Clotrimazole vaginal preparations were switched from POM to P in November 1995.
- 200 Clotrimazole as anticandidal, 1% cream and 200mg inserts. Original approval in 1990. Strength change in 1996
- 201 Switched in 1994: S4 until December 1994. In topical preparations for vaginal use and when containing 2 per cent or less of miconazole for the treatment of oral candidiasis.
Switched in 1999: effective June 1999, concentration limitation removed i.e. miconazole for human use in topical preparations for treatment of oral candidiasis; or for vaginal use.
- 202 Ovules: 400mg.
- 203 Miconazole vaginal preparations were switched from POM to P in November 1995.
- 204 Miconazole nitrate as anticandidal, 4% cream. Three-day vaginal yeast infection treatment switched in 1996.
- 205 As from 1 January 2004, S4 to S3 for two 0.75mg tablet packs for emergency contraception. Levonorgestrel also in S4.
- 206 Levonorgestrel approved for pharmacy-only (Schedule II) status on 20 April 2005.
- 207 Switched to OTC status in 1999 as part of a government birth control programme.
- 208 When used for emergency contraception and sold by recognised professionally competent registered nurses and pharmacists in the field of sexual and reproductive health.
- 209 Levonorgestrel was switched to OTC status for emergency contraception for women over 18 years on 24 August 2006 following a protracted and highly publicised approval process spanning several years. Since April 2009, the product is available for women 17 years and over.
- 210 General sale.
- 211 395mg/ml solution for topical use.
- 212 S2 – Benzylamine in preparations for topical use, except in preparations for dermal use.
S4 – Benzylamine except: (a) when included in Schedule 2; or (b) in preparations for dermal use.
Effective 1 September 2007: S2 to GSL switch for dermal preparations, i.e. preparations for application to the skin primarily for localised effect.
- 213 General sale: in preparations for dermal use containing 5% or less of bufexamac or in suppositories (Otherwise Rx)
- 214 S4 to S2 effective date 20 September 1997, in preparations for dermal use containing 1% or less of diclofenac.
S4 to S3 switch effective 17 March 2000: all preparations other than dermal preparations containing 1% or less of diclofenac in divided preparations for oral use containing 25mg or less per dosage unit in a pack containing 30 or less dosage units.
Effective 1 September 2005, S3 entry only for oral dose preparations containing > 12.5 mg and ≤ 25 mg in packs of up to 30 dosage units. Effective 1 September 2005,

standardised label warnings (statements 101 and 104 on stomach ulcer, pregnancy, allergic status, asthma, length of treatment and concomitant use with other antiinflammatories) added for S2 and S3 entries.

215 Oral diclofenac is OTC since 1998.

216 Diclofenac and its salts in preparations for topical use on the skin was switched to non-prescription status when sold as a single medicinal ingredient in a concentration equivalent to 1% or less.

217 Diclofenac for topical use is on general sale.

218 Both Diclofenac K and Diclofenac Na are Rx.

219 Diclofenac topical preparations switched to pharmacy sale in 1998. Topical preparations 1% switched to general sale in October 2002.

220 Gel 3%.

221 Switched from S3 to S2 effective 1 May 2003, in divided preparations for topical oral use containing ≤ 10 mg flubiprofen per dosage unit.

222 OTC in throat lozenges containing 10mg or less.

223 Oral tablets.

224 However, a glucosamine derivative is used as an additive in OTC preparations.

225 Glucosamine is OTC as part of a fixed-dose combination (e.g glucosamine sulfate plus chondroitin sulfate; or glucosamine hydrochloride plus manganese, goto cola, ginger, celery). Glucosamine Rx as a single component product.

226 Glucosamine has “dietary supplement” status in the United States with structure/function claims, but disease claims are not allowed.

227 400mg switched to OTC status in 2002.

228 S2 - Pharmacy Only in preparations for oral use when labelled with a recommended daily dose of 1200mg or less of ibuprofen: (a) in liquid preparations when sold in the manufacturer’s original pack containing 4 grams or less of ibuprofen; or (b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of 100 or less dosage units except when: (i) as the only therapeutically active constituent other than an effervescent agent; (ii) packed in blister or strip packaging or in a container with a child-resistant closure; (iii) in a primary pack of 25 or less dosage units; (iv) the primary pack is labelled with warning statements.

Effective 1 September 2005, standardised label warnings (statements 101 and 104) added to GSL, S2 and S3 entries.

S3 – Effective 1 May 2007: –Ibuprofen in divided preparations, each containing 400 mg or less of ibuprofen, in a primary pack containing not more than 50 dosage units when labelled: (a) with a recommended daily dose of 1200 mg or less of ibuprofen; and (b) not for the treatment of children under 12 years of age except when included in or expressly excluded from Schedule 2. Unscheduled packs of ibuprofen must not be labelled for the treatment of children under the age of 6.

229 Ibuprofen combinations were switched in 1994.

230 For oral preparation, maximum dose is 0.2g per tablet per pack or pill; for release-controlled capsules or tablets, maximum dose is 0.3g; for oral solutions, maximum strength is 1%.

231 400mg is Rx.

232 Oral solids maximum 200mg/dose. 25 units now General Sale.

233 200mg (also combination “ibuprofen 200mg & paracetamol 325mg”).

- 234 Ibuprofen oral tablets/caplets 200 mg and 100mg/5ml suspension became available for pharmacy only sale in restricted pack sizes from 15 April 2002 for the relief of headache, menstrual pain, backache, muscular and arthritic pain, toothache, and the aches of cold and flu as well as for the reduction of fever. In children: for the reduction of fever, including post-immunisation pyrexia, and the relief of mild to moderate pain such as sore throat, teething pain and toothache, earache, minor aches and sprains. It is indicated for use in infants from 2 to 6 months old for post-immunisation pyrexia only.
- 235 Ibuprofen as internal analgesic / antipyretic. Adult dosage is 200mg / 4-6 hours. Migraine indication added in 2000. In 1995, ibuprofen suspension received OTC approval as internal analgesic / antipyretic with a paediatric dosage of 7.5mg/kg up to 4 times a day.
- 236 Since 1 May 2003, GSL in preparations for external use.
- 237 For cream or pains, maximum strength is 5%; for suppositories, maximum dose is 100mg per unit.
- 238 Ibuprofen piconol (in the treatment of acne).
- 239 Topical preparations switched in 1998.
- 240 Switched in 1994: S4 until March 1994. S2 as the only therapeutically active in spray preparations for external use containing 1 per cent or less of indomethacin
Switched in 2000: S2 entry extended to preparations for external use containing 1 per cent or less of indomethacin, effective 17 March 2000.
- 241 For external preparations. Maximum strength is 1% for plasters, maximum dose is 12.5mg per plaster. Suppositories rescheduled to Rx on 1 January 2006.
- 242 Oral.
- 243 Topical use only.
- 244 Ketoprofen as internal analgesic with a dosage of 12.5mg (lower strength than the Rx version) every 4 to 6 hours.
- 245 Switched to S2 in preparations for dermal use on 17 March 2000. Effective September 2003, ketoprofen in preparations for dermal use switched from S2 to GSL.
- 246 Topical preparations switched in 1998.
- 247 Switched in 1999: Combinations S4 until September 1999. S2 in divided preparations for oral use in packs of 30 or less for treatment of dysmenorrhoea.
- 248 250mg (tablets and capsules).
- 249 S2 Naproxen in divided preparations containing 250 mg or less of naproxen per dosage unit in packs of 20 or less dosage units for the treatment of dysmenorrhoea. S3 Naproxen in divided preparations containing 250mg or less of naproxen per dosage unit in packs of 30 or less dosage units except when included in S2 (Otherwise Rx e.g. dermal or rectal application).
- 250 Oral naproxen is OTC.
- 251 Naproxen sodium tablets 220mg became available OTC in September 2003
- 252 Naproxen received OTC approval as internal analgesic / antipyretic with an adult dosage of 200mg / 8-12 hours (oral).
- 253 Switched in 1998: S4 until March 1998. S2 in dermal preparations containing 0.5% or less of piroxicam
Switched in 2000: effective 17 March 2000, limit on concentration increased. S2 in dermal preparations containing 1% or less of piroxicam.
- 254 0.5% topical gel, 1% lotion.
- 255 0.50% topical gel.
- 256 Piroxicam dermatological preparations were switched from POM to P in January 2000.
- 257 Topical use.

- 258 S2 when in lozenges, pastilles, capsules or tablets each containing 30mg or less of benzocaine or suppositories containing 200mg or less of benzocaine or preparations for topical use, other than eye drops, containing 10% or less of local anaesthetic substances.
- 259 General sale.
- 260 Benzocaine is OTC in combination with eucalyptus.
- 261 Effective 1 June 2002, dermal preparations containing 2 per cent or less of total local anaesthetic substances were switched from Rx to GSL (S4 to GSL). Effective 1 June 2002, dermal preparations containing 2 per cent or less of total local anaesthetic substances.
- 262 Switched in 1995: S4 until July 1995. In preparations for external use other than eye drops containing 0.5% or less of cinchocaine.
Switched in 1996: effective December 1996, use extended to topical (rectal administration) i.e. in preparations for topical use, other than eye drops, containing 0.5% or less of cinchocaine.
- 263 Dyclonine hydrochloride as oral anaesthetic. Adult dosage is 0.05 to 0.1% in rinse, mouthwash, gargle or spray, 3-4 times daily; dosage is 1 to 3mg as lozenge.
- 264 S2 when in lozenges, pastilles, capsules or tablets each containing 30mg or less of lidocaine or suppositories containing 200mg or less of lidocaine or preparations for topical use, other than eye drops, containing 10% or less of local anaesthetic substances.
- 265 In compound preparations.
- 266 General sale 2% or less external; 30mg or less lozenges.
- 267 S2 for internal use (Otherwise Rx).
- 268 For stomach aches.
- 269 For internal use (effective since July 1999).
- 270 S2 in preparations for dermal use, other than eye drops, containing 10% or less of local anaesthetic substances (Rx to S2 (1993)).
- 271 For dermal use 10% or less.
- 272 1000mg switched to OTC status in 2003.
- 273 Acetylsalicylic acid is GSL as individually wrapped powders or sachets of granules in packs of 12 or less dosage units each containing 650mg or less of aspirin as the only therapeutically active substance and labelled with specified warnings, or as tablets or capsules when contained in child-resistant packaging in packs of either – 25 or less dosage units each containing 325mg or less of aspirin as the only therapeutically active substance, or 16 or less dosage units each containing 500mg or less of aspirin as the only therapeutically active substance provided the pack is labelled with specific warnings. New mandatory warning statements as from 1 May 2005. Revised Reye's Syndrome warning statement as from 1 January 2006.
ASA is Rx when in combination with caffeine, paracetamol or salicylamide or any derivative of these substances.
S2 when present other than as above.
- 274 Maximum dose = 0.5g per tablet; for enteric-coated tablets, maximum dose = 0.3g per tablet and maximum dose is 0.6g per pack; for suppository, maximum dose is 0.5g per unit.
The Chinese regulatory authority, the *State Food and Drug Administration*, in April 2004 issued a guideline and a procedure for switching medicines from prescription to non-prescription status designed to facilitate the reclassification of ingredients to non-prescription status. During the second half of 2004, a total of 75 products (chemical and Traditional Chinese Medicine products) were evaluated and switched to OTC status.
- 275 General Sale except for slow release forms; in enteric coated forms containing more than 300mg per dose. (Restricted = Pharmacist Only Medicine).
- 276 325mg and below (tablets and capsules).

- 277 S3 when compounded with one or more other therapeutically active substances, and in divided preparations containing 10mg or less per dosage unit and with a recommended dose of 15mg or less of dihydrocodeine, or in undivided preparations containing 0.25% or less of dihydrocodeine with a recommended dose of 15mg or less of dihydrocodeine. S2 when compounded with aspirin and no other therapeutically active substance in divided preparations in child-resistant packaging in packs of 25 or less dosage units with each dosage unit containing 5mg or less of dihydrocodeine and labelled with a recommended dose of 10mg or less of dihydrocodeine. (Otherwise Rx)
- 278 General sale: when as individually wrapped powders or sachets of granules in packs of 12 or less dosage units each containing 1000 mg or less of paracetamol as the only therapeutically active substance labelled with specified warnings and NOT labelled for the treatment of children younger than 7 years
OR as tablets or capsules when contained in child-resistant packaging in packs of 25 or less dosage units each containing 500 mg or less of paracetamol as the only therapeutically active substance labelled with specified warnings and NOT labelled for the treatment of children younger than 7 years.
Effective 1 May 2005, new mandatory warning statements required on small, unscheduled packs.
Effective 1 January 2008:
S2 – Paracetamol – Paracetamol for therapeutic use except: (a) when included in Schedule 4; (b) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine or when combined with effervescent agents) when: (i) enclosed in a primary pack that contains not more than 12 such powders or sachets of granules; (ii) compliant with the requirements of the Required Advisory Statements for Medicine Labels; (iii) not labelled for the treatment of children 6 years of age or less; and (iv) not labelled for the treatment of children under 12 years of age when combined with phenylephrine; or (c) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than phenylephrine or when combined with effervescent agents) when: (i) packed in blister or strip packaging or in a container with a child-resistant closure; (ii) in a primary pack containing not more than 25 tablets or capsules; (iii) compliant with the requirements of the *Required Advisory Statements for Medicine Labels*; (iv) not labelled for the treatment of children 6 years of age or less; and (v) not labelled for the treatment of children under 12 years of age when combined with phenylephrine.
S4 –Paracetamol:
(a) when combined with aspirin or salicylamide or any derivative of these substances except when separately specified in these Schedules;
(b) in slow release tablets or capsules containing more than 665 mg of paracetamol;
(c) in non-slow release tablets or capsules containing more than 500 mg of paracetamol; or
(d) in individually wrapped powders or sachets of granules each containing more than 1000 mg of paracetamol.
- 279 Solid dose max 10g (20 x 500mg) or powder form in sachets containing up to 1000mg or less and in packs containing 10g or less are available for General Sale. Suppositories; in liquid form; in tablet, capsule, or powder form containing 500mg or less and in packs containing more than 10g; in powder form in sachets containing 1000mg or less and in packs containing more than 10g are Pharmacy-Only Medicines.
- 280 500mg and below (also combination “ibuprofen 200mg & paracetamol 325mg”), in tablets and capsules.
- 281 S3 when present in a form specified in the S3 entry for dihydrocodeine (Otherwise Rx).
- 282 The combination paracetamol + dihydrocodeine is registered in Japan as a cough and cold product and not as an analgesic.
- 283 Switched in 2000: effective 17 March 2000, S3 when manufactured, packed and labelled for oral use, only for the treatment of nausea associated with migraine, in packs containing not more than 10 tablets.
- 284 Oral use. Maximum 10 tablets.

- 285 S2 – Nicotine for use as an aid in withdrawal from tobacco smoking in preparations for inhalation.
S4 – Nicotine in preparations for human therapeutic use except:
(a) when included in Schedule 2; or
(b) for use as an aid in withdrawal from tobacco smoking in chewing gum, lozenges, or preparations for sublingual or transdermal use.
S6 – Nicotine in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.
S7 – Nicotine except:
(a) when included in Schedule 6;
(b) in preparations for human therapeutic use; or
(c) in tobacco prepared and packed for smoking.
- 286 Both 2mg and 4mg strength (the latter switched in 1997).
- 287 General sale.
- 288 Nicotine oral (lozenges/gum) was proposed for declassification from Rx to OTC in 2002.
- 289 2mg & 4mg.
- 290 For use as an aid in withdrawal from tobacco smoking, in preparations for inhalation or sublingual use (S4 to S3 (1999)).
- 291 Cartridges for oral inhalation containing 10mg or less of nicotine per dosage unit were switched from S4 to S3 in June 1999 and from S3 to S2 on 1 September 2002.
- 292 Nicotine oral inhaler switched to OTC - Schedule III (pharmacy only) in 2003. The conditions are 4mg or less of nicotine per dosage unit.
- 293 Nicotine inhaler 10 mg switched from prescription-only to pharmacy-only in August 2002.
- 294 Approved as Rx medicine in 1997.
- 295 Effective 1 May 2004, nicotine chewing gum and transdermal patches switched from S2 to GSL. S2 entry: Nicotine for use as an aid in withdrawal from tobacco smoking: (a) in lozenges; or (b) in preparations for inhalation.
22mg/day and less, as an aid in smoking cessation.
- 296 One dose (15mg) patch to be used no longer than six weeks. Also in 21, 14, and 7 mg patch series.
- 297 Effective 1 September 2004, S2 to GSL switch for nicotine lozenges.
S2 entry: Nicotine for use as an aid in withdrawal from tobacco smoking in preparations for inhalation.
Effective 1 January 2005, nicotine sublingual preparations switched from S3 to S2. S3 entry deleted.
S2 entry: Nicotine for use as an aid in withdrawal from tobacco smoking in preparations for inhalation or sublingual use.
Effective 1 January 2006, S2 to GSL switch for sublingual use.
- 299 The 4mg sublingual lozenge was switched to non-prescription status in 2006.
- 300 General sale.
- 301 Nicotine lozenges and gums were approved as ‘Pharmacy’ medicines in July 2003 and January 2004, respectively.
- 302 Switched to OTC status in 2002 as the first amoebicide to obtain this status.
- 303 S2 for human therapeutic use.

304 For oral preparation, maximum dose is 200mg per tablet, suspension: 100ml/2g
305 Tablets: 500mg and below; suspension: 100mg/5ml.
306 Pyrantel embonate. S2 for human therapeutic use.
307 Pyrantel parnoate.
308 Pyrantel pamoate. For oral preparation, maximum dose is 0.3g per tablet per pill or pack.
309 Pyrantel pamoate.
310 Pyrantel embonate.
311 Pyrantel pamoate is OTC (switched in 1998).
312 Pyrantel embonate.
313 Pyrantel pamoate is OTC: 500mg and below (tablets); 250mg/5ml and below (oral suspensions). The combination “Pyrantel pamoate + Oxantel” is also OTC: 20mg + 20mg/ml (for oral suspension) or 100mg + 100mg (tablets);
314 Pyrantel pamoate/embonate. Switched from P to GSL in September 2000.
315 Pyrantel embonate.
316 General sale.
317 As additives.
318 General sale.
319 Only in combinations (lotions) “sulphur + benzyl benzoate” as 5% and 25% respectively.
320 S2 in preparations for human external therapeutic use containing 2% or less of lindane.
321 Effective 1 September 2006 - S3 for use in eye at 0.05%. S2 for nasal use.
322 For nasal use.
323 Switched from S4 to S3 in 1999 in aqueous nasal sprays delivering 50mcg or less per actuation when the maximum recommended daily dose is no greater than 400mcg for the treatment of seasonal and allergic rhinitis. Switched from S3 to S2 effective 1 September 2003: beclomethasone in aqueous nasal sprays delivering $\leq 50 \mu\text{g}$ beclomethasone per actuation when the maximum recommended daily dose is $\leq 400 \mu\text{g}$ and when packed in a primary pack containing ≤ 200 actuations, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.
324 Beclomethasone nasal spray for adults, maximum daily dose 400mcg.
325 Pharmacy-only medicine 50mcg per dose; maximum daily dose 400mcg.
326 Beclomethasone nasal spray for prevention and treatment of allergic rhinitis for persons at least 18 years of age at a maximum daily dose of 200 mcg/ nostril and a maximum of 3 months’ supply.
327 S3 to S2 effective 1 January 2004. Budesonide in aqueous nasal sprays delivering 50 μg or less of budesonide per actuation when the maximum recommended daily dose is no greater than 400 μg and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.
328 0.64mg/ml.

- 329 Rx for epidermal use.
- 330 Nasal use.
- 331 Budesonide nasal spray for prevention and treatment of allergic rhinitis for persons at least 18 years of age. Pharmacy-only medicine.
- 332 Switched in 2000: ophthalmic preparations S4 until March 2000. Effective 17 March 2000, S2 in preparations for nasal or ophthalmic use. (Note: nasal preparations for topical use were switched from S3 to S2 in 1990).
- 333 Sodium cromoglycate, 2% nasal solution and 2% ophthalmic solution, for the prevention and relief of seasonal allergy symptoms (this dosage form is antihistamine).
- 334 For nasal sprays and eye drops.
- 335 For nose and eyes.
- 336 Sodium cromoglycate 2% nasal spray for the treatment of allergic rhinitis.
- 337 Sodium cromoglycate 4% nasal spray for relief and prevention of the nasal symptoms of hay-fever and other nasal allergies in adults and children six years of age and older.
- 338 1% (nasal).
- 339 Now controlled drug effective April 2005.
- 340 Ephedrine sulphate as topical anorectal. Dosage is 0.1 to 1.25%. Also ephedrine HCl for asthma (bronchodilator) as 12.5mg.
- 341 General sale: in preparations containing 0.02% or less of adrenaline.
S3 in preparations containing more than 0.02% but not more than 1% of adrenaline.
Note: The schedules make no distinction between asthma and non-asthma use but, in practice, asthma use would generally be S3, e.g. metered-dose aerosols.
- 342 Eye drops only.
- 343 Epinephrine hydrochloride as topical anorectal / vasoconstrictor. Dosage is 0.005 to 0.01%. Also epinephrine as a bronchodilator as 5.5 mg/ml.
- 344 See previous entry on epinephrine not for asthma.
- 345 Effective 1 January 2006, rescheduled from S3 to S4 status.
- 346 Effective 1 May 2004, S3 to S2 switch.
S2 - Fluticasone in aqueous nasal sprays delivering 50 µg or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 400 µg and when packed in a primary pack containing 200 actuations or less, for the prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.
All other fluticasone preparations are prescription-only (Schedule 4).
- 347 S2 -Pharmacy Only in topical eye or nasal preparations. All other preparations S4 Prescription Only
- 348 Nasal or ophthalmic use: Pharmacy only medicine.
- 349 Ophthalmic solution or drops.
- 350 Effective 1 May 2003, Mometasone in aqueous nasal sprays delivering ≤50µg mometasone per actuation when the maximum recommended daily dose is ≤200µg and when packed in a primary pack containing ≤200 actuations, for the short-term prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over. Effective 1 January 2004, S3 to S2 in aqueous nasal sprays delivering ≤ 50 µg per actuation when the maximum recommended daily dose is ≤ 200 µg and when packed in a primary pack containing ≤ 200 actuations, for the short-term prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over. Restriction on primary pack containing ≤ 200 actuations removed for S2 entry from 1 September 2006.

351 Up to 50mcg per actuation, maximum daily dose up to 200mcg.
352 S2.
353 S2.
354 0.05%.
355 Nasal spray.
356 Oxymetazoline hydrochloride. Topical nasal decongestant as 0.05% in aqueous solution. In 1986, oxymetazoline HCl was approved OTC as ocular vasoconstrictor with a dosage of 0.025% solution / drops (topical).
357 General sale: in oral preparations containing 50 mg or less of phenylephrine per recommended daily dose in packs containing 250 mg or less of phenylephrine, or in topical eye or nasal preparations containing 1% or less of phenylephrine. Rx: in preparations for ophthalmic use containing 5% or more of phenylephrine or in preparations for injection. S2 all other forms and strengths.
358 General Sale nasal or ophthalmic use in medicines 1% or less; oral use 50mg or less daily dose; maximum 250mg per pack.
359 Phenylephrine hydrochloride 10mg/5ml and below (syrups) and 0.25mg (nasal spray).
360 Phenylephrine hydrochloride as topical anorectal / vasoconstrictor. Dosage is 0.25%.
361 In combinations.
362 Effective January 2006, pseudoephedrine-containing products in various pack sizes were switched from S2 to S3 (pharmacist only) status (S3) and are no longer available for advertising directly to the consumer. Products remain non-prescription so long as liquid preparations do not contain a total of more than 800 mg of pseudoephedrine hydrochloride or equivalent and tablet or capsule forms do not contain more than 720 mg.
Effective 1 April 2006, S3 to S4 switch of pseudoephedrine single active and combination products:
a) liquids containing >800 mg
b) all other preparations containing >720 mg
363 OTC for oral rhinitis as of 2002.
364 Controlled Drug C3 in cough/cold/flu/decongestant packs not exceeding 1.8g pseudoephedrine. Advertising to consumers permitted.
365 Pseudoephedrine in combination with brompheniramine maleate is OTC.
366 Pseudoephedrine hydrochloride or sulphate. Oral form. Adult dosage is 60mg / 4 or 4-6 hours. For hydrochloride, maximum dose is 240mg / 24 hours.
367 All preparations containing this substance are available as Pharmacy (Schedule 2) medicines.
368 Tetrahydrozoline in combination is OTC.
369 All preparations containing this substance are available as Pharmacy (Schedule 2) medicines.
370 S2.
371 Nasal drops: 0.1% and below.
372 Xylometazoline hydrochloride as topical nasal decongestant with adult dosage as 0.01% in aqueous solution.
373 Mupirocin was proposed for declassification from Rx to OTC in 2002.
374 Registered formulations are always combination products with reomycin sulphate.

- 375 In compound preparations.
- 376 Inhalations.
- 377 S3 as the only therapeutically active substance in metered aerosols delivering 100 micrograms or less of salbutamol per metered dose or in capsules of dry powder for inhalation delivering 200 micrograms or less of salbutamol per dose.
- 378 Oral form only.
- 379 Oral formulations such as tablets and syrups are OTC.
- 380 S3 in liquid oral preparations.
- 381 Oral forms.
- 382 Liquid for oral use.
- 383 Effective 1 May 2003, switched from S2 to GSL in preparations for oral use that are labelled with a recommended daily dose of $\leq 1\text{g}$ acetylcysteine. All other acetylcysteine preparations for oral use remain as S2.
- 384 Tablets: 30mg.
- 385 Ambroxol 4mg/5ml elixir and 30mg tablets switched to OTC status in November 2002. Ambroxol lozenges reclassified from Prescription Only Medicine (POM) to Pharmacy only medicine (P) status, with effect from 20 July 2005.
- 386 S2 all forms.
- 387 Tablets: 8mg; Suppositories: 2mg/ml and below.
- 388 Bromhexine HCl 8mg tablets and 4mg/5ml liquid switched from POM to P status in November 2002. Bromhexine HCl plus pholcodine as well as Bromhexine HCl liquid 12mg/15ml reclassified from POM to P status with effect from 6 October 2004.
- 389 S2 (pharmacy only medicine).
- 390 Capsules: 500mg and below; Suspension: 250mg/5ml and below.
- 391 Chlophendianol HCl as antitussive. Adult dosage is 25mg / 6-8 hours (oral).
- 392 S2. Effective 1 September 2003: limit on pack size ($\leq 600\text{ mg}$) for both divided and undivided preparations has been included in the schedule entry, and the concentration permitted for undivided preparations has increased from 0.3% to 0.6% with a recommended daily dose of $\leq 120\text{ mg}$ dextromethorphan. As from 1 January 2004, limit on pack size ($\leq 600\text{ mg}$) and recommended daily dose of $\leq 120\text{ mg}$ dextromethorphan now applies to both divided and undivided preparations. Dextromethorphan also in S4.
- 393 General sale 0.25% or less, 15mg or less.
- 394 Tablets: 15mg and below; Syrup (alcohol-free): 15mg/5ml and below.
- 395 OTC in liquid dosage forms and in pack sizes of no more than 300mg; Rx in pack sizes containing more than 300mg or in other than liquid dosage forms.
- 396 S2 in all forms.
- 397 S3 in oral preparations (Rx to S3 (1988)).
- 398 S2: Brompheniramine when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day-night pack containing brompheniramine in the bed-time dose, except in preparations for the treatment of children two years of age or less.

S3: Brompheniramine in oral preparations other than those in S2 above.

S4: Brompheniramine except when included in Schedule 2 or 3.

Effective 1 September 2008: S3 to S4 for children under 2 years of age.

399 In compound preparations.

400 Harmonisation of schedules of Australia and New Zealand. See note under Australia..

401 Harmonisation of schedules of Australia and New Zealand. See note under Australia..

402 Brompheniramine maleate. Oral form. Adult dosage is 4mg /4-6 hours.

403 Brompheniramine is OTC in certain combinations.

404 Switched in 1997: S4 until 19 December 1997. S3 as the only therapeutically active substance in divided preparations for oral use containing 10mg or less.

Switched in 1998: in September 1998, liquid formulations permitted and dosage limitation removed. Entry modified to read as the only therapeutically active substance in oral preparations

405 1 mg/1ml (children's syrup), 5 mg, and 10 mg, and 5 mg in combination with 120 mg pseudoephedrine.

406 S2: Chlorpheniramine when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:

- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- in a day-night pack containing chlorpheniramine in the bed-time dose, except in preparations for the treatment of children two years of age or less.

S3: Chlorpheniramine in oral preparations other than those in S2 above

S4: Chlorpheniramine except when included in Schedule 2 or 3.

Effective 1 September 2008: S3 to S4 for children under 2 years of age.

407 Harmonisation of schedules of Australia and New Zealand. See note under Australia.

408 Tablets: 2mg and below; syrup: 2mg/5ml.

409 Chlorpheniramine maleate. Oral form. Adult dosage is 4mg/4-6 hours. In 1981, it received OTC approval for oral time-released form with adult dosage of 12 mg / 12 hours.

410 Effective 1 May 2007:

S3 – Clemastine in preparations for oral use

S4 - Clemastine except when included in Schedule 3.

411 Clemastine hydrogen fumarate 1mg/tablet; also combination “clemastine + phenylpropanolamine” 1mg + 50mg (tablets).

412 Clemastine fumarate as antihistamine. Adult dosage is 1.34 mg/12 hours. Same dosage when used in combination with phenylpropanolamine HCl as antihistamine / decongestant.

413 S3 in oral preparations.

- 414 Dexbrompheniramine maleate as antihistamine. Adult dosage is 6mg/12 hours (oral time-released). In 1985, it received OTC approval with an adult dosage of 2mg/4-6 hours (oral). In 1987, it received OTC approval with an adult dosage of 3mg/6-8 hours (oral).
- 415 S2: Dexchlorpheniramine when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:
- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
 - in a day-night pack containing dexchlorpheniramine in the bed-time dose,
- except in preparations for the treatment of children two years of age or less.
- S3: Dexchlorpheniramine in oral preparations except when included in Schedule 2.
- Effective 1 September 2008: S3 to S4 for children under 2 years of age.
- 416 Harmonisation of schedules of Australia and New Zealand. See note under Australia.
- 417 In 1992, dexchlorpheniramine maleate received OTC approval as antihistamine with an adult dosage of 2mg / 4-6 hours (oral).
- 418 Topical cream.
- 419 S2: Diphenhydramine: (a) in primary packs of 10 doses or less, for the prevention or treatment of motion sickness; or (b) when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when: (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or (ii) in a day-night pack containing diphenhydramine in the bed-time dose, except in preparations for the treatment of children two years of age or less.
- S3: Diphenhydramine in oral preparations except when included in Schedule 2.
- S4: Diphenhydramine except when included in Schedule 2 or 3.
- Effective 1 September 2008: S3 to S4 for children under 2 years of age.
- 420 Maximum dose is 25mg per tablet; for syrup, maximum strength is 0.2%.
- 421 Harmonisation of schedules of Australia and New Zealand. See note under Australia.
- 422 Diphenhydramine hydrochloride 12.5mg/5ml (syrup) ; 1% topical cream.
- 423 Diphenhydramine hydrochloride as antitussive. Oral form. Adult dosage is 25mg/4 hours. In 1982, diphenhydramide both hydrochloride and monocation received OTC approval as sleep aid with a single oral dose of 50mg and 76mg respectively. In 1985, diphenhydramine hydrochloride received OTC approval as antihistamine with an adult dosage of 25-50mg / 4-6 hours (oral). In 1987, it received OTC approval with the same dosage but as antiemetic.
- In 1982, OTC approval of diphenhydramine hydrochloride and diphenhydramine monocation as sleep-aid with an adult dosage of 50mg and 76mg, respectively, both single oral doses.
- 424 Effective 1 January 2006, S2 and S3 entries deleted (ingredient rescheduled to S4 status).
- 425 Harmonisation of schedules of Australia and New Zealand. See note under Australia.
- 426 S2: Doxylamine when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:
- at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
 - in a day-night pack containing doxylamine in the bed-time dose,

except in preparations for the treatment of children two years of age or less.

S3: Doxylamine in oral preparations except when included in Schedule 2.

S4: Doxylamine except when included in Schedule 2 or 3.

Effective 1 September 2008: S3 to S4 for children under 2 years of age.

427 Harmonisation of schedules of Australia and New Zealand. See note under Australia.

428 Switched in 1997 to S3 (Pharmacist only) as the only therapeutically active substance in divided preparations for oral use.

429 Put on the market in August 1997.

430 Likely to be switched to OTC status following an FDA hearing in June 2001.

431 Ophthalmic use. 0.025% or less.

432 For oral use.

433 Switched to S3 in 1994. S3 as the only therapeutically active substance in divided preparations for oral use containing 10mg or less of loratadine per dosage unit in a pack containing 10 or less dosage units. In June 1996, liquid preparations were added. From March 1997, the pack size restrictions were no longer applied. From September 1998, combinations with pseudoephedrine as the only other active substance were permitted in preparations containing 5mg or less of loratadine per dose unit.

434 On 22 September 2002, the Nonprescription Drug Scheduling Advisory Committee recommended that loratadine and its salts and preparations in products marketed for adult use (age 12 years and over) be unscheduled. Loratadine marketed for paediatric use (under 12 years) will remain Schedule III.

435 Tablets: 10mg.

436 Tablets: 10mg; syrup: 5mg/5ml.

437 10 mg/day tablets or syrup antihistamine.

438 Effective 1 January 2005, small packs of meclizine, when indicated for motion sickness, switched from S4 to S2.

S2 entry: Meclozine in primary packs containing 12 or less tablets or capsules of meclizine for the prevention or treatment of motion sickness, except in preparations for the treatment of children under two years of age.

439 25 mg, for the prevention and treatment of nausea, OTC as of July 2000.

440 Maximum 12 tablets. Restricted to authorised travel outlets.

441 Tablets: 100mg and below.

442 S3 in oral preparations. S2 for dermal use.

443 Topical use.

444 S2 entry: Promethazine: (a) in primary packs of 10 doses or less, for the prevention or treatment of motion sickness; or (b) when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when: (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or (ii) in a day-night pack containing promethazine in the bed-time dose, except in preparations for the treatment of children two years of age or less. Reference to “in oral preparations for the treatment of symptoms of coughs, colds or influenza” removed 1 September 2006.

S3 in oral preparations other than those in S2 above.

445 For oral preparation, maximum dose is 12.5mg per tablet; for syrup, maximum strength is 0.1%.

- 446 Harmonisation of schedules of Australia and New Zealand. See note under Australia.
- 447 Effective 1 September 2004, S2 entry changed to require that oral combination preparations include a sympathomimetic decongestant, or that triprolidine is only included in the night component of a day-night pack. This means that the many cough and cold products that do not contain a sympathomimetic decongestant have been switched from S2 to S3. S2 entry: Triprolidine when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when: (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or (b) in a day-night pack containing triprolidine in the bed-time dose except in preparations for the treatment of children two years of age or less.
S3 in oral preparations other than those in S2 above.
Effective 1 September 2008: S3 to S4 for children under 2 years of age.
- 448 Harmonisation of schedules of Australia and New Zealand. See note under Australia.
- 449 Triprolidine hydrochloride as antihistamine. Adult dosage is 2.5mg/4-6 hours. In 1985, triprolidine HCl was approved OTC with a dosage of 5mg / 12 hours.
- 450 S3 in preparations for ophthalmic use containing 10% or less of sulfacetamide (Rx to S3 (1996)).
- 451 10%, 15% for eye care.
- 452 For topical use.
- 453 For eyes.
- 454 Only in combinations (ointments) “oxytetracycline + polymixin B sulfate” as 30mg + 4000U.
- 455 Imipenem-Cilastatin combination.
- 456 Dequalinium chloride: solution (paint) 5mg/ml.
- 457 General sale.
- 458 Toothpaste as a quasi-drug. .
- 459 However, strontium acetate (toothpaste) is available on general sale.
- 460 General sale.