

Legal classification status of selected ingredients in new EU and non-EU European countries

Last major update: 19 December 2008

Important remarks:

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 However, because of the rapidly changing situation, some information may be outdated.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

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(Data for the European Union of 15 and selected countries Worldwide are available in separate tables)

| Ingredient | Bulgaria | Croatia | Czech Republic | Hungary | Lithuania | Norway | Poland | Slovak Republic | Slovenia | Switzerland |
|--|--------------------|------------------|-------------------|-------------------|-----------|--------------------|-------------------|-----------------|--------------------|--------------------|
| A. ALIMENTARY TRACK AND METABOLISM | | | | | | | | | | |
| A01 Stomatological preparations | | | | | | | | | | |
| Fluoride (sodium) | OTC | Rx | OTC | OTC ¹ | OTC | OTC | OTC ² | Rx | OTC | OTC ³ |
| Hexetidine | OTC | OTC | OTC | N.R. | OTC | N.R. | N.R. | OTC | N.R. | OTC ⁴ |
| Triamcinolone (oral) | N.R. | N.R. | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| A02 Drugs for acid-related disorders | | | | | | | | | | |
| Aluminium hydroxide | N.R. | N.R. | OTC | OTC ⁵ | OTC | OTC | OTC | OTC | N.R. | OTC |
| Calcium carbonate | OTC | OTC | OTC | OTC ⁶ | OTC | OTC | OTC ⁷ | 1992 | OTC | OTC |
| Carbenoxolone | N.R. | N.R. | N.R. | OTC ⁸ | OTC | N.R. | N.R. | N.R. | N.R. | Rx |
| Cetraxate | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Cimetidine | Rx | OTC ⁹ | Rx | Rx | Rx | Rx | OTC ¹⁰ | 1992 | Rx | Rx |
| Famotidine | Rx | Rx | Rx | OTC ¹¹ | Rx | OTC ¹² | OTC ¹³ | Rx | Rx | Rx |
| Lansoprazole | Rx | | Rx | Rx | | Rx | Rx | Rx | Rx | Rx |
| Nizatidine | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Omeprazole | Rx | Rx | Rx | Rx | Rx | 2006 ¹⁴ | Rx | Rx | Rx | Rx |
| Pantoprazole | 2009 ¹⁵ | | 2009 | 2009 | 2009 | Rx | 2009 | 2009 | 2009 | Rx |
| Ranitidine | Rx | Rx | OTC ¹⁶ | OTC ¹⁷ | OTC | 1997 ¹⁸ | OTC ¹⁹ | 1992 | 1997 ²⁰ | 1996 ²¹ |
| Sucralfate | Rx | N.R. | Rx | OTC ²² | Rx | Rx | Rx | Rx | Rx | Rx |
| A03 Drugs for functional gastrointestinal disorders | | | | | | | | | | |
| Dicyclomine (Dicycloverine) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Dimeticone | OTC | OTC | Rx | OTC ²³ | OTC | N.R. | OTC ²⁴ | OTC | OTC | OTC |

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|---|--------------------|---------|-------------------|-------------------|-----------|-------------------|--------------------|-----------------|----------|-------------------|
| Domperidone | Rx | N.R. | OTC ²⁵ | Rx | Rx | N.R. | Rx | N.R. | Rx | OTC ²⁶ |
| Hyoscine butylbromide | Rx | Rx | OTC | 2003 | 1996 | N.R. | 2000 ²⁷ | Rx | 2007 | OTC |
| Mebeverine | Rx | Rx | Rx | Rx | N.R. | N.R. | Rx | N.R. | N.R. | Rx |
| Metoclopramide | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Propantheline | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²⁸ |
| A04 Antiemetics and Antinauseants | | | | | | | | | | |
| Dimenhydrinate (diphenhydramine and chlorotheophylline) | | | | OTC | | | | | N.R. | |
| Hyoscine (Scopolamine) | Rx | Rx | Rx | 2004 | Rx | Rx | OTC ²⁹ | Rx | N.R. | OTC |
| A05 Bile and liver therapy | | | | | | | | | | |
| Hymecromone | Rx | N.R. | OTC | N.R. | OTC | N.R. | Rx | OTC | N.R. | Rx |
| A06 Laxatives | | | | | | | | | | |
| Bisacodyl | OTC | OTC | OTC | OTC ³⁰ | OTC | OTC | OTC ³¹ | OTC | OTC | OTC ³² |
| Lactitol | OTC | N.R. | OTC ³³ | N.R. | OTC | OTC | OTC | OTC | OTC | OTC |
| Lactulose | OTC | Rx | OTC | OTC ³⁴ | OTC | OTC | OTC ³⁵ | OTC | OTC | OTC |
| Picosulfate (sodium) | OTC | N.R. | OTC | N.R. | OTC | OTC | N.R. | OTC | N.R. | OTC |
| A07 Antidiarrheals | | | | | | | | | | |
| Loperamide | Rx | Rx | OTC ³⁶ | OTC ³⁷ | OTC | OTC ³⁸ | OTC ³⁹ | OTC | Rx | OTC ⁴⁰ |
| Nifuroxazide | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | 2007 | 2007 | N.R. | N.R. |
| A08 Antiobesity preparations | | | | | | | | | | |
| Orlistat | 2009 ⁴¹ | | 2009 | 2009 | 2009 | Rx | 2009 | 2009 | 2009 | Rx |

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|--|----------|---------|-------------------|-------------------|-----------|--------------------|-------------------|-----------------|-------------------|-------------------|
| A10 Drugs used in diabetes | | | | | | | | | | |
| Insulin | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| A11 Vitamins | | | | | | | | | | |
| Vitamin A (Retinol) | OTC | Rx | OTC ⁴² | OTC ⁴³ | OTC | N.R. | OTC ⁴⁴ | OTC | OTC ⁴⁵ | OTC |
| A12 Mineral supplements | | | | | | | | | | |
| Selenium | N.R. | N.R. | OTC ⁴⁶ | OTC ⁴⁷ | OTC | OTC | OTC | OTC | OTC ⁴⁸ | OTC |
| B. BLOOD AND BLOOD FORMING ORGANS | | | | | | | | | | |
| B02 Antihemorrhagics | | | | | | | | | | |
| Tranexamic acid | | | | Rx | | Rx | | | N.R. | |
| B03 Antianemic preparations | | | | | | | | | | |
| Iron and folic acid preparations | OTC | Rx | OTC | Rx ⁴⁹ | Rx | N.R. ⁵⁰ | OTC | OTC | OTC ⁵¹ | OTC ⁵² |
| C. CARDIOVASCULAR SYSTEM | | | | | | | | | | |
| C01 Cardiac therapy | | | | | | | | | | |
| Adenosine | Rx | N.R. | Rx | Rx | OTC | Rx | Rx ⁵³ | Rx | N.R. | Rx |
| Nitro-glycerine | Rx | Rx | Rx | OTC ⁵⁴ | Rx | Rx | Rx | Rx | Rx | Rx |
| Ubidecarenone | N.R. | N.R. | N.R. | Rx | OTC | N.R. | OTC | N.R. | N.R. | N.R. |
| C10 Lipid modifying agents | | | | | | | | | | |
| Colestyramine | N.R. | N.R. | Rx | N.R. | N.R. | Rx | N.R. | Rx | N.R. | N.R. |
| Lovastatin | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | N.R. |
| Pravastatin | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Simvastatin | 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. | | Rx | Rx | | Rx | Rx | Rx | Rx | Rx |
| Bifonazole | Rx | Rx | 2002 | Rx | N.R. | OTC ⁵⁵ | 2002 ⁵⁶ | OTC | OTC | N.R. |
| Butenafine | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | N.R. | N.R. |
| Ciclopirox olamine | Rx | N.R. | Rx | OTC ⁵⁷ | N.R. | N.R. | Rx | N.R. | Rx | Rx |
| Clotrimazole (topical) | Rx | Rx | OTC | OTC | Rx | OTC ⁵⁸ | OTC ⁵⁹ | OTC | OTC ⁶⁰ | OTC ⁶¹ |
| Croconazole | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Econazole | Rx | Rx | OTC ⁶² | Rx | Rx | OTC ⁶³ | Rx | Rx | OTC ⁶⁴ | OTC ⁶⁵ |
| Fenticonazole (topical) | | | Rx | | | N.R. | | | N.R. | |
| Haloprogin (topical) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Isoconazole (topical) | N.R. | Rx | N.R. | N.R. | Rx | N.R. | Rx | N.R. | N.R. | Rx |
| Ketoconazole (topical) | OTC ⁶⁶ | Rx | OTC | OTC ⁶⁷ | Rx | OTC ⁶⁸ | OTC | OTC | OTC | 1998 ⁶⁹ |
| Miconazole (topical) | N.R. | Rx | Rx | Rx | N.R. | OTC ⁷⁰ | OTC ⁷¹ | OTC | OTC ⁷² | OTC ⁷³ |
| Miconazole & Hydrocortisone (topical) | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ⁷⁴ | Rx | N.R. | N.R. | Rx |
| Naftifine (topical) | Rx | N.R. | Rx | Rx | Rx | N.R. | Rx | N.R. | N.R. | Rx |
| Natamycin (topical) | N.R. | N.R. | Rx | Rx | N.R. | N.R. | Rx | Rx | N.R. | Rx |
| Nystatin | Rx | Rx | OTC ⁷⁵ | N.R. | Rx | Rx | Rx | OTC | Rx | Rx |
| Oxiconazole | N.R. | N.R. | 1998 ⁷⁶ | N.R. | Rx | N.R. | N.R. | OTC | N.R. | OTC ⁷⁷ |
| Selenium sulfide | N.R. | N.R. | N.R. | N.R. | N.R. | OTC | OTC ⁷⁸ | N.R. | N.R. | OTC ⁷⁹ |
| Sulconazole nitrate (topical) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ⁸⁰ |

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|---|----------|---------|-------------------|-------------------|-----------|--------------------|-------------------|-----------------|-------------------|--------------------|
| Terbinafine | Rx | Rx | OTC ⁸¹ | OTC ⁸² | Rx | 2000 | OTC | Rx | OTC ⁸³ | OTC ⁸⁴ |
| Tioconazole | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | OTC ⁸⁵ |
| Tolnaftate | N.R. | N.R. | N.R. | OTC ⁸⁶ | OTC | N.R. | N.R. | N.R. | N.R. | OTC ⁸⁷ |
| D03 Treatment of wounds and ulcers | | | | | | | | | | |
| Hyaluronic acid (topical) | OTC | Rx | OTC | Rx | Rx | N.R. | Rx | OTC | N.R. | OTC |
| D06 Antibiotics and Chemotherapeutics for dermatological use | | | | | | | | | | |
| Aciclovir (topical) | Rx | Rx | OTC | OTC ⁸⁸ | OTC | Rx | OTC ⁸⁹ | 1996 | OTC ⁹⁰ | 1994 ⁹¹ |
| Chlortetracycline | N.R. | N.R. | Rx | N.R. | Rx | Rx | Rx | Rx | N.R. | Rx |
| Docosanol (topical) | N.R. | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | N.R. |
| Idoxuridine (topical) | Rx | N.R. | N.R. | N.R. | Rx | Rx | N.R. | Rx | N.R. | Rx |
| Lysozyme HCl | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ⁹² |
| Mupirocin (topical) | Rx | Rx | Rx | Rx | N.R. | N.R. | Rx | Rx | N.R. | Rx |
| Penciclovir | Rx | N.R. | OTC ⁹³ | OTC ⁹⁴ | OTC | Rx | N.R. | OTC | N.R. | 2004 ⁹⁵ |
| Podofilox (Podophyllotoxin) | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | Rx |
| Silver sulfadiazine 1% | Rx | Rx | Rx | OTC | N.R. | Rx | Rx | Rx | Rx | OTC |
| Tetracycline | Rx | N.R. | N.R. | Rx | Rx | Rx | Rx | Rx | N.R. | Rx |
| D07 Corticosteroids, dermatological preparations | | | | | | | | | | |
| Alclomethasone (topical) | N.R. | | Rx | N.R. | N.R. | N.R. | | Rx | Rx | N.R. |
| Clobetasone butyrate (topical) | Rx | Rx | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Hydrocortisone (topical) | Rx | Rx | OTC ⁹⁶ | Rx | Rx | OTC ⁹⁷ | OTC ⁹⁸ | OTC | Rx | OTC ⁹⁹ |
| Prednisolone | Rx | Rx | Rx | Rx | Rx | OTC ¹⁰⁰ | Rx | Rx | Rx | Rx |
| Triamcinolone (topical) | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | N.R. | Rx |

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| D08 Antiseptics and Disinfectants | | | | | | | | | | |
| Benzalkonium chloride | OTC | OTC | OTC | OTC ¹⁰¹ | OTC | N.R. | OTC | OTC | OTC ¹⁰² | OTC |
| Povidone iodine | OTC | OTC ¹⁰³ | OTC | OTC ¹⁰⁴ | N.R. | N.R. | OTC ¹⁰⁵ | OTC | OTC ¹⁰⁶ | OTC ¹⁰⁷ |
| Triclosan | N.R. | N.R. | OTC | N.R. | N.R. | N.R. ¹⁰⁸ | OTC | OTC | N.R. | OTC ¹⁰⁹ |
| D10 Antiacne preparations | | | | | | | | | | |
| Benzoyl peroxide | OTC | N.R. | OTC | OTC ¹¹⁰ | OTC | OTC | OTC ¹¹¹ | OTC | N.R. | OTC |
| Clindamycin | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Erythromycin (<i>topical</i>) | Rx | N.R. | Rx | Rx | Rx | Rx | Rx ¹¹² | Rx | N.R. | Rx |
| Tretinoin | Rx | Rx | Rx | OTC ¹¹³ | Rx | Rx | Rx | Rx | N.R. | Rx |
| D11 Other dermatological preparations | | | | | | | | | | |
| Minoxidil | Rx | Rx | OTC | OTC ¹¹⁴ | | 2004 | OTC ¹¹⁵ | OTC | OTC | 1998 ¹¹⁶ |
| G. GENITO-URINARY SYSTEM AND SEX HORMONES | | | | | | | | | | |
| G01 Gynecological antiinfectives and antiseptics | | | | | | | | | | |
| Amphotericin (<i>topical</i>) | N.R. | Rx | N.R. | N.R. | N.R. | N.R. ¹¹⁷ | N.R. | N.R. | N.R. | Rx |
| Butoconazole | Rx | N.R. | N.R. | Rx | N.R. | Rx | N.R. | Rx | N.R. | N.R. |
| Clotrimazole (<i>vaginal</i>) | Rx | Rx | Rx | Rx | Rx | 1995 | Rx | Rx | OTC ¹¹⁸ | 1998 ¹¹⁹ |
| Miconazole (<i>vaginal</i>) | N.R. | Rx | Rx | Rx | N.R. | 1995 | Rx | Rx | Rx | Rx |
| Propionate Ca+Na (<i>vaginal</i>) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Terconazole | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| G03 Sex hormones and Modulators in the genital system | | | | | | | | | | |
| Estriol (<i>vaginal</i>) | Rx | Rx | Rx | 2007 ¹²⁰ | Rx | OTC | Rx | Rx | Rx | Rx |
| Levonorgestrel | Rx | Rx | Rx | Rx | Rx | 2000 | Rx | Rx | Rx | Rx ¹²¹ |

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| G04 Urological | | | | | | | | | | |
| Phenazopyridine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | Rx |
| J. ANTIINFECTIVES FOR SYSTEMIC USE | | | | | | | | | | |
| J01 Antibacterials for systemic use | | | | | | | | | | |
| Azithromycin | | | | Rx | | Rx | | | Rx | |
| Methenamine | Rx | N.R. | N.R. | N.R. | N.R. | Rx | OTC ¹²² | N.R. | N.R. | OTC ¹²³ |
| J02 Antimycotics for systemic use | | | | | | | | | | |
| Itraconazole | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| M. MUSCOLO-SKELETAL SYSTEM | | | | | | | | | | |
| M01 Antiinflammatory and Antirheumatic products | | | | | | | | | | |
| Benzydamine | OTC | N.R. | OTC | OTC ¹²⁴ | OTC | N.R. | OTC ¹²⁵ | Rx | OTC | OTC |
| Bufexamac (<i>topical</i>) | N.R. | N.R. | OTC | OTC | OTC | N.R. | N.R. | OTC | N.R. | Rx |
| Diclofenac | Rx | Rx | OTC ¹²⁶ | OTC ¹²⁷ | Rx | 2008 ¹²⁸ | OTC | OTC | Rx | 2000 ¹²⁹ |
| Diclofenac (<i>topical</i>) | OTC | OTC | OTC | OTC | Rx | 2001 ¹³⁰ | OTC | OTC | OTC | OTC |
| Etofenamate (<i>topical</i>) | N.R. | N.R. | OTC | OTC | N.R. | N.R. | 1999 | OTC | N.R. | OTC |
| Felbinac (<i>topical</i>) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | 1998 ¹³¹ |
| Flurbiprofen (<i>lozenges</i>) | OTC | Rx | N.R. | OTC | N.R. | N.R. | OTC | OTC | N.R. | Rx |
| Glucosamine | OTC | | OTC | Rx | N.R. | Rx | N.R. ¹³² | OTC | 2006 ¹³³ | N.R. |
| Ibuprofen (<i>oral</i>) | Rx | 2000 ¹³⁴ | OTC ¹³⁵ | OTC | Rx | 1989 ¹³⁶ | OTC ¹³⁷ | OTC | OTC ¹³⁸ | OTC ¹³⁹ |
| Ibuprofen (<i>topical</i>) | OTC | OTC | OTC | OTC | Rx | 2000 | OTC | OTC | OTC | OTC ¹⁴⁰ |
| Indomet(h)acin (<i>topical</i>) | OTC | Rx | OTC | OTC | OTC | Rx ¹⁴¹ | OTC ¹⁴² | OTC | N.R. | OTC ¹⁴³ |
| Ketoprofen | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx ¹⁴⁴ |

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| Ketoprofen (topical) | Rx | OTC | OTC | OTC | Rx | 2003 ¹⁴⁵ | OTC | OTC | OTC | Rx |
| Meclofenamic acid | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | Rx | N.R. | N.R. | Rx |
| Naproxen | Rx | OTC ¹⁴⁶ | Rx | OTC ¹⁴⁷ | OTC | 1996 ¹⁴⁸ | 1998 ¹⁴⁹ | OTC | OTC ¹⁵⁰ | 1999 ¹⁵¹ |
| Niflumic acid (topical) | OTC | N.R. | OTC | N.R. ¹⁵² | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Piroxicam (topical) | OTC | 2000 | OTC | OTC | OTC | N.R. ¹⁵³ | OTC | OTC | OTC | OTC ¹⁵⁴ |
| Tolmetin | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ¹⁵⁵ |
| M03 Muscle relaxants | | | | | | | | | | |
| Chlorzoxazone | N.R. | Rx | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Idrocilamide | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC |
| Methocarbamol | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | Rx |
| Orphenadrine | Rx | Rx | Rx | Rx | N.R. | Rx | N.R. | N.R. | N.R. | Rx |
| N. NERVOUS SYSTEM | | | | | | | | | | |
| N01 Anaesthetics | | | | | | | | | | |
| Benzocaine | OTC | N.R. | OTC | OTC | OTC | N.R. | OTC | OTC ¹⁵⁶ | OTC ¹⁵⁷ | Rx |
| Butyl aminobenzoate | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Cinchocaine (topical) | N.R. | N.R. | OTC | N.R. | Rx | OTC ¹⁵⁸ | Rx | OTC | N.R. | OTC |
| Dyclonine (oral) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Lidocaine (topical/oral topical) | OTC | OTC ¹⁵⁹ | OTC | OTC ¹⁶⁰ | OTC | OTC ¹⁶¹ | OTC ¹⁶² | 1992 | OTC | OTC ¹⁶³ |
| Oxetacaine | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Oxybuprocaine | N.R. | N.R. | Rx | Rx | N.R. | Rx | Rx | N.R. | N.R. | OTC ¹⁶⁴ |
| Pramocaine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ¹⁶⁵ |
| Prilocaine | N.R. | N.R. | OTC ¹⁶⁶ | N.R. | N.R. | Rx | Rx | OTC | N.R. | Rx |

Legal classification status of selected ingredients in new EU and non-EU European countries (last major update: 19 December 2008)

(Data for the European Union of 15 and selected countries Worldwide are available in separate tables)

| Ingredient | Bulgaria | Croatia | Czech Republic | Hungary | Lithuania | Norway | Poland | Slovak Republic | Slovenia | Switzerland |
|---------------------------------------|----------|---------|--------------------|---------|-----------|---------------------|--------------------|-----------------|----------|-------------|
| N02 Analgesics | | | | | | | | | | |
| Acetylsalicylic acid | OTC | OTC | OTC ¹⁶⁷ | OTC | OTC | OTC ¹⁶⁸ | OTC ¹⁶⁹ | 1982 | OTC | OTC |
| Diflunisal | N.R. | N.R. | N.R. | N.R. | Rx | Rx | N.R. | N.R. | N.R. | N.R. |
| Dihydrocodeine | N.R. | N.R. | Rx | Rx | Rx | N.R. | Rx | Rx | Rx | OTC |
| Naratriptan | Rx | | Rx | N.R. | N.R. | Rx | Rx | Rx | Rx | Rx |
| Paracetamol | OTC | OTC | OTC | OTC | OTC | 1988 ¹⁷⁰ | OTC ¹⁷¹ | 1982 | OTC | OTC |
| Paracetamol + dihydrocodeine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Sumatriptan | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Zolmitriptan | N.R. | | Rx | Rx | N.R. | Rx | Rx | Rx | Rx | Rx |
| N05 Psycholeptics | | | | | | | | | | |
| Chlorproethazine (<i>topical</i>) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Hydroxyzine | Rx | N.R. | Rx | Rx | Rx | Rx | Rx | Rx | N.R. | Rx |
| Prochlorperazine | N.R. | N.R. | Rx | N.R. | N.R. | Rx | Rx | N.R. | N.R. | Rx |
| N06 Psychoanaleptics | | | | | | | | | | |
| Pyritinol | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | Rx | OTC | N.R. | Rx |
| N07 Other nervous system drugs | | | | | | | | | | |
| Nicotine (<i>gum</i>) | OTC | | OTC | OTC | OTC | OTC | OTC | OTC | OTC | OTC |
| Nicotine (<i>nasal spray</i>) | N.R. | | N.R. | N.R. | N.R. | Rx | OTC | N.R. | N.R. | Rx |
| Nicotine (<i>oral inhaler</i>) | N.R. | | OTC | N.R. | N.R. | OTC | OTC | N.R. | N.R. | 2009 |
| Nicotine (<i>patch</i>) | OTC | | OTC | OTC | OTC | OTC | OTC | OTC | OTC | 2000 |
| Nicotine (<i>sublingual</i>) | N.R. | | N.R. | N.R. | N.R. | N.R. | OTC | Rx | N.R. | OTC |

Legal classification status of selected ingredients in new EU and non-EU European countries (last major update: 19 December 2008)

(Data for the European Union of 15 and selected countries Worldwide are available in separate tables)

| Ingredient | Bulgaria | Croatia | Czech Republic | Hungary | Lithuania | Norway | Poland | Slovak Republic | Slovenia | Switzerland |
|---|--------------------|---------|--------------------|--------------------|-----------|--------------------|--------------------|-----------------|----------|---------------------|
| P. ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLANTS | | | | | | | | | | |
| P01 Antiprotozoals | | | | | | | | | | |
| Carnidazole | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Quinfamide | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| P02 Anthelmintics | | | | | | | | | | |
| Flubendazole | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Mebendazole | Rx | Rx | Rx | Rx | OTC | OTC ¹⁷² | Rx | Rx | Rx | OTC ¹⁷³ |
| Pyrantel | Rx | N.R. | N.R. | N.R. | OTC | N.R. | Rx | N.R. | N.R. | OTC ¹⁷⁴ |
| P03 Ectoparasiticides | | | | | | | | | | |
| Benzyl benzoate (<i>topical</i>) | OTC | OTC | N.R. | OTC ¹⁷⁵ | OTC | OTC | OTC | N.R. | N.R. | Rx |
| Lindane (<i>topical</i>) | N.R. | N.R. | OTC | OTC ¹⁷⁶ | N.R. | N.R. | OTC ¹⁷⁷ | OTC | N.R. | OTC |
| R. RESPIRATORY SYSTEM | | | | | | | | | | |
| R01 Nasal preparations | | | | | | | | | | |
| Azelastine | Rx | N.R. | Rx | Rx | OTC | Rx | Rx | Rx | Rx | OTC ¹⁷⁸ |
| Beclometasone (<i>nasal</i>) | Rx | Rx | OTC ¹⁷⁹ | Rx | Rx | Rx | OTC | Rx | N.R. | 1998 ¹⁸⁰ |
| Budesonide (<i>nasal</i>) | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Cromoglicic acid | OTC ¹⁸¹ | | Rx | OTC ¹⁸² | Rx | OTC ¹⁸³ | OTC ¹⁸⁴ | Rx | N.R. | OTC ¹⁸⁵ |
| Ephedrine (<i>topical</i>) | N.R. | N.R. | Rx | N.R. | Rx | N.R. | Rx | 1982 | N.R. | OTC ¹⁸⁶ |
| Epinephrine (<i>not for asthma</i>) (adrenaline) | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx ¹⁸⁷ |
| Epinephrine (<i>asthma</i>) | Rx | | Rx | N.R. | Rx | Rx | Rx | Rx | N.R. | N.R. |
| Flunisolide (<i>nasal</i>) | N.R. | N.R. | Rx | N.R. | Rx | Rx | Rx | Rx | N.R. | Rx |

Legal classification status of selected ingredients in new EU and non-EU European countries (last major update: 19 December 2008)

(Data for the European Union of 15 and selected countries Worldwide are available in separate tables)

| Ingredient | Bulgaria | Croatia | Czech Republic | Hungary | Lithuania | Norway | Poland | Slovak Republic | Slovenia | Switzerland |
|--|----------|--------------------|--------------------|--------------------|-----------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Fluticasone | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Levocabastine | Rx | OTC ¹⁸⁸ | OTC | OTC ¹⁸⁹ | Rx | OTC | Rx | Rx | Rx | OTC ¹⁹⁰ |
| Mometasone (<i>nasal</i>) | Rx | Rx | Rx | Rx | Rx | N.R. | Rx | Rx | Rx | Rx |
| Naphazoline | OTC | OTC | OTC | OTC ¹⁹¹ | OTC | N.R. | OTC ¹⁹² | OTC | OTC ¹⁹³ | OTC ¹⁹⁴ |
| Oxymetazoline | OTC | OTC | OTC | OTC ¹⁹⁵ | OTC | OTC ¹⁹⁶ | OTC | OTC | OTC | OTC ¹⁹⁷ |
| Phenylephrine | OTC | OTC | OTC | OTC ¹⁹⁸ | OTC | Rx | OTC ¹⁹⁹ | OTC | OTC ²⁰⁰ | OTC ²⁰¹ |
| Pseudoephedrine | OTC | OTC | OTC ²⁰² | OTC ²⁰³ | Rx | N.R. | OTC ²⁰⁴ | OTC ²⁰⁵ | OTC ²⁰⁶ | OTC ²⁰⁷ |
| Tetrahydrozoline | OTC | N.R. | OTC | OTC ²⁰⁸ | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²⁰⁹ |
| Tramazoline | OTC | N.R. | OTC | OTC ²¹⁰ | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²¹¹ |
| Xylometazoline (<i>nasal</i>) | OTC | N.R. | OTC | OTC ²¹² | OTC | OTC ²¹³ | OTC | OTC | N.R. | OTC ²¹⁴ |
| R02 Throat preparations | | | | | | | | | | |
| Bacitracin (<i>topical</i>) | Rx | Rx | Rx | Rx | N.R. | OTC | OTC ²¹⁵ | Rx | Rx | OTC ²¹⁶ |
| Tyrothricin | OTC | N.R. | OTC ²¹⁷ | N.R. | OTC | N.R. | N.R. | OTC | N.R. | OTC ²¹⁸ |
| R03 Drugs for obstructive airway diseases | | | | | | | | | | |
| Fenoterol | Rx | N.R. | Rx | Rx | Rx | Rx ²¹⁹ | Rx | Rx | Rx | Rx |
| Orciprenaline | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | Rx | Rx | N.R. | OTC ²²⁰ |
| Salbutamol | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Theophylline | Rx | Rx | Rx | OTC | Rx | Rx ²²¹ | Rx | Rx | Rx | Rx |
| R05 Cough and Cold preparations | | | | | | | | | | |
| Acetylcysteine | OTC | OTC | OTC | OTC ²²² | OTC | Rx | Rx | OTC | OTC | OTC |
| Ambroxol | Rx | Rx | OTC | OTC ²²³ | OTC | N.R. | OTC ²²⁴ | OTC | Rx | Rx |
| Benproperine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |

Legal classification status of selected ingredients in new EU and non-EU European countries (last major update: 19 December 2008)

(Data for the European Union of 15 and selected countries Worldwide are available in separate tables)

| Ingredient | Bulgaria | Croatia | Czech Republic | Hungary | Lithuania | Norway | Poland | Slovak Republic | Slovenia | Switzerland |
|--|----------|--------------------|--------------------|---------------------|-----------|---------------------|--------------------|-----------------|---------------------|--------------------|
| Benzonatate | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²²⁵ |
| Bromhexine | OTC | OTC | OTC | OTC ²²⁶ | OTC | OTC ²²⁷ | OTC ²²⁸ | OTC | OTC ²²⁹ | OTC ²³⁰ |
| Carbocisteine | OTC | OTC | OTC | OTC ²³¹ | OTC | N.R. | Rx | OTC | N.R. | OTC |
| Chlorphendianol | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Dextromethorphan | Rx | 2000 | OTC | OTC ²³² | OTC | N.R. | OTC ²³³ | OTC | 2005 ²³⁴ | OTC ²³⁵ |
| Dimemorfan | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Noscapine | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²³⁶ | N.R. | N.R. | N.R. | OTC ²³⁷ |
| R06 Antihistamines for systemic use | | | | | | | | | | |
| Acrivastine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | Rx |
| Azatadine | Rx | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Brompheniramine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC | N.R. | OTC ²³⁸ |
| Carbinoxamine | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | OTC |
| Cetirizine | Rx | Rx | OTC ²³⁹ | 2007 ²⁴⁰ | Rx | 1994 ²⁴¹ | OTC ²⁴² | OTC | OTC ²⁴³ | OTC ²⁴⁴ |
| Chlorpheniramine | Rx | N.R. | OTC | N.R. | N.R. | N.R. | OTC ²⁴⁵ | Rx | N.R. | OTC ²⁴⁶ |
| Clemastine | Rx | N.R. | Rx | N.R. | Rx | Rx | Rx | Rx | Rx | OTC ²⁴⁷ |
| Cyproheptadine | Rx | N.R. | Rx | Rx | N.R. | N.R. ²⁴⁸ | Rx | Rx | N.R. | Rx |
| Dexbrompheniramine | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | OTC | OTC | N.R. | OTC |
| Dexchlorpheniramine | N.R. | N.R. | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | N.R. | OTC ²⁴⁹ |
| Dimetindene | OTC | OTC ²⁵⁰ | OTC | OTC ²⁵¹ | OTC | Rx | OTC | OTC | OTC ²⁵² | OTC |
| Diphenhydramine | Rx | Rx | OTC | OTC ²⁵³ | Rx | N.R. | OTC ²⁵⁴ | OTC | N.R. | OTC ²⁵⁵ |
| Diphenylpyraline | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²⁵⁶ |
| Doxylamine succinate | N.R. | N.R. | Rx ²⁵⁷ | N.R. | N.R. | N.R. | OTC ²⁵⁸ | N.R. | 2005 ²⁵⁹ | OTC |

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(Data for *the European Union of 15* and *selected countries Worldwide* are available in separate tables)

| Ingredient | Bulgaria | Croatia | Czech Republic | Hungary | Lithuania | Norway | Poland | Slovak Republic | Slovenia | Switzerland |
|---|----------|---------|--------------------|---------------------|-----------|---------------------|--------------------|--------------------|--------------------|---------------------|
| Ebastine | N.R. | N.R. | Rx | N.R. | Rx | 2005 ²⁶⁰ | Rx | Rx | N.R. | N.R. |
| Fexofenadine | Rx | N.R. | Rx | Rx | Rx | Rx | Rx | N.R. | Rx | Rx |
| Ketotifen | Rx | | Rx | Rx | | 2004 ²⁶¹ | Rx | Rx | Rx | Rx |
| Levocetirizine | | | | | | Rx | | | Rx | |
| Loratadine | Rx | 2003 | OTC ²⁶² | 2005 ²⁶³ | Rx | 1994 ²⁶⁴ | OTC ²⁶⁵ | OTC ²⁶⁶ | OTC ²⁶⁷ | OTC ²⁶⁸ |
| Meclozine | N.R. | N.R. | Rx | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | OTC ²⁶⁹ |
| Mepyramine maleate | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²⁷⁰ | N.R. | N.R. | OTC ²⁷¹ |
| Mequitazine | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. ²⁷² |
| Oxatomide | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. ²⁷³ |
| Promethazine | Rx | N.R. | OTC | Rx | OTC | Rx | OTC | Rx | N.R. | OTC ²⁷⁴ |
| Tripelennamine | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | Rx | N.R. | N.R. | N.R. |
| Trip(r)olidine | N.R. | OTC | Rx | N.R. | N.R. | N.R. | OTC | N.R. | N.R. | OTC ²⁷⁵ |
| S. SENSORY ORGANS | | | | | | | | | | |
| S01 Ophthalmologicals | | | | | | | | | | |
| Sulfacetamide (<i>topical</i>) | Rx | N.R. | Rx | N.R. | OTC | N.R. | Rx | Rx | N.R. | Rx |
| S03 Other ophthalmological and otological preparations | | | | | | | | | | |
| Chloramphenicol | Rx | Rx | Rx | N.R. | Rx | Rx | Rx | Rx | Rx | Rx |
| Polymyxin B (<i>topical</i>) | Rx | Rx | Rx | Rx | Rx | Rx | OTC ²⁷⁶ | Rx | Rx | Rx |
| NON-CLASSIFIED | | | | | | | | | | |
| Bronopol | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | OTC ²⁷⁷ |
| Cilastatin | N.R. | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx | Rx |
| Decaline | N.R. | N.R. | OTC | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |

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|---|----------|---------|----------------|---------|-----------|--------|---------------------|-----------------|----------|-------------|
| Potassium nitrate (<i>toothpaste</i>) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. |
| Strontium chloride (<i>toothpaste</i>) | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. | N.R. ²⁷⁸ | N.R. | N.R. | OTC |

Endnotes:

- 1 Ointment, buccal tablets.
- 2 Topical forms, including dental varnish.
- 3 Maximum daily dose 1 mg fluor, maximum 250 mg fluor/pack.
- 4 For topical use.
- 5 Aluminium - aceticum tartaricum boricum solutum ointment; Aluminium hydroxide suspension.
- 6 500mg effervescent tablets and chewing tablets.
- 7 Maximum 1000mg per unit, pack size up to 30 units.
- 8 Gel, 0.15g.
- 9 200mg.
- 10 Maximum 100 mg per unit, pack size up to 10 units.
- 11 10mg film-coated tablets.
- 12 Pack sizes up to 12 x 10mg tablets. In 2002, *Pepciduo*® (famotidine combination) was approved and launched as an OTC product in packages of up to 24 tablets.
- 13 Maximum 10 mg per unit, pack size up to 10 units.
- 14 Tablets 10 mg.
- 15 Pantoprazole 20 mg was switched to non-prescription status in the entire European Union through a Decision of the European Commission under the centralised procedure.
- 16 Limit per unit is 75mg, pack sizes up to 12 units.
- 17 In packs of 6 and 12 75mg tablets.
- 18 Tablets 75mg approved in June 1997.
- 19 Maximum 150 mg per unit, pack size up to 10 units.
- 20 Since 1997: 75mg, maximum pack size 12 units. Since 2005: Maximum 150 mg per unit, pack size up to 10 units for heartburn and dyspeptic disorders.
- 21 Dosage is 75mg (maximum pack size is 12 tablets) and indication is heartburn.
- 22 Suspension 200mg/ml; tablets 20, 50, 60 and 100 x 1g; granules 50 x 1g;
- 23 Spray, suspension and chewing tablets.
- 24 Maximum 80 mg per unit, pack size up to 100 units.
- 25 Limit per unit is 10mg, pack sizes up to 10 units.
- 26 OTC up to 10mg.
- 27 OTC in packs of up to 10 tablets.
- 28 Topical forms are OTC.
- 29 Maximum 10 mg per tablet, pack size up to 10 tablets.

30 In film coated tablets and dragees.
31 Maximum 5 mg per unit, pack size up to 20 units.
32 Maximum single dose 15mg.
33 As an antidiarrhoeal.
34 Syrup and powder.
35 Maximum 667 mg/ml, pack size up to 200 ml oral solution.
36 Limit per unit is 2mg, pack sizes up to 20 units.
37 Film-coated tablets up to 20mg; capsules up to 50 x 2mg; tablets 8x 2mg; effervescent tablets 10 x 2mg; chewing tablets 6 x 2mg.
38 100ml mixture and 2mg tablets x 16.
39 Maximum 2 mg per unit, pack size up to 10 units.
40 Up to 2mg, maximum pack size 20 tablets.
41 Orlistat 60 mg was switched to non-prescription status in the entire European Union through a Decision of the European Commission under the centralised procedure.
42 Mainly in combination, Rx high dosed vitamin A.
43 OTC only in combinations.
44 Maximum 6 000 IU, pack size up to 60 tablets; topical forms – OTC.
45 Only topical forms are OTC. In combination with vitamins or minerals also as a food supplement (1500 micrograms as a maximum daily dosage).
46 Mainly in combination with vitamins or minerals, selenium only as injections.
47 Classified as a “paramedicine”.
48 In combination with vitamins or minerals as a food supplement with a maximum daily dosage of 100 micrograms.
49 Iron and ascorbic acid combinations are OTC. Folic acid is OTC.
50 Iron and folic preparations in combination are N.R. Iron preparations are OTC. Folic preparations are Rx.
51 Iron: as a food supplement in combination with vitamins and minerals. Folic acid: OTC in maximum daily dosage of 0.4 mg
52 Maximum daily dose 1.5mg folic acid.
53 Available in hospitals only.
54 Aerosols of 0.4 mg/dose and 0.5mg sublingual tablets.
55 Cream, 15g.
56 1% single topical forms are OTC; Rx in combinations with urea.
57 Only talcum powder.
58 Cream, powder and lotion 1% up to 30g.
59 1% cream, solution.

- 60 Cream (20 g), powder (30 g) and solution (30 ml) up to 1%. Vaginal form is Rx.
- 61 Up to 10mg (1%).
- 62 Only topical vaginal form.
- 63 For vaginal use (1995) and cream, powder, gel and lotion 1% up to 30g for topical use.
- 64 Topical form is OTC;.vaginal form is Rx.
- 65 Topical use is OTC; vaginal use is Rx.
- 66 Shampoos are OTC. Creams are Rx.
- 67 OTC in shampoos. Cream is Rx.
- 68 Shampoos are OTC. Creams are Rx.
- 69 Creams are OTC. Ointments are N.R.
- 70 Cream, powder and lotion 1% up to 30g.
- 71 Including oromucosal gel.
- 72 Cream and oromucosal gel up to 2%.
- 73 Topical use up to 2%.
- 74 Cream 15g.
- 75 For topical use only, other forms are Rx.
- 76 Topical form is OTC, other forms are Rx.
- 77 Topical form is OTC but vaginal use is Rx.
- 78 Shampoo.
- 79 For topical use.
- 80 Topical use up to 1%.
- 81 Only topical form.
- 82 In cream, gel 1% and 15ml spray.
- 83 Cream, solution and spray 1%.
- 84 Topical use only.
- 85 Topical use up to 1%.
- 86 In talcum powder, cream and spray.
- 87 Topical use up to 2%.
- 88 OTC cream for labial herpes.
- 89 Maximum 50 mg/g, pack size up to 10 g.
- 90 Maximum strength 50mg, maximum pack size 2g.

- 91 Pack size is 2g maximum. Maximum strength 5% (50mg).
- 92 Maximum daily dose 200 mg; topical use.
- 93 For topical use only, other forms are Rx.
- 94 1% cream.
- 95 Topical use, maximum pack size 2g, 1% cream.
- 96 Maximum 1%.
- 97 Ointment and cream 25g containing up to 1% active ingredient.
- 98 Maximum 5mg/g, pack size up to 50g. Rectal – OTC.
- 99 Maximum concentration for OTC status is 5mg.
- 100 Ointment in pack size up to 30g. Other forms are Rx.
- 101 In vaginal cream, vaginal suppositories, vaginal tablets and vaginal tampons.
- 102 In combination with hexylresorcinol in lozenges for sore throat.
- 103 Mouthwash solution.
- 104 Ointment, 100mg active ingredient per gram, and solution for throat disinfection.
- 105 Including vaginal globules.
- 106 Mouthwash solution (1g/100 ml) and topical solution (10 mg/100ml) in packsize up to 100 ml, vaginal globules (200 mg).
- 107 For topical use.
- 108 Withdrawn.
- 109 For topical use.
- 110 In gel, emulsion and suspension.
- 111 Maximum 100 mg/g, pack size up to 50g.
- 112 Rx, but the smallest registered pack can be sold OTC; public advertising prohibited (Polish symbol of the status – Rp*). Maximum 40 mg/ml, pack size up to 30 ml.
- 113 Cream and solution are OTC.
- 114 Solution.
- 115 Maximum 50 mg/ml, pack size up to 60 ml.
- 116 Hair growth stimulant, up to 20mg (2%).
- 117 Oral form is Rx.
- 118 Only cream for topical use.
- 119 For recurrent therapy of vaginal fungal infections, creams 2% or vaginal tablets simple dose 500mg, limitation 500mg (1 daily therapy) or vaginal tablets simple dose 200mg, limitation 600mg (3 daily therapies).
- 120 In tubes of 15g..

- 121 As monopreparation in single dose of 0.75mg also available if counselling by pharmacist + doctor possible.
- 122 OTC: maximum 300mg in packs up to 20 tablets. Topical forms – OTC
- 123 Topical form.
- 124 Topical (mouth) solution, toothpaste and pastilles are OTC.
- 125 Oral form is OTC up to 3mg; topical form is OTC.
- 126 Tablets - strength 25mg, maximum single dose 25mg, maximum daily dose 75mg; suppositories - strength 100mg, maximum single dose 100mg, maximum daily dose 150mg.
- 127 Oral forms are OTC only in combinations.
- 128 12.5 mg 20 tablets..
- 129 In 2000, switch of solid oral forms of diclofenac (and salts). Maximum single dose 25 mg, maximum daily dose 75 mg, maximum 3 days OTC use.
- 130 *Otriflu*® (diclofenac potassium).
- 131 Up to 30mg (3%).
- 132 Glucosamine has food supplement status in Poland.
- 133 OTC: capsules 400 mg (maximum daily dose 1200 mg). Topical forms are classified as cosmetics.
- 134 200mg.
- 135 Tablets - strength 400mg, maximum single dose 400mg, maximum daily dose 1200mg; syrup - maximum single dose 12mg/kg, maximum daily dose 35mg/kg; suppositories - strength 600mg, maximum single dose 600mg, maximum daily dose 600mg.
- 136 20 tablets x 200mg.
- 137 Maximum 400 mg per tablet, maximum pack size 12 tablets.
- 138 Maximum 300 mg per tablet, pack size 12 tablets.
- 139 Since 1997, all oral forms may be non-prescription: strength 200mg simple dose (maximum 400mg), maximum daily dose 1.2g and maximum pack size 4g. In 2003, the 400mg strength was switched to non-prescription status.
- 140 OTC up to 100mg/g (10%).
- 141 Eye drops only.
- 142 Only 1% aerosol.
- 143 OTC up to 10mg (1%).
- 144 For all forms, including topical forms.
- 145 Gel 2.5% for the treatment of moderate topical pain.
- 146 275mg.
- 147 Film-coated tablets.
- 148 Naproxen oral was switched in 1996: 20 tablets x 250mg to be used to treat menstrual pain.
- 149 Maximum 220mg per unit, maximum pack size 20 units; topical gel up to 3%, maximum pack size 40g.

- 150 Tablets, 275 mg.
- 151 Topical and oral form, tablets 200 mg, daily dose 600 mg.
- 152 Non-topical forms are Rx.
- 153 Piroxicam oral is Rx.
- 154 OTC up to 5mg (0.5%).
- 155 Topical form is OTC up to 50mg (5%). Not marketed.
- 156 200mg is OTC.
- 157 In combination with cetylpyridinium chloride in lozenges for sore throat.
- 158 Ointment in pack sizes up to 30g.
- 159 Oral topical gel.
- 160 Gel and ointment.
- 161 Cream 10g and lotion 100ml.
- 162 Maximum 20 mg/g.
- 163 Topical use. Lozenges: maximum single dose 1mg, maximum 60mg/pack.
- 164 For topical use.
- 165 For topical use.
- 166 Patch – pack size 2 pieces is OTC.
- 167 Strength 500mg, maximum single dose 1g, maximum daily dose 4g.
- 168 Pack sizes up to 20 units or up to 10g acetylsalicylic acid per pack.
- 169 Up to 1000 mg per unit, pack size up to 20 units (max 20 g per pack).
- 170 Maximum 1g per dose and 10g per pack.
- 171 Maximum 1000 mg per unit.
- 172 OTC for 30ml mixture and 6 tablets.
- 173 Maximum single dose 100 mg; maximum daily dose 200 mg; maximum 3 days OTC use.
- 174 Pyrantel embonate.
- 175 Emulsion.
- 176 Emulsion, gel.
- 177 Maximum 3 mg/ml, pack size up to 100 ml.
- 178 For seasonal allergic rhinitis, in packs up to 5 ml.
- 179 Up to 50microg per dose.
- 180 For nasal applications in seasonal allergic rhinitis, simple dose 50µg, limitation 50mg.

181 Eye drops are OTC. Cromoglycic acid for inhalation is Rx.
182 Nasal spray, 110 doses of 2.7mg/dose..
183 Eye drops (20 mg/ml) 5 ml and nasal spray (5.2 mg/dose) 15ml to treat pollen allergy.
184 Only cromoglycic acid on the market and only eye drops up to 20 mg/ml, pack size up to 10 ml.
185 Maximum single dose 10mg, maximum daily dose 40mg; topical use.
186 In cough/asthma preparations: maximum single dose 50mg, maximum daily dose 150mg; nasal use up to 3%; topical use.
187 Topical use OTC up to 0.01%.
188 Eye and ear drops.
189 Nasal spray.
190 Topical use (eye drops, nose spray).
191 Solution, eye drops.
192 Only eye drops up to 0.33 mg/ml, pack size up to 10 ml.
193 Nasal and eye drops.
194 Topical use up to 0.1%.
195 Nasal drops 0.01, 0.025%; nasal spray.
196 Up to 20 nebulas or 10ml nasal spray.
197 Topical use up to 0.1%.
198 OTC only in combinations.
199 Topical and oral forms up to 10mg are OTC.
200 OTC only in combinations.
201 Maximum single dose 65mg, maximum daily dose 200mg; nasal drops up to 2.5%.
202 Limit per unit is 30mg.
203 OTC only in combinations.
204 Single form maximum 60mg up to 12 units per pack (cold); maximum 120 mg per unit in combination with cetirizine up to 14 units per pack (allergy).
205 Only in combination.
206 Only in OTC combinations.
207 Maximum single dose 100mg.
208 0.05% nasal drops for children.
209 Topical use up to 0.1%.
210 Nasal spray.
211 Topical use up to 0.05%.

- 212 Nasal drops, nasal gel and nasal spray.
- 213 Nasal spray up to 10ml.
- 214 Topical use up to 0.1%.
- 215 Available OTC doses: 400 IU/g – pack of 15 g; 10 mg/g – 10 doses.
- 216 Topical use including lozenges and nasal preparations.
- 217 For treating sore throat.
- 218 Topical use including lozenges
- 219 Only products for inhalation on the market (and Rx). Oral products have been withdrawn.
- 220 Maximum single dose 15mg.
- 221 Oral forms.
- 222 Effervescent tablets up to 600mg; 100 mg buccal tablets; 200mg capsules and syrup.
- 223 All forms are OTC except injectables.
- 224 OTC: maximum 30mg 30 tablets, or 6 mg/ml up to 120 ml oral solution. The presentation of 60mg per tablet, maximum 20 tablets or 75mg per capsule, in a pack size up to 10 is Rx, but the smallest registered pack can be sold OTC - public advertising prohibited (Polish symbol of the status – Rp*).
- 225 Maximum single dose 100mg.
- 226 In solutions, nasal spray and tablets.
- 227 OTC for solution 125ml or 50 tablets.
- 228 Maximum 8 mg per unit, pack size up to 20 units; up to 2mg/ml, pack size up to 30ml oral solution.
- 229 Only syrup and oral solution are OTC.
- 230 Maximum single dose 20 mg, maximum daily dose 60 mg.
- 231 In syrups and capsules.
- 232 In syrups.
- 233 Maximum 15 mg per unit, pack size up to 20 units (single or in combination with paracetamol); up to 2mg/ml, pack size up to 150ml oral solution.
- 234 Also in combination products with paracetamol. Since 2005 as a single product: in syrups 20 mg/15 ml, pack size up to 180 ml.
- 235 Since 2001: maximum 400mg/pack, maximum 4 days therapy.
- 236 250 ml mixture and 50 tablets.
- 237 Maximum single dose 30mg, maximum daily dose 150mg.
- 238 Maximum daily dose 50 mg.
- 239 Maximum dose 10mg; maximum pack size 7 units.
- 240 In packs of 7 tablets.
- 241 Pack sizes up to 30 tablets to treat pollen allergy.

242 Maximum 10 mg per tablet, pack size up to 10 tablets.
243 Maximum 10mg per tablet, maximum pack size 10 tablets.
244 10 mg per tablet. OTC version has 10 tablets per package. Rx version has 30 tablets per package.
245 Maximum 2.5mg per capsule, pack size up to 20 capsules.
246 Maximum single dose 4 mg, maximum daily dose 20 mg.
247 Maximum single dose 1 mg, maximum daily dose 4 mg.
248 Withdrawn.
249 Maximum single dose 4 mg, maximum daily dose 20 mg.
250 Gel 30g.
251 Available as gel, nasal gel, nasal drops and nasal spray.
252 Only gel.
253 OTC in tablets and suppositories. Suppositories for children are Rx.
254 Only eye drops (in combination with naphazoline) is Rx.
255 Maximum single dose 50 mg; topical use.
256 Maximum single dose 10 mg; maximum daily dose 50 mg.
257 Only in combination.
258 In combination with paracetamol only; up to 6.25 mg per dose.
259 Since 2005: only syrup in cough and cold OTC combinations.
260 10mg, 10 tablets for treatment of allergy.
261 Ketotifen eye drops 0.25 mg/ml switched to OTC status in 2004.
262 Limit per unit is 10mg, pack sizes up to 7 units.
263 Loratadine 10mg tablets switched to non-prescription status in 2005.
264 Pack size up to 10 tablets to treat pollen allergy.
265 Maximum 10 mg per tablet, pack size up to 10 tablets.
266 70mg is OTC.
267 Maximum 10 mg per tablet, maximum pack size 10 tablets.
268 10mg per tablet. The OTC version has 14 tablets per pack, the Rx version has 28 tablets per pack.
269 Maximum single dose 50 mg, maximum daily dose 100 mg.
270 In combination with paracetamol only; up to 15 mg per unit, up to 12 units.
271 Maximum single dose 100 mg; topical use.
272 An OTC speciality containing 5mg mequitazine per tablet was withdrawn in 1997.

- 273 Withdrawn.
- 274 Maximum single dose 25 mg; topical use.
- 275 Maximum single dose 2.5 mg, maximum daily dose 10 mg; topical use.
- 276 Available OTC doses: 5000 IU/g – pack 15 g; 10 mg/g – 10 doses.
- 277 For topical use.
- 278 Strontium chloride is classified as a cosmetic in Poland.