

Natural remedies

A natural remedy denotes a medicinal product in which the active ingredient or ingredients derive from natural sources, have not been processed too highly and consist of part of a plant or animal, bacterial culture, mineral, salt or salt solution. Natural remedies may only be products which are suitable for self-medication in accordance with tested national tradition or tradition in countries close to Sweden with respect to drug usage.

During the last two years the committees of the European Council and the European Parliament have worked extensively reviewing and revising the medicinal legislation.

Herbal Medicinal Products

The concept herbal medicinal product was introduced in the Swedish Medicinal Products legislation already in October 2003 (LVFS 2003:7). An herbal medicinal product can be authorised, like any other medicinal product, after submission of a full application according to either Article 8 in the Directive 2001/83/EC (PDF) or to Article 10 a from the same Directive. (Notice to Applicants)

Traditional Herbal Medicinal Products

In the revised Directive for Medicinal Products special provisions for traditional herbal medicinal products have been added. A simplified registration procedure is introduced for traditional herbal medicinal products (2004/24/EC) (not an approval, which is the case for regular medicinal products). The requirements on the chemical-pharmaceutical documentation are equal to that of conventional medicinal products, i.e. full documentation is required.

The therapeutical indications are strictly limited to self-medication that does not require a physician's diagnosis, prescription or supervision of treatment. The products may only be intended for peroral intake, external application and/or inhalation.

To fulfil the requirements regarding safety and efficacy the applicant must be able to verify that the product in question or a corresponding product has been used for medicinal purposes for a period of at least 30 years at the time of the application, including at least 15 years of use within the European Union.

Committee for Herbal Medicinal Products

The Directive also states that a committee for herbal medicinal products is installed at the EMEA. The provisions in the Medicinal Products ordinance that concern the committee for human medicinal products shall apply by analogy to the Herbal Medicinal Products Committee, HMPC. The most important mission defined for the HMPC is to compile a Community Register of herbal substances and preparations that may be part of traditional herbal medicinal products. The register will list data concerning indication, strength, dosage and route of administration for every herbal substance/preparation. Furthermore, the Committee will produce Community monographs both for traditional herbal medicinal products and for herbal medicinal products with well established medicinal use.

MRP for Herbal Medicinal Products

The Mutual Recognition Procedure will be applicable for any herbal medicinal product that is included either in the register or in a monograph. Cases of arbitration will be decided in the Committee for Herbal Medicinal Products.

The Directives concerning Herbal Medicinal Products are:

Directive 2001/83/EC of the European Parliament and of the Council relating to medicinal products for human use.

Commission Directive 2003/63/EC (PDF) amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

This Directive contains the definition of Herbal Medicinal Products.

Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Directive 2004/27/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Herbal Medicinal Products may be approved according to:

Article 8 from the Directive 2001/83/EC

Article 10 a) ii from the Directive 2001/83/EC

the new simplified registration procedure as per Directive 2004/24/EC, only for traditional herbal medicinal products

Authorised Natural Remedies (as of November 15, 2007)

ACO Omega-3, capsules, soft (Fish oil containing omega-3-fatty acid triglycerides) 2002-06-13.
Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

ACO Omega-3 Forte, capsules, soft (Fish oil containing omega-3-fatty acid triglycerides) 2002-06-13
Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

Alkala, powder for oral solution (Sodium bicarbonate, potassium bicarbonate, sodium citrate) 2002-12-18

Approved indication: Traditionally used for heartburn.

Activeen (former Aptiveen), film-coated tablet (*Zea mays*, *Secale cereale*, *Dactylis glomerata*, *Pinus sylvestris*, *Zea mays*) 2006-03-14

Approved indication: Traditionally used as a tonic in case of fatigue and sensation of weakness and by loss of appetite.

Aqualette, film-coated tablet (*Equisetum arvense*, *Taraxacum officinale*) 2005-06-28

Approved indication: Traditionally used to relieve a sensation of swelling, for example due to PMS (premenstrual syndrome)

Australian Bodycare Tea Tree Oil, cutaneous solution (*Melaleuca alternifolia*) 1998-11-24

Approved indication: Traditionally used for the treatment of mild acne, against itch in mild cases of tinea pedis (athlete's foot) and uncomplicated insect-bites.

Basotabs, tablet (Sodium bicarbonate) 2002-12-18

Approved indication: Traditionally used for heartburn.

Bifolac, gastro-resistant capsule, hard (*Lactobacillus rhamnosus*, *Bifidobacterium longum*) 2001-01-24

Approved indication: Traditionally used for normalization of the intestinal flora in case of temporary gastro-intestinal trouble such as mild diarrhoea and constipation, and as prophylaxis and treatment of common uncomplicated traveller's diarrhoea.

Bio-Biloba, film-coated tablet (*Ginkgo biloba* L) 2003-09-30

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo tinnitus and feeling of tiredness. Prior to treatment other serious conditions have been ruled out by doctor.

Bio-Garlic Pharma Nord gastro-resistant tablet (*Allium sativum*)
1998-10-13

Approved indication: Traditionally used for the relief of cold symptoms.

Cernitol tablets (watersoluble pollen extract, lipidsoluble pollen extract) 1998-10-13

Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e g frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Cirkulamin, film-coated tablets (*Ginkgo biloba* L.) 2004-09-21

Approved indication: Natural remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, feeling of tiredness and tinnitus. Prior to treatment other serious conditions should have been ruled out by doctor.

Curbisal, capsul, soft (*Serenoa repens*) 2006-03-23

Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e g frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Cyclodyn, film-coated tablets (*Vitex agnus-castus L.*) 2004-11-02

Approved indication: Traditionally used to relieve symptoms of PMS (premenstrual syndrome), such as tender breasts, bloating, irritability, anxiety and sudden dejection that appear during the week before menstruation and usually disappear when the menstruation starts. To be used only when physician has established that no other serious disease is present.

Cynaramin, oral drops, solution (*Taraxacum officinale, Peumus boldus*) 2005-12-06

Approved indication: Traditionally used against occasional indigestion such as loss of appetite, sensation of fullness and flatulence.

Dormeasan drops (*Valeriana officinalis, Humulus lupulus*) 1997-01-09

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Echinacea Active Care, capsule, hard (*Echinacea angustifolia*) 2005-12-09

Approved indication: Traditionally used for the relief of cold symptoms.

Echinadrops, oral drops, solution (*Echinacea purpurea*) 2004-11-02

Approved indication: Traditionally used for the relief of cold symptoms.

Echinaforce, oral drops, solution (*Echinacea purpurea*) 2004-11-02

Approved indication: Traditionally used for the relief of cold symptoms.

Echinaforce, tablets (*Echinacea purpurea.*) 2004-12-15

Approved indication: Traditionally used for the relief of cold symptoms.

Echinagard, oral solution (*Echinacea purpurea*) 2006-01-31

Approved indication: Traditionally used for the relief of cold symptoms.

Echinagard drops (*Echinacea purpurea*) 1995-08-24

Approved indication: Traditionally used for the relief of cold symptoms.

Echinagard lozenge (*Echinacea purpurea*) 1995-12-21

Approved indication: Traditionally used for the relief of cold symptoms.

Echinatex, oral drops, solution (*Echinacea purpurea*) 2004-11-02

Approved indication: Traditionally used for the relief of cold symptoms.

Echinova, powder oral solution (*Echinacea purpurea*) 2000-03-21 Approved indication: Traditionally used for the relief of cold symptoms.

Echinova, lozenge (*Echinacea purpurea*) 2000-03-21

Approved indication: Traditionally used for the relief of cold symptoms.

Echitonil, chewable tablet (*Echinacea purpurea*) 2004-12-15

Approved indication: Traditionally used for the relief of cold symptoms.

Efabene, ointment (*Solanum dulcamara*) 2006-03-29

Approved indication: Traditionally used for the relief of mild chronic eczema.

EFI Ginkgo Biloba capsules (*Ginkgo biloba*) 1998-05-25

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Enteroplant, gastro-resistant capsules, soft (*Mentha piperita L, Carum carvi L*) 2004-11-02

Approved indication: Traditionally used for temporary indigestion to relive symptoms like feeling bloated, flatulence and stomach ache.

Esbericum capsules (*Hypericum perforatum*) 1996-03-29

Approved indication: Traditionally used in case of slight mood lowering and for minor nervous tension.

Eskimo-3, oral solution (Fish oil containing omega-3-fatty acid triglycerides) 1999-03-10

Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

Eskimo-3, capsules (Fish oil containing omega-3-fatty acid triglycerides) 1999-03-10

Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

Esberitox, oral solution(Extract of *Baptisia tinctoria L.*, Extract of *Echinacea purpurea* (coneflower), Extract of *Echinacea pallida* (coneflower) Extract of *Thuja occidentalis L.*)2002-12-18

Approved indication: Traditionally used for the relief of cold symptoms.

Esberitox, tablet(Extract of *Baptisia tinctoria L.*, Extract of *Echinacea purpurea* (coneflower), Extract of *Echinacea pallida* (Blek solhatt) Extract of *thuja occidentalis L.*) 2002-12-18

Approved indication: Traditionally used for the relief of cold symptoms.

Euvekan, tablets (*Valeriana officinalis, Melissa officinalis*) 1999-10-14

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Femicur, capsule, hard (*Vitex agnus castus*) 2005-10-12

Approved indication: Traditionally used to relive symptoms of PMS (premenstrual syndrome), such as tender breasts, bloating, irritability, anxiety and sudden dejection that appear during the week before menstruation and usually disappear when the menstruation starts. To be used only when physician has established that no other serious disease is present.

Floralax, herbal tea, tea bags (Cassia senna, Cassia angustifolia) 2005-04-27

Approved indication: Traditionally used for the treatment of temporary constipation

Friggs Echinacea, effervescent tablet (*Echinacea purpurea L*) 2003-09-30

Approved indication: Traditionally used for the relief of cold symptoms.

Friggs Ginkgo biloba, coated tablets (*Ginkgo biloba*) 2001-05-18

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Galexir, oral solution (Cynara scolymus, Gentiana lutea, Curcuma longa) 2006-02-21
Traditionally used for symptoms of temporary indigestion such as feeling bloated and flatulence.

Gastrosan, tablet (Kalciumpkarbonat, Magnesiumtrisilikat) 2005-04-27
Approved indication: Traditionally used for heartburn.

Gericomplex, capsules (*Panax ginseng*) 1999-03-30
Approved indication: Traditionally used as a tonic in case of decreased performance such as fatigue and sensation of weakness.

Gericomplex, film-coated tablets (*Panax ginseng*) 2001-04-09
Approved indication: Traditionally used as a tonic in case of decreased performance such as fatigue and sensation of weakness.

Gericomplex, effervescent tablet (*Panax ginseng*) 2006-03-10
Approved indication: Traditionally used as a tonic in case of decreased performance such as fatigue and sensation of weakness.

Ginkgo Biloba Macronova, film-coated tablets (*Ginkgo biloba* L.) 2004-04-27
Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Ginkgo Biloba Vitalas, film-coated tablet (*Ginkgo biloba*) 2006-01-31
Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Ginkomax, tablets (*Ginkgo biloba*) 1999-06-16
Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Gink-Yo tablets (*Ginkgo biloba*) 1997-09-04
Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Ginsana, capsules (*Panax ginseng*) 1999-03-30
Approved indication: Traditionally used as a tonic in case of decreased performance such as fatigue and sensation of weakness.

Ginsana, oral solution (*Panax ginseng*) 1999-03-30
Approved indication: Traditionally used as a tonic in case of decreased performance such as fatigue and sensation of weakness.

Hametan, cream (*Hamamelis virginiana*) 2002-03-20

Approved indication: Traditionally used for the treatment of superficial, non-infected wounds, such as minor burns, minor scalding and light sunburns, and for the treatment of light atopic eczema and minor non-bleeding haemorrhoids.

Helaflex, film-coated tablet (*Harpagophytum procumbens*) 2005-12-09

Approved indication: Traditionally used for relief of pain and stiffness in cases of mild joint wear (osteoarthritis)

Herbalax, tablets (*Cassia senna*, *Cassia angustifolia*) 1998-03-05

Approved indication: Traditionally used for the treatment of temporary constipation.

Herstat, ointment (Propolis) 2004-09-23

Approved indication: Traditionally used for the treatment of sore on the lips.

Husk Lindroos, powder (*Plantago ovata testa*) 1998-12-16

Approved indication: Traditionally used for temporary constipation, mild and temporary diarrhoea. Softens the stool in case of haemorrhoids, anal fissures or pregnancy.

Hyperiforce drops (*Hypericum perforatum*, *Melissa officinalis*, *Humulus lupulus*) 1997-01-09

Approved indication: Traditionally used for minor nervous tension.

Hypermin, tablets (*Hypericum perforatum*) 1998-11-24

Approved indication: Traditionally used in case of slight mood lowering and for minor nervous tension.

Johannesört Salus, herbal tea, tea bag (*Hypericum perforatum* L.) 2004-04-27

Approved indication: Traditionally used in case of slight mood lowering and minor nervous tension.

Johannesört Salus, herbal tea (*Hypericum perforatum* L.) 2004-04-27

Approved indication: Traditionally used in case of slight mood lowering and minor nervous tension.

Japol, oral drops (*Mentha arvensis* L. var *piperascens* Malinv. ex. Holmes) 2003-12-12

Approved indication: Traditionally used for temporary indigestion with symptoms like feeling bloated, flatulence and stomach ache.

Kan Jang, coated tablet (*Justicia adhatoda*, *Echinacea purpurea*, *Eleutherococcus senticosus*) 2006-03-29

Approved indication: Traditionally used for the relief of cold symptoms.

Kan Jang, oral solution (*Justicia adhatoda*, *Echinacea purpurea*, *Eleutherococcus senticosus*) 2006-03-29

Approved indication: Traditionally used for the relief of cold symptoms.

Klimadynon (former Menofem), tablet, film-coated (*Cimicifuga racemosa*) 2006-03-24

Approved indication: Traditionally used in case of minor climacteric symptoms such as hot flushes, sweating, sleep disturbances and nervous.

Kwai, tablets (*Allium sativum*) 2001-04-09

Approved indication: Traditionally used for the relief of cold symptoms.

Kwai Forte, tablets (*Allium sativum*) 2001-04-09

Approved indication: Traditionally used for the relief of cold symptoms.

Kyolic, tablet (*Allium sativum*) 2006-02-21

Approved indication: Traditionally used for the relief of cold symptoms.

Kyoton (previous name FK Ginkgo Biloba), tablets (*Ginkgo biloba*) 2000-03-21

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Lejguar, granules (Guargalaktomannan) 2001-05-18

Approved indication: Traditionally used for the treatment of temporary constipation.

Libramin, tablets (*Hypericum perforatum*) 2002-03-20

Approved indication: Traditionally used in case of slight mood lowering, for minor nervous tension and temporary insomnia.

Linella, tablets (*Cassia senna*) 1999-06-16

Approved indication: Traditionally used for the treatment of temporary constipation.

Melival Kliniplex, tablets (*Valeriana officinalis*) 1999-06-16

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Memazoc oral liquid (*Ginkgo biloba*) 1997-06-19

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Memazoc tablets (*Ginkgo biloba*) 1997-06-19

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Memoplant, film-coated tablets (*Ginkgo biloba* L.) 2002-06-13

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, feeling of tiredness and tinnitus. Prior to treatment other serious conditions should have been ruled out by doctor.

Movina tablets (*Hypericum perforatum*) 1997-09-04

Approved indication: Traditionally used in case of slight mood lowering, for minor nervous tension and temporary insomnia.

Neurokan, tablets (*Hypericum perforatum*) 1999-03-10

Approved indication: Traditionally used in case of slight mood lowering, for minor nervous tension and temporary insomnia.

Neval capsules (*Valeriana officinalis*) 1996-06-28

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Nosweat capsules (*Salvia officinalis*) 1997-09-04

Approved indication: Traditionally used against temporarily exaggerated sweating.

Oleum Basileum, inhalation vapour, solution (*Mentha piperitae aetheroleum, Eucalypti aetheroleum, Cajeputi aetheroleum*) 2001-04-09

Approved indication: Traditionally used for the relief of cold symptoms such as nasal congestion and cough.

Oleum Salvum, inhalation vapour, ointment (*Mentha piperitae aetheroleum, Eucalypti aetheroleum, Cajeputi aetheroleum*) 2004-12-15

Approved indication: Traditionally used for the relief of cold symptoms such as nasal congestion and cough.

PanAcido, capsule, hard (*Enterococcus faecium*) 2003-06-23

Approved indication: Traditionally used for normalization of the intestinal case of temporary gastro-intestinal trouble such as mild diarrhoea and constipation, and as prophylaxis and treatment of common uncomplicated traveller's diarrhoea.

Pikasol Forte, capsules (Concentrated fish oil containing omega-3-fatty acid triglycerides) 1999-06-16

Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

Proginko, film-coated tablet (*Ginkgo Biloba* L) 2003-12-12

Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Prostakan, capsules (*Serenoa repens, Urtica dioica/Urtica urens*) 2000-06-15

Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e g frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Prospan, oral solution (*Hedera helix*) 2006-03-14

Approved indication: Traditionally used for relief of cough with viscous phlegm.

Prosabal, capsules, soft (*Serenoa repens*) 2006-03-06

Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e g frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Prostagard, capsules, soft (*Serenoa repens*) 2006-03-06

Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e g frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Relana (previous name Valerina Dag) tablets (*Valeriana officinalis*, *Melissa officinalis*) 1995-11-01
Approved indication: Traditionally used for minor nervous tension.

Relaxin Natt tablets (*Valeriana officinalis*, *Passiflora incarnata*, *Melissa officinalis*) 1997-02-26
Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Remifemin, tablets (*Cimicifuga racemosa*) 1998-12-16
Approved indication: Traditionally used in case of minor climacteric symptoms such as hotflashes, sweating, sleep disturbances and nervous tension.

Rysk rot Svenska Örtmedicinska Institutet AB, tablet (*Eleutherococcus senticosus*) 2006-03-29
Approved indication: Traditionally used as a tonic in case of decreased performance such as fatigue and sensation of weakness.

Sabamin capsule, soft (*Serenoa repens*) 2004-06-29
Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e g frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Salus Migränte te (*Ilex paraguariensis*, *Salix alba* spp, *Valeriana officinalis*, *Cola nitida*, *Juniperus communis*) 1998-03-05
Approved indication: Traditionally used for the treatment of occasional mild migraine attacks.

Salva vid munsår, ointment (*Echinacea purpurea*) 2005-12-06
Approved indication: Traditionally used for treatment of sores on the lips and other small, superficial wounds such as chapping in the corner of the mouth or on the fingertips.

Samarin single-dose powders (Sodium hydrogen carbonate, tartaric acid, citric acid, sodium carbonate, sodium potassium carbonate) 1997-01-09
Approved indication: Traditionally used for heartburn.

Samarin oral powder (Sodium hydrogen carbonate, tartaric acid, citric acid, sodium carbonate, sodium potassium carbonate) 1997-01-09
Approved indication: Traditionally used for heartburn.

Samarin effervescent powder (Sodium citrate, sodium hydrogen carbonate, potassium hydrogen carbonate, citric acid, sodium carbonate, sodium potassium carbonate) 1997-04-02
Approved indication: Traditionally used for heartburn.

SamarinAntacid Mint, chewable tablets (Magnesium hydroxide, calcium carbonate, magnesium carbonate) 1997-04-02
Approved indication: Traditionally used for heartburn.

Samarin PersikaCitron (former Samarin Apelsin), single-dose powders (Sodium hydrogen carbonate, tartaric acid, citric acid, sodium carbonate, sodium potassium carbonate) 1997-01-09
Approved indication: Traditionally used for heartburn.

Sanaxeen, film-coated tablet (*Secale cereale*, *Phleum pratense*, *Zea mays*) 2006-03-29
Approved indication: Traditionally used in case of micturition problems caused by benign prostatic hyperplasia, e.g. frequent need to urinate and nocturia. Prior to treatment other serious conditions should have been ruled out by doctor.

Sanumar, capsules (Concentrated fish oil containing omega-3-fatty acid triglycerides) 1999-06-16
Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

Schoenenberger Senna-sirap oral liquid (*Cassia angustifolia*) 1998-05-26
Approved indication: Traditionally used for the treatment of temporary constipation.

Sedacur, coated tablet (*Valeriana officinalis*, *Humulus lupulus*, *Melissa officinalis*) 2005-12-06
Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Seredrin, tablets (*Ginkgo biloba*) 1999-06-16
Approved indication: Herbal remedy for the treatment of long-standing symptoms in elderly people such as difficulties of memory and concentration, vertigo, tinnitus and feeling of tiredness. Prior to treatment other serious conditions should have been ruled out by doctor.

Sinova, coated tablets (*Gentiana lutea*, *Primula veris*, *Primula elatior*, *Rumex acetosa*, *Rumex acetosella*, *Rumex obtusifolius*, *Rumex patientia*, *Rumex crispus*, *Rumex thyrsoiflorus*, *Sambucus nigra*, *Verbena officinalis*) 2001-05-18
Approved indication: Traditionally used for the relief of symptoms of cold in the nose and sinus.

Sinova forte, coated tablet (*Gentiana lutea*, *Primula veris*, *Primula elatior*, *Rumex acetosa*, *Rumex acetosella*, *Rumex obtusifolius*, *Rumex patientia*, *Rumex crispus*, *Sambucus nigra*, *Verbena officinalis*) 2005-03-30
Approved indication: Traditionally used for the relief of symptoms of cold in the nose and sinus.

Sinupret, coated tablets (*Gentiana lutea*, *Primula veris*, *Primula elatior*, *Rumex acetosa*, *Rumex acetosella*, *Rumex obtusifolius*, *Rumex patientia*, *Rumex crispus*, *Rumex thyrsoiflorus*, *Sambucus nigra*, *Verbena officinalis*) 2001-05-18
Approved indication: Traditionally used for the relief of symptoms of cold in the nose and sinus.

Sinupret forte, coated tablet (*Gentiana lutea*, *Primula veris*, *Primula elatior*, *Rumex acetosa*, *Rumex acetosella*, *Rumex obtusifolius*, *Rumex patientia*, *Rumex crispus*, *Sambucus nigra*, *Verbena officinalis*) 2005-03-30
Approved indication: Traditionally used for the relief of symptoms of cold in the nose and sinus.

Solidamin, oral drops, solution (*Solidago virgaurea*) 2005-12-06
Approved indication: Traditionally used for symptomatic relief of lower urinary tract disorders of the type that may benefit from an increased flow through the urinary tract, for example urinary tract irritation or light pain caused by passing urinary stones or kidney gravel.

Songha Natt tablets (*Valeriana officinalis*, *Melissa officinalis*) 1997-12-11

Approved indication: Traditionally used for temporary insomnia.

Soval tablets (*Valeriana officinalis*, *Melissa officinalis*) 1995-12-21

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Symbioplex, capsules (*Lactobacillus acidophilus*, *Bifidobacterium lactis*, *Streptococcus thermophilus*) 1999-10-14

Approved indication: Traditionally used for normalization of the intestinal flora in case of temporary gastro-intestinal trouble such as mild diarrhoea and constipation, and as prophylaxis and treatment of common uncomplicated traveller's diarrhoea.

Thursday Plantation Tea Tree olja, cutaneous solution (*Melaleuca alternifolia*) 1998-10-13

Approved indication: Traditionally used for the treatment of mild acne, against itch in mild cases of tinea pedis (athlete's foot) and uncomplicated insect-bites.

Timjan Recip, lozenge (Thymi herba) 2001-01-24

Approved indication: Traditionally used for the relief of temporary coughing.

Trevis, capsules (*Lactobacillus acidophilus*, *Bifidobacterium lactis*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus*) 1999-06-17

Approved indication: Traditionally used for normalization of the intestinal flora in case of temporary gastro-intestinal trouble such as mild diarrhoea and constipation, and as prophylaxis and treatment of common uncomplicated traveller's diarrhoea.

TRILAC, capsule, hard (*Lactobacillus acidophilus*, *Bifidobacterium lactis*, *Lactobacillus bulgaricus*) 2002-12-18

Approved indication: Traditionally used for normalization of the intestinal flora in case of temporary gastro-intestinal trouble such as mild diarrhoea and constipation, and as prophylaxis and treatment of common uncomplicated traveller's diarrhoea.

Triomar capsules (Concentrated fish oil containing omega-3-fatty acid triglycerides) 1998-10-13

Approved indication: Natural remedy containing omega-3-fatty acids which can contribute to the protection against cardiovascular disease.

Turbinal, capsules (*Lactobacillus acidophilus*, *Bifidobacterium lactis*) 1999-06-16

Approved indication: Traditionally used for normalization of the intestinal flora in case of temporary gastro-intestinal trouble such as mild diarrhoea and constipation, and as prophylaxis and treatment of common uncomplicated traveller's diarrhoea.

Uva-E tablets (*Taraxacum officinalis*, *Arctostaphylos uva-ursi*, *Mentha piperita*) 1997-09-04

Approved indication: Traditionally used for relief of symptoms in connection with infection of the urinary tract as an adjunct to other treatment. Contact a doctor before treatment.

Valeriana Bioforce drops (*Valeriana officinalis*) 1997-04-17

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Valerina Forte tablets (*Valeriana officinalis*) 1995-11-01

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Valerina Natt tablets (*Valeriana officinalis*, *Melissa officinalis*, *Humulus lupulus*) 1996-03-29

Approved indication: Traditionally used for temporary insomnia.

Valeriana Nycomed, film-coated tablet (*Valeriana officinalis* L) 2003-09-30

Approved indication: Traditionally used for minor nervous tension and temporary insomnia.

Wesa Lax, tablet (*Cassia senna*, *Cassia angustifolia*) 2006-01-31

Approved indication: Traditionally used for the treatment of temporary constipation.

Vivag vaginal capsules (*Lactobacillus acidophilus*) 1997-06-19

Approved indication: Traditionally used in case of imbalance of the normal vaginal bacterial flora. Symptoms could be slightly increased discharge and slight itch.

Venastat, prolonged-release capsules (*Aesculus hippocastanum* L.) 2002-09-06

Approved indication: Herbal medicinal product to relieve symptoms caused by disturbances in the venous blood flow in the legs, so called chronic venous insufficiency, which is often accompanied by varicose veins, and which is characterised by swelling, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calf. To be used after chronic venous insufficiency has been established by a physician.

Venokan, prolonged-release tablets (*Aesculus hippocastanum* L.) 2002-09-06

Approved indication: Herbal medicinal product to relieve symptoms caused by disturbances in the venous blood flow in the legs, so called chronic venous insufficiency, which is often accompanied by varicose veins, and which is characterised by swelling, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calf. To be used after chronic venous insufficiency has been established by a physician.

Ziara, film-coated tablet (*Vitex agnus-castus*) 2005-12-09

Approved indication: Traditionally used to relieve symptoms of PMS (premenstrual syndrome), such as tender breasts, bloating, headache, irritability, anxiety and sudden dejection that appear during the week before menstruation and usually disappear when the menstruation starts. To be used only in cases when a physician has established that no other serious disease is present