

Newly Registered Products

alfacalcidol

1-alpha-hydroxy vitamin D

One-alpha®: Leo, Ireland

oral solution 0.2 µg/ml

Indications: uraemic bone disease, hypo- and hyperparathyroidism, osteoporosis, rickets; prophylactic and therapeutic use in infants of low birth weight.

alteplase

recombinant tissue plasminogen activator (TPA), a glycoprotein which promotes conversion of plasminogen to plasmin.

Activase®: Genentech, USA

Actilyse®: Boehringer Ingelheim, Austria, Luxembourg

powder for injection 20 mg/ampoule

Indication: fibrinolytic therapy in acute coronary thrombosis.

Contraindications: increased bleeding tendency, internal bleeding, cerebral bleeding, severe cardiovascular disease, recent trauma or major surgery, uncontrolled severe hypertension, bacterial endocarditis, acute pancreatitis, severe diabetes mellitus, diabetic retinopathy, sickle-cell anaemia.

Caution: safety not established during pregnancy and lactation or in children.

Adverse effects: spontaneous bleeding, cardiac dysrhythmias.

amiodarone

antidysrhythmic agent

Cordarone®: Labaz, Netherlands, Sweden

injection fluid 50 mg/ml

Indications: paroxysmal atrial fibrillation in Wolff-Parkinson-White syndrome, resistant life-threatening supraventricular and ventricular tachycardia.

Caution: thyroid, hepatic and cardiovascular function must be monitored regularly and ECGs performed at regular intervals.

(Netherlands only) To be administered exclusively by competent specialists.

aztreonam

lactamase-resistant antibiotic

Azactam®: Squibb, Austria, Finland

powder for injection 1 g/ampoule

Indications: infections due to susceptible micro-organisms.

Caution: For hospital use only.

benzbromarone

uricosuric agent

Besuric®: Labaz, Luxembourg

tablet 100 mg

Indications: gout, idiopathic hyperuricaemia.

betaxolol

beta-adrenoreceptor blocking agent

Alcon®: Alcon-Fin, Finland

eyedrops 5 mg/ml

Indication: open-angle glaucoma.

bisoprolol fumarate

beta-adrenoreceptor blocking agent

Emconcor®: Merck, Belgium

coated tablet 10 mg

Indications: hypertension, angina pectoris, cardiac dysrhythmia.

budesonide

glucocorticosteroid

Pulmicort®: Astra, Austria

aerosol 0.2 mg/puff

Indications: bronchial asthma and chronic obstructive bronchitis.

buserelin

synthetic analogue of luteinizing hormone releasing factor

Suprefact®: Behringwerke, Austria

Boehringer Ingelheim, Iceland

Hoechst, Ireland

injection fluid 0.1, 1 mg/ml

Indications: advanced prostatic cancer when suppression of testicular hormones is required.

cadexomer iodine

disinfectant

Iodosorb®: SK-RIT, Belgium
powder 100/

Indications: dressing for decubitus ulcer.

carboplatin

cytostatic

Paraplatin®: Bristol, Belgium
powder for injection 50, 150, 450 mg/
ampoule

Indications: ovarian cancer, small-cell lung cancer, carcinoma of the head and neck.

carteolol

beta-adrenoreceptor blocking agent

Caltidren®: Liphar, Belgium
tablet 20 mg

Indications: mild to moderate hypertension, angina pectoris.

cefamandole

cefalosporin antibiotic

Kefadol®: Lilly, Ireland
powder for injection 750 mg

Indications: infections with susceptible microorganisms, prophylaxis in surgery.

cefmenoxime

cefalosporin antibiotic

Cemix®: Erga, Belgium
powder for injection 0.5, 1 g/ampoule

Indications: severe infections in adults due to susceptible microorganisms.

Contraindication: meningitis.

ceftizoxime

cefalosporin antibiotic

Cefizox®: Wellcome, Netherlands
powder for injection 0.5, 1, 2 mg/ampoule

Indications: infections due to susceptible microorganisms.

ciclopirox olamine

antimycotic

Batrafen®: Hoechst, Ireland
solution 1%

Indication: topical treatment of skin infection.

ciprofloxacin

quinolone antibiotic

Ciproxin®: Bayer
Australia: tablet 250, 500, 750 mg
Austria: coated tablet 100, 250, 500, 750 mg;
capsule 250 mg; injection fluid 1, 2 mg/ml
Finland: capsules 250 mg; injection fluid 10 mg/ml

Indications: infections due to susceptible microorganisms involving the genitourinary tract, respiratory and gastrointestinal tract, skin and soft tissues, bones and joints; recurrent exacerbation of severe infections in patients with mucoviscidosis; peritonitis; active chronic otitis media; panophthalmitis; prophylaxis in immunocompromised patients. Gonorrhoea.

clemastine

antihistamine

Allereze®: Intercare, Ireland
elixir 0.1 mg/ml

Indications: allergic conditions.

collagen (equine)

Tachotop®: Hormon-Chemie, Austria
desiccated foam pads

Indication: treatment of bleeding resulting from dental surgery and small wounds.

dacarbazine

cytostatic

Dacatic®: Orion, Finland
powder for injection 100 mg/ampoule

Indications: malignant melanoma, sarcoma, Hodgkin's disease.

deflazacort

glucocorticosteroid

Flantadin®: Lepetit, Italy
tablet 6 mg, 30 mg

Indications: adrenocortical insufficiency, rheumatic disease, collagen and selected skin diseases, allergic conditions, selected respiratory and ocular disease, haematologic disorders, selected malignancies, oedema, gastro-intestinal disease.

Contraindications: active tuberculosis, peptic ulcer, herpetic eye infection, systemic mycotic infection, psychoses.

Precautions, warnings and adverse effects as usual for other drugs of this class.

desogestrel + ethinylestradiol

oral contraceptive

Desolett®: Organon, Sweden

tablet 0.15 mg + 30 µg

Indications: contraception, functional dysmenorrhoea.

diacerein

nonsteroidal anti-inflammatory agent

Artrodar®: Proter, Italy

capsule 25, 50 mg

Indication: osteoarthritis.

Contraindication: hypersensitivity.

Caution in patients with a history of enterocolitis.

Safety not established during pregnancy or lactation.

doxepin

benzodiazepine tranquilizer

Doxans®: Schiapparelli, Italy

capsule 10 mg

Indication: short-term treatment of insomnia.

Contraindications, precautions and warnings as for other drugs of this class.

enflurane

inhalation anaesthetic

Allyrane®: Anaquest, Ireland

liquid 100%

Indication: induction and maintenance of general anaesthesia.

flumazenil

benzodiazepine antagonist

Anexate®: Roche, Austria, Luxembourg

injection fluid 0.5, 1 mg/ml

Indications: reversal of the central effect of benzodiazepines, as required, during anaesthesia and intensive care.

flutamide

antiandrogenic cytostatic

Flugerel®: Essex, Austria

Drogenil®: Essex, Ireland

tablet 250 mg

Indications: palliative treatment of advanced prostatic carcinoma.

ipratropium bromide (1)

anticholinergic

Atrovent®: Boehringer Ingelheim, Ireland

solution 5 mg/ml

Indication: reversible airways obstruction.

ipratropium bromide (2)

anticholinergic

Bitrop®: Boehringer Ingelheim, Luxembourg

Itrop®: Boehringer Ingelheim, Switzerland

tablets 10 mg, injection fluid 0.5 mg/ml

Indications: sinus bradycardia of vagal origin, atrial fibrillation, bradycardia with sinoatrial block, atrio-ventricular block.

Contraindications: glaucoma, prostatic hypertrophy, gastrointestinal stenosis, megacolon, tachycardia.

leuprorelin

synthetic analogue of luteinizing hormone releasing factor

Lupron®: Abbot, Iceland, Sweden

injection fluid 5, 25 mg/ml

Indications: advanced prostatic cancer when orchidectomy is not indicated.

lidocaine + prilocaine

local anaesthetic

Emla®: Astra, Netherlands

cream 25 + 25 mg/g

Indications: analgesia of intact skin.

Caution: apply at least one hour and no more than two hours before surgical intervention.

meclofenamic acid

nonsteroidal anti-inflammatory agent

Meclomen®: Parke-Davis, Austria

capsule 100 mg

Indications: inflammatory and degenerative rheumatic disease.

Contraindications, precautions and warnings as for other drugs of this class.

mitoxantrone

cytostatic

Novantrone®: Lederle, Sweden

solution (concentrate) for infusion 2 mg/ml

Indication: advanced metastatic breast cancer.

mupirocin

antibiotic

Bactroban®: Beecham, Ireland
ointment 2 g/100 g*Indication:* acute primary skin infection due to susceptible bacteria.**nabumetone**

nonsteroidal anti-inflammatory agent

Mebutan®: Bencard, Luxembourg
tablet 500 mg, syrup 100 mg/ml*Indications:* rheumatic and other inflammatory conditions of joints.**naltrexone**

opioid antagonist

Nalorex®: Dupont, Ireland
tablet 50 mg*Indications:* adjunct in management of opiate withdrawal.**omeprazole**

inhibitor of gastric acid secretion.

Losec®: Astra, Luxembourg

Parfenac®: Vital Pharma, Luxembourg
powder for injection 40 mg/ampoule
capsule 20 mg, containing enteric coated granules*Indications:* duodenal ulcer, Zollinger-Ellison syndrome.*Adverse effects:* occasional nausea, headache, diarrhoea.*Caution:* Possible interaction with phenytoin, diazepam and other drugs metabolized by the liver.**podophyllotoxin**

a component of podophyllin with antimitotic and cytolytic properties.

Condyline®: Gist-Brocades, Netherlands, Norway

Wartec®: Conpharm: Norway
liniment 5 mg/ml*Indication:* condyloma acuminata.*Contraindications:* pregnant or lactating women, children.*Warnings, precautions:* Not to be used in combination with other podophyllin preparations. Avoid contact with the eyes. Do not apply to large epithelial surfaces.**propofol**

anaesthetic

Diprivan®: ICI, Netherlands
injection fluid 10 mg/ml*Indication:* induction and maintenance of anaesthesia.**rilménidine**

Centrally-acting alpha-2-adrenoreceptor antagonist

Rilménidine Servier®: Servier, France

Hyperium®: Biopharma
tablet 1 mg*Indication:* essential hypertension.*Contraindications:* severe depressive states, severe renal insufficiency (creatinine clearance <15 mg/min).*Precautions and warnings:* Treatment must not be discontinued abruptly. Monitoring required following a recent vascular accident. Safety has not been established during pregnancy and in children. Since it is excreted in breast milk, it should not be taken during lactation.**simfibrate**

antihyperlipidaemic, which increases HDL and decreases LDL cholesterol concentration.

Cholesolvin®: Yoshitomi, Japan

capsule 250 mg, granules 50 mg/g

Indications: hyperlipidaemia associated with arteriosclerosis, cerebral atherosclerosis, coronary arteriosclerosis, hypertension, diabetes.*Caution:* in concurrent treatment with anticoagulants. Periodic monitoring of hepatic function is recommended during long-term treatment.**somatrem**

methionyl growth hormone

Somatonorm®: KabiVitrum, Australia

powder for injection 4 IU/ampoule

Indication: short stature due to growth hormone deficiency.**somatropin**

human growth hormone

Humatrope®: Lilly, Norway

Genotropin®: KabiVitrum, Sweden

Norway: powder for injection 4, 12 IU/ampoule

Sweden: 12 IU/ampoule

Indication: growth retardation due to pituitary insufficiency.

spiramycin

macrolide antibiotic

Rovamycine®: Rhone-Poulenc, Luxembourg

tablet 500 mg

powder for injection 500 mg/ampoule

Indications: infections due to susceptible micro-organisms.**tenoxicam**

nonsteroidal anti-inflammatory agent

Tilcotil®: Roche, Luxembourg

coated tablet 20 mg

Indications: rheumatic disease, arthritis, gout.**terlipressin**

precursor of lyspressin

Glypresin®: Ferring, Ireland

powder for injection 1 mg/ampoule

Indications: short-term management of bleeding oesophageal varices in an intensive care setting.*Contraindication:* pregnancy.*Caution* in patients with hypertension, renal dysfunction or cardiac insufficiency.*Adverse effects:* abdominal pain including colic, peripheral blanching, headache, hypertension, antidiuretic effect.**terodiline**

anticholinergic

Terolin®: KabiVitrum, Ireland

Mictrol®: KabiVitrum, Norway

tablet 12.5 mg

Indication: urinary incontinence in patients with detrusor instability or neurogenic bladder.**tertatolol**

beta-adrenoreceptor blocking agent

Artex®: Servier, Luxembourg

tablet 5 mg

Indications: hypertension, angina pectoris.**tianeptine**

tricyclic antidepressant

Stablon®: Servier, Luxembourg

tablet 12.5 mg

Indications: neurotic depression, anxiety with somatic overlay, alcohol withdrawal.*Contraindications:* children younger than 15 years; patients undergoing treatment with MAO inhibitors.**tiaprofenic acid**

nonsteroidal anti-inflammatory agent

Surgamyl®: Roussel, Finland

tablet 600 mg

Indications: rheumatoid arthritis, osteoarthritis.**tixocortol pivalate**

corticosteroid

Pivalone®: ACF Farma, Netherlands

nose spray 10 mg/ml

Indications: allergic and vasomotor rhinitis.**zuclopenthixol**

neuroleptic

Clopixol-Acutard®: Lundbeck, Luxembourg, Switzerland

Cisordinol-Acutard®: Austria, Sweden

injection fluid 50 mg/ml

Indications: acute psychoses and exacerbations of chronic psychoses, particularly schizophrenia.*Contraindications:* acute alcohol, barbiturate or opioid intoxication, coma. To be used in pregnancy and lactation only when absolutely necessary.*Caution* in epileptic patients.