

# Pharmaceutical Products Approved

---

## alfentanil

Narcotic analgesic

Rapifen®: Janssen, Austria

injection fluid 0.5 mg/ml

*Indication:* anaesthesia in short-lasting surgical procedures, and as an adjuvant analgesic in procedures of longer duration.

## amrinone

Coronary vasodilator

Inocor®: Winthrop, Sweden

injection fluid 5 mg/ml

*Indication:* acute cardiac insufficiency when the response to treatment with glycosides, diuretics and vasodilators is insufficient.

## amiodarone

Antidysrhythmic

Cordaronex®: Sanofi, Sweden

tablet 200 mg

injection fluid 50 mg/ml

*Indication:* tachydysrhythmia in Wolff-Parkinson-White syndrome and other paroxysmal tachydysrhythmias.

*Contraindications:* sinus bradycardia, AV-block.

Injectable form only: circulatory collapse, arterial hypotension.

## befunolol

β-adrenoreceptor blocking agent

Glauconex®: Dr Thilo, Austria

eye drops 5 mg/ml

*Indication:* glaucoma.

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

## bepidil

Calcium influx blocking agent

Cordium®: Organon, Ireland

tablet 100, 200, 300 mg

*Indication:* prophylaxis of stable angina pectoris.

*Contraindications:* hypersensitivity, second degree or complete heart block, cardiogenic shock, severe hypotension, concurrent treatment with β-adrenoreceptor blocking agents, uncompensated

heart failure, severe bradycardia, sick sinus syndrome, hypo- or hyperkalaemia, severe renal or hepatic insufficiency.

*Caution:* To be used only under specialist supervision. Not to be used during pregnancy or lactation.

## bifonazole

Antimycotic

Mycosporin®: Bayer, Austria

solution 0.01 mg/ml

*Indication:* topical treatment of dermal mycoses.

## cadexomer iodine

Topical antiseptic

Iodosorb®: SKF, Austria

powder 100% (iodine 1%)

*Indication:* wound dressing, in particular ulcer cruris and decubitus.

*Contraindications:* iodine hypersensitivity, hyperthyroidism, pregnancy, lactation and young children.

## calcitonin, synthetic salmon

Synthetic salmon calcitonin

Miacalcic®: Sandoz, Ireland

*Indications:* Paget's disease of bone, hypercalcaemia, pain associated with metastatic bone cancer, post-menopausal osteoporosis.

*Contraindication:* lactation.

*Caution:* Specialist supervision with appropriate monitoring of clinical biochemical and radiological response is required. Not to be used in women of childbearing age unless considered essential since animal studies suggest a causal relationship between calcitonin and retardation of fetal growth and inhibition of lactation.

## carboplatin

Cytostatic

Paraplatin®: Bristol, Luxembourg, Ireland

powder for intravenous injection 50, 150,

450 mg/ampoule

*Indication:* advanced ovarian carcinoma of epithelial origin, small-cell lung carcinoma, epithelial carcinoma of head and neck.

*Adverse effects:* subclinical hearing loss has occasionally been reported.

*Contraindications, precautions, warnings* as usual for drugs of this class.

### carpipramine

Tricyclic antidepressant

Defekton®: Yoshitomi Pharmaceutical Industry, Japan

coated tablet 25, 50 mg

*Indications:* chronic schizophrenia with loss of volition, depression and hypochondria.

*Adverse effects:* extrapyramidal effects, anticholinergic and neurological symptoms including anxiety, excitation, drowsiness, vertigo, headache.

### cefpimizole

Cefalosporin antibiotic

Ajicef®: Ajimomoto, Japan

powder for injection 0.5, 1 g/ampoule

*Indications:* septicaemia, infection of respiratory, urinary and biliary tracts, peritonitis and pelvic inflammatory disease.

### cicletanine

Peripheral vasodilator

Secletan®: Ipsen, Luxembourg

capsule 50, 100 mg

*Indication:* essential hypertension.

*Contraindications:* severe renal or hepatic insufficiency.

*Caution* in hypokalaemic individuals. Avoid administration in renal insufficiency with creatinine clearance below 30 ml/min.

### ciclopirox olamine

Antimycotic

Cicloche®: Novag, Spain

cream 100 mg/g, powder 10 mg/g, solution 10 mg/g

*Indication:* topical treatment of dermal and mucosal mycoses.

*Contraindications:* hypersensitivity.

*Caution:* Not to be applied to the eyes.

### ciprofloxacin

Broad-spectrum quinolone antibiotic

Ciproxin®: Bayer, Luxembourg

tablet 100, 250, 500, 750 mg

injection fluid 1, 2 mg/ml

*Indication:* infection due to susceptible microorganisms.

*Contraindications, cautions, warnings* as usual for drugs of this class.

### clenbuterol

β-adrenoreceptor stimulating agent

Spiropent®: Castejon, Spain

syrup 0.01 mg/5 ml

*Indication:* bronchial asthma, asthmatic bronchitis, spastic bronchitis.

*Contraindications, cautions, warnings* as usual for drugs of this class.

### dinoprostone

Prostaglandin derivative

Prostin E2®: Upjohn, Netherlands

infusion fluid (concentrate) 1, 10 mg/ml

*Indications:* induction of labour, therapeutic termination of pregnancy, "missed abortion", hydatiform mole.

*Contraindications:* hypersensitivity; uterine scarring; fetal disproportion.

### elcatonin

Eel calcitonin

Elcitonin®: Toyo Jozo, Japan

injection fluid 50 IU/ml

*Indication:* hypercalcaemia, Paget's disease.

*Caution* in patients with bronchial asthma, hypersensitivity.

*Adverse effects:* anaphylactic shock, sweating, fever, hot flushes or palpitations, headache, vertigo, transient rise in serum transaminase concentration, hyponatraemia, pain at injection site. Safety of use has not been established in children, during pregnancy or lactation.

### febuprol

Choleretic

Valbil®: Röhm Pharma, Luxembourg

capsule 100 mg

*Indication:* gastrointestinal complaints due to insufficient biliary secretion.

*Contraindications:* severe liver dysfunction, acute exacerbation of chronic liver disease, biliary duct obstruction, intestinal obstruction, acute inflammation of liver, bile duct or intestine, gastrointestinal ulcer or tumours. Not to be taken during the first trimester of pregnancy or during lactation. Not to be used for treatment of biliary colic.

### flumazenil

Benzodiazepine antagonist

Anexate®: Roche, Switzerland

injection fluid 0.1 mg/ml

*Indication:* treatment of benzodiazepine over-dosage, reversal of benzodiazepine-induced anaesthesia.

*Contraindication:* hypersensitivity.

*Caution:* ability to drive or operate machinery may be impaired. When used to reverse anaesthesia it should not be administered whilst a muscle relaxant remains effective.

### fluoxetine

Antidepressant

Prozac®: Lilly, Luxembourg  
capsule 20, 30, 40, 60 mg

*Indication:* depression with anxiety in hospitalized or ambulatory patients.

*Contraindications:* hypersensitivity. Not to be administered to children.

### flutoprazepam

Minor tranquilizer

Restar®: Sumitomo Chemical, Japan  
tablet 2 mg

*Indications:* anxiety, depression, sleep disturbances; psychosomatic disorders, including gastrointestinal ulcer, irritable bowel syndrome.

### gestrinone

Synthetic gonadotropin antagonist

Nemestran®: Roussel, Switzerland  
capsule 2.5 mg

*Indication:* endometriosis.

*Contraindications:* pregnancy, lactation, cardiac insufficiency, severe hepatic or renal malfunction.

### gonadorelin (1)

Synthetic gonadotropic hormone releasing factor  
Lutrelaf®: Ferring, Ireland, Sweden, Switzerland

powder for injection 0.8, 3.2 mg/ampoule  
*Indications:* anovulatory infertility; azoospermia and severe oligospermia; induction of puberty.

Switzerland only: amenorrhoea of hypothalamic origin, support of the luteal phase after ovulation and implantation, male hypogonadism.

### gonadorelin (2)

Synthetic gonadotropic hormone releasing factor  
Cryptocur®: Hoechst, Ireland

metered-dose nasal spray 0.2 mg/dose  
*Indication:* cryptorchidism.

### gonadorelin (3)

Synthetic gonadotropic hormone releasing factor

Fertiral®: Hoechst, Luxembourg  
Lutrelaf®: Ferring, Switzerland

injection fluid 0.5 mg/ml

*Indication:* hypogonadotropic hypogonadism

*Contraindications:* endometrial cysts, polycystic ovaries, amenorrhoea in women with a weight index of less than 19.5. Treatment must be discontinued if pregnancy occurs.

Switzerland: Phase I hypothalamic amenorrhoea (clomifene-positive with bleeding) should not be treated with gonadorelin.

### idebenone

Cerebral vasodilator

Avan®: Takeda, Japan  
tablet [strength not indicated]

*Indications:* sequelae of cerebral infarction or haemorrhage, cerebral arteriosclerosis.

### interferon alfa-2a

Synthetic interferon

Roferon-A®: Roche, Luxembourg, Ireland, Switzerland

powder for injection  
3 x 10<sup>6</sup> IU; 9 x 10<sup>6</sup> IU (Ireland only);  
18 x 10<sup>6</sup> IU/ampoule

*Indications:* metastatic melanoma, Kaposi's sarcoma in AIDS patients, hairy-cell leukaemia.

*Contraindications:* hypersensitivity, severe cardiac disease, hepatic insufficiency, convulsive disorders, neurological or organic psychiatric disturbances.

### interferon alfa-2b (1)

Synthetic interferon

Introna®: Essex, Finland  
powder for injection 5 x 10<sup>6</sup> IU/ampoule

*Indications:* hairy-cell leukaemia, condylomata, laryngeal papilloma.

### interferon alfa-2b (2)

Synthetic interferon

Introna®: Aesca, Austria  
powder for injection 30 x 10<sup>6</sup> IU/ampoule  
Intron A®: Essex, Australia  
powder for injection 1.5, 10,  
30 x 10<sup>6</sup> IU/ampoule

*Indications:*

Austria: hairy-cell leukaemia, multiple myeloma, Kaposi's sarcoma in AIDS patients. On a tentative basis: malignant melanoma, superficial tumours of the bladder, juvenile laryngeal papilloma, hypernephroma, leukaemia, lymphomas and viral disease such as condylomata acuminata.

Australia: hairy cell leukaemia only.

*Adverse effects:* influenza-like symptoms.

**interferon alfa-2c (1)**

Synthetic interferon

Berofor®: Bender, Austria

powder for injection 15 µg/ampoule

*Indications:* hairy-cell leukaemia, juvenile laryngeal carcinoma.*Contraindications:* serious cardiovascular disease, bone marrow insufficiency.*Caution:* not effective in the treatment of carcinoma of the breast, colon, or bronchus.*Adverse effects:* influenza-like symptoms.**interferon alfa-2c (2)**

Synthetic interferon

Berofor®: Bender, Austria

eye drops 1.5 x 10<sup>6</sup> IU/ml*Indications:* acute epithelial herpes simplex keratitis, as an adjunct to basic therapy.*Caution:* contact lenses should not be worn during treatment.**iopromide**

Radiocontrast medium

Ultravist®: Schering, Netherlands

infusion fluid 499 mg/ml (240 mg iodine)

*Indications:* contrast enhancement in computer tomography, digital subtraction angiography, urography, phlebography of the extremities.*Contraindications:* clinical hyperthyroidism, hypersensitivity.*Caution:* Not to be used for myelography.**ketanserin**

Serotonine-antagonist

Sufrexal®: Janssen, Luxembourg, Switzerland

coated tablet 20, 40 mg

injection fluid 5 mg/ml

*Indications:* acute and chronic hypertension (essential or renal); pre- or post-surgical hypertension, pre-eclampsia. As monotherapy or in combination with diuretics or β-adrenoreceptor blocking agents.*Contraindications:* concurrent treatment with antacids or H<sub>2</sub> antihistamines.*Precautions:* initial dose in patients with impaired liver function may not exceed 2 x 20 mg/day.*Adverse effects:* occasional vertigo, headache, fatigue, dry mouth.**loxoprofen**

Nonsteroidal anti-inflammatory agent

Loxonin®: Sankyo, Japan

tablet 60 mg

granules 100 mg/g

*Indications:* pain and inflammation in rheumatic disease.*Adverse effects, precautions* as usual for drugs of this class.**lenampicillin hydrochloride**

Penicillin antibiotic

Varacillin®: Kanebo, Japan

Takacillin®: MECT Corporation, Japan

tablets 250 mg

*Indications:* various infections including respiratory, urinary tract, skin and soft tissue, surgical, otolaryngological, ophthalmological and dental infections due to susceptible microorganisms.**levocarnitine**

Essential constituent of living tissues

Carnitene®: Sigma-Tau, Switzerland

tablet 330 mg

injection fluid 100, 200 mg/ml

*Indications:* myopathy due to carnitine deficiency; re-establishment of carnitine levels after dialysis.**lisuride**

Dopamine agonist

Dopergin®: Schering, Netherlands

tablet 0.5, 1 mg

*Indications:* inhibition of lactation, galactorrhoea, amenorrhoea, acromegaly, parkinsonism.*Contraindications:* severely impaired peripheral circulation, coronary insufficiency.**lobenzarit sodium**

Antirheumatic agent

Carfenil®: Chugai Pharmaceutical, Japan

tablet 40, 80 mg

Indication: rheumatoid arthritis.

**mesalazine**

Anti-inflammatory agent

Salofalk®: Falk, Switzerland

Salofalk®: Rowell Laboratories, Netherlands

enema 4 g/60 g

*Indications:* severe distal ulcerative colitis.*Contraindications:* impaired hepatic and renal function, gastroduodenal ulcer, bleeding diatheses, hypersensitivity to salicylates.**metipranolol**

β-adrenoreceptor blocking agent

Glausyn®: Mann Pharma, Denmark

eye drops 3, 6 mg/g

*Indication:* wide-angle glaucoma.

**micronomicin**

Broad spectrum aminoglycoside antibiotic

Sagamycin®: Kyowa Hakko Kogyo, Japan  
injection fluid 40, 80 mg/ml*Indication:* infection due to susceptible micro-organisms, in particular multiresistant strains.*Contraindications, precautions and warnings* as usual for drugs of this class.**minoxidil**

Vasodilator

Regaine®: Upjohn, Ireland  
topical solution 20 mg*Indication:* male-pattern baldness.*Caution:* Application under occlusion or on shaved or abraded skin may induce systemic effects through increased absorption.**nafamostat mesilate**

Enzyme inhibitor

Futhan®: Torii, Japan  
powder for injection 10 mg/ampoule*Indication:* acute symptoms of pancreatitis.*Adverse effects:* local reaction at the injection site.**nedocromil**

Antiasthmatic

Tilade®: Fisons, Ireland  
inhalation suspension 2 mg/dose*Indications:* reversible obstructive airways disease including bronchial asthma, asthmatic bronchitis, exercise-induced asthma, late onset asthma and bronchospasm.*Caution:* Not to be used in acute attack.*Adverse effects:* headache, nausea, unpleasant taste, local irritation.**nimodipine**

Calcium influx blocking agent

Nimotop®: Bayer, Switzerland  
injection fluid 0.2 mg/ml*Indications:* cerebral vasospasm following sub-arachnoidal bleeding.**nizatidine**H<sub>2</sub>-receptor blocking agentCalmaxid®: Lilly, Switzerland  
capsule 150, 300 mg*Indications:* gastrointestinal ulcer.**olsalazine sodium**

Anti-inflammatory agent

Dipentum®: Pharmacia, Switzerland  
capsule 250 mg*Indication:* ulcerative colitis.*Contraindication:* hypersensitivity to salicylates.*Caution:* Occasionally diarrhoea occurs. Safety not established during pregnancy and lactation.**pinaverium bromide**

Spasmolytic agent

Dicetel®: Triosol, Luxembourg  
tablet 25, 50 mg*Indication:* irritable colon.*Contraindication:* paralytic ileus.**piretanide**

Diuretic

Diumax®: Cusi, Spain  
tablet 6 mg*Indication:* oedema, hypertension.*Contraindications:* renal insufficiency with oliguria or anuria, severe electrolyte deficiency, hepatic precoma or coma.*Caution:* Not to be used in the first trimester of pregnancy or during lactation. It is excreted in the milk and may decrease milk production. Nephrotoxicity and ototoxicity of cephalosporin and aminoglycoside antibiotics may be potentiated.**pranoprofen**

Nonsteroidal anti-inflammatory agent with anti-pyretic activity

Niflan®: Yoshitomi, Japan  
capsule 75 mg*Indications:* pain and inflammation in rheumatic disease, upper airways inflammation, dental procedures, trauma.*Adverse effects, precautions* as usual for drugs of this class.**roxatidine**H<sub>2</sub>-receptor blocking agentAltat®: Teikoku Hormone, Japan  
capsule 75 mg*Indication:* gastroduodenal ulcer, Zollinger-Ellison syndrome, reflux oesophagitis, pre-anaesthetic medication to prevent aspiration pneumonia.**somatropin**

Synthetic human growth hormone

Humatrope®: Lilly, Sweden  
powder for injection 4 IU/ampoule*Indication:* pituitary dwarfism.*Caution:* in diabetes mellitus, malignant disease.

**somatrem**

Synthetic methionyl growth hormone (human)

Somatonorm®: Fides, Spain

powder for injection 4 IU/ampoule

*Indication:* short stature due to deficient growth hormone secretion.

*Contraindication:* diabetes mellitus.

**sufentanil**

Narcotic analgesic

Sufenta®: Janssen, Austria

injection fluid 0.05 mg/ml

*Indication:* induction and maintenance of anaesthesia in extensive surgery.

*Caution:* safety during pregnancy and lactation has not been established. Obstetric use should be avoided because sufentanil passes the placenta and may cause respiratory depression in the neonate.

**thymopentine**

Synthetic pentapeptide

Immunox®: Cilag, Luxembourg

injection fluid 10, 100 mg/ml

*Indications:* Di George syndrome (absence or immaturity of the thymus gland), severe herpes labialis or genitalis not responding to other antiviral agents.

*Contraindications:* hereditary hyper-IgE syndrome.

*Caution:* Local skin reactions may occur. Leukocyte count should be monitored.

**tizanidine**

Central muscle relaxant

Sirdalud®: Sandoz, Finland

tablet 2, 4, 6 mg

*Indications:* painful muscle spasms, spasticity due to neurological disorders.

**trazodone**

Antidepressant

Molipaxin®: Roussel, Ireland

tablet 150 mg

*Indication:* anxiety, depression.

*Warnings:* Use in children is not recommended.

Safety of use during pregnancy and lactation has not been established. Ability to drive or operate machinery may be impaired.

*Caution:* in patients with renal or hepatic dysfunction and in epileptic patients.

**trimazosin**

Vasodilator

Cardiovar®: Pfizer, Ireland

tablet 50, 100, 150 mg

*Indication:* hypertension, moderate to severe congestive cardiac failure unresponsive to other measures, under direct medical supervision in the hospital.

*Contraindication:* hypersensitivity.

*Caution:* Experience of use in children under 12 years of age is insufficient. Renal impairment may necessitate dose adaptation. A concomitantly given thiazide diuretic may potentiate the hypertensive effect.

**triptorelin**

Synthetic luteotropic hormone releasing factor

Decapeptyl®: Ferring, Switzerland

micro-encapsulated powder for injection

3.75 mg/ampoule

*Indication:* advanced hormone dependent prostatic cancer.

*Contraindications:* proven non-hormone dependent carcinoma; after surgical castration.

*Caution:* Initial exacerbation of symptoms may occur.

**zidovudine (1)**

Antiviral agent

Retrovir®: Wellcome, Netherlands

infusion fluid (concentrate) 200 mg/10 ml

capsule 100 mg

*Indication:* short-term treatment of AIDS and AIDS-related complex.

*Contraindications:* hypersensitivity, neutropenia, anaemia.

*Caution:* Only to be administered by experienced specialists.

**zidovudine (2)**

Antiviral agent

Retrovir®: Wellcome, Sweden, Switzerland

capsules 100, 250 mg

*Indication:* severe manifestations of infection with HIV virus.