

# Pharmaceutical Products Approved

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## **Aclarubicin** (cytostatic)

Jaclacin®, Lundbeck, Iceland, Sweden.  
powder for injection 20 mg/ampoule.

*Indications:* acute nonlymphoblastic leukaemia, recurrent or unresponsive to other therapy.

*Contraindications, precautions, warnings:* as for other cytostatic compounds.

## **Amfenac** (nonsteroidal anti-inflammatory agent)

Fenazox®, Meiji Seika Kaisha, Japan.  
capsule 50 mg.

*Indications:* pain in arthritic disease and after surgical or dental procedures.

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

## **Arotinolol** ( $\beta$ -adrenoreceptor blocking agent)

Almarl®, Sumitomo, Japan.  
tablets 5 and 10 mg.

*Indications:* mild to moderate essential hypertension, angina pectoris, tachycardia.

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

## **Brovincamine** (vasodilator)

Sarbromin®, Sandoz, Japan.  
tablet 20 mg.

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

*Contraindications:* acute phase of cerebral infarction or haemorrhage; pregnancy (teratogenic at high dosage in rabbits); hypersensitivity.

*Caution:* patients with hepatic insufficiency, hypotension.

*Adverse effects:* somnolence, tinnitus, vertigo, gastrointestinal distress.

## **Cloconazole** (antimycotic)

Pilzcin®, Shionogi, Japan.  
cream, gel 10 mg/g.

*Indications:* dermatomycoses.

*Contraindications:* hypersensitivity.

*Caution:* not to be applied to the cornea, conjunctiva or open skin.

*Adverse effects:* local irritation.

## **Cloperastine** (antihistamine)

Novotusil®, Inpharzam, Luxembourg.  
syrup 2 mg/ml.

*Indications:* symptomatic treatment of cough.

## **Enoxacin** (antibiotic)

Flumark®, Dainippon, Japan.  
tablet 100 and 200 mg.

*Indications:* infection caused by susceptible microorganisms.

*Contraindications:* hypersensitivity, pregnancy, lactation.

*Caution:* in patients with severe renal dysfunction or convulsive disorders.

## **Famotidine** ( $H_2$ -receptor blocking agent)

Pepcidin®, MSD, Iceland, Sweden.  
tablets 20 and 40 mg;

powder for injection 40 mg/ampoule.

*Indication:* gastroduodenal ulcer.

## **Fomoterol** ( $\beta$ -adrenoreceptor agonist)

Atock®, Yamanouchi, Japan.  
tablets 20 and 40  $\mu$ g.

*Indication:* obstructive airway disease.

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

**Gemeprost** (prostaglandin derivative)

Cervagem®, Rhone-Poulenc, Finland.  
tablet 1 mg.

*Indication:* termination of pregnancy.

**Gestrinone** (progesterone antagonist)

Nemestran®, Roussel, Netherlands  
capsule 2,5 mg.

*Indications:* severe endometriosis, infertility due to laporoscopically confirmed endometriosis.

*Contraindications:* pregnancy, epilepsy, severe cardiac, hepatic and renal insufficiency.

*Caution:* migraine. Effective contraceptive measures must be instituted throughout treatment.

**Mesalazine** (anti-inflammatory agent)

Salofalk®, Falk, Netherlands.  
suppositories 500 mg;

Asacol®, Cedona, Netherlands.  
tablet 400 mg.

Claversal®, S. K. & F., Luxembourg.

*Indications:* ulcerative colitis, Crohn's disease.

**Moxisylyte** (vasodilator)

Moxyl®, Fujirebio, Japan.  
tablet 30 mg.

*Indications:* symptomatic management of sequelae of cerebral infarction or haemorrhage.

*Contraindications:* acute phase of cerebral infarction or haemorrhage; hepatic insufficiency.

*Caution:* hypotension, recent angina pectoris or myocardial infarction. Safety during pregnancy and lactation not established

**Nifuroxazide** (intestinal disinfectant)

Bacifurane®, Meram, Luxembourg.  
capsule 200 mg.

*Indications:* diarrhoea of bacterial origin, secondary infection in inflammatory colonic conditions.

*Adverse effects:* cutaneous or anaphylactic reactions.

**Ofloxacin** (quinolone antibiotic)

Tarivid®, Hoechst, Luxembourg, Austria, Japan.  
coated tablet 100 mg.

*Indications:* infection caused by susceptible micro-organisms.

**Somatorelin** (synthetic growth hormone releasing factor)

GHRH-Labaz®, Labaz, Luxembourg.  
powder for injection 0.08 mg/ampoule.

*Indications:* diagnosis and treatment of deficient pituitary growth hormone secretion.

**Somatrem** (methionyl growth hormone)

Somatonorm®, KabiVitrum, Ireland.  
Genotropin®, KabiVitrum, Sweden.

Humatrope®, Lilly, Sweden.  
injection 4 IU/ampoule.

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

*Caution:* diabetes mellitus.

**Thymostimulin** (synthetic thymostimulin analogue)

TP-1®, Serono, Luxembourg.  
powder for injection 10, 25, 50 mg/ampoule.

*Indications:* primary or secondary immune deficiency with a proven or suspected cellular component.

**Tilactase** (enzyme preparation)

Millact®, Shionogi, Japan.  
granules 0,5 mg/g.

*Indications:* lactose intolerance in infants, and older patients requiring parenteral nutrition or a fluid diet.

*Caution:* patients with a familial history of urticaria, bronchial asthma, hypersensitivity.

*Adverse effects:* rarely, shock and gastrointestinal symptoms.

**Tofisopam (benzodiazepine tranquillizer)**

Grandaxim®, Mochida, Japan.

*Indications:* psychosomatic symptoms such as headache, fatigue, tachycardia, sweating.

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

**Trilostane (inhibitor of corticosteroid synthesis)**

Desopam®, Mochida, Japan.

tablet 60 mg.

*Indication:* hypersecretion of aldosterone and cortisol.

*Caution:* renal or hepatic disease, adrenocortical insufficiency. Not to be administered during pregnancy.

*Adverse effects:* raised serum transaminases, hypersensitivity.

**Trimebutine (antispasmodic agent)**

Debridat®, Croma-Pharma, Austria.

tablet 100 mg.

*Indication:* irritable colon.

*Contraindications:* hypersensitivity, pregnancy, lactation.

**Vindesine (cytostatic)**

Fildesine®, Shionugi, Japan.

powder for injection 1 and 3 mg/ampoule.

Eldesine®, Lilly Iceland.

powder for injection 5 mg/ampoule.

*Indications:* pulmonary carcinoma, malignant melanoma, non-Hodgkin lymphoma, acute lymphatic leukaemia in children.

**Zidovudine (antiviral)**

Retrovir®, Wellcome, France, Luxembourg, Ireland, Norway.

capsules 100 and 250 mg.

powder for inject. 200 mg/ampoule (Ireland only).

*Indication:* severe manifestations of HIV infection.

*Contraindications:* hypersensitivity, severe blood dyscrasia, pregnancy, lactation.

*Caution:* combination with paracetamol (increased incidence of neutropenia), probenecid (diminished excretion of zidovudine) and potentially nephrotoxic or myelotoxic compounds must be avoided.

*Adverse effects:* anaemia, neutropenia, leucopenia, nausea, headache, rash, abdominal pain, fever, myalgia, paraesthesiae, vomiting, anorexia.