

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Siprox

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ciprofloxacin hydrochloride 250 mg or 500 mg.

For excipients see 6.1

3. PHARMACEUTICAL FORM

Tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Infections caused by sensitive bacteria, such as urinary tract infections, gastro-intestinal infections (e.g. salmonella), bone infections, gonorrhoea and prostatic infections.

4.2 Posology and method of administration

Dosage for adults:

Urinary tract infections: 100-250 mg two or three times daily.

Gonorrhoea: A single dose of 250 mg.

Gastro-intestinal infections: 500 mg two or three times daily.

Bone infections: 750 mg two or three times daily.

Dosage for children:

The drug is not recommended for children.

4.3 Contra-indications

Hypersensitivity to ciprofloxacin and related compounds such as nalidixic acid and quinolones. Pregnancy and lactation.

4.4 Special warnings and precautions for use.

The drug should not be administered to growing children because of risk of damage to cartilage caused by the drug. The drug should also be administered with caution in patients with a lowered seizure threshold. Caution should be exercised in patients with impaired renal and hepatic function. Exposure to strong sunlight or sunlamps should be avoided during the treatment period.

If patients feel pain or inflammation of tendons, or even rupture, they should stop the treatment immediately, rest the affected area and avoid movement as much as possible because of risk of tendon damage or rupture.

4.5 Interactions with other medicinal products and other forms of interactions

The drug inhibits the metabolism of theophylline and related drugs and hence increases their plasma concentrations. If concomitant use of the drugs is necessary, the plasma concentration of theophylline should be closely monitored. Antacids containing magnesium or aluminium compounds can reduce the absorption of ciprofloxacin. Ciprofloxacin increases the effects of anticoagulants. Probenecid delays the excretion of the drug. Concurrent administration of minerals such as calcium, bivalent iron or zinc ions should be avoided as they inhibit the absorption of ciprofloxacin by 30-50%.

4.6 Pregnancy and lactation

The drug should not be administered during pregnancy. The drug is secreted to breast milk and may affect a breast fed child.

4.7 Effects on ability to drive and use machines

The drug could possible effect individual patients ability to drive and use machines. (See section regarding side effects).

4.8 Undesirable effects

The frequency of side effects is dose related.

Common (>1%):

Gastro-intestinal system: Nausea, vomiting, diarrhoea.

Metabolic: Elevation of liver enzymes (reversible).

Uncommon: (0,1-1%):

General: Fatigue, headache, dizziness, fever.

Haematology: Eosinophilia, leucopenia, thrombocytopenia, pancytopenia, anaemia.

Cardiovascular system: Tachycardia.

Central nervous system: Agitation.

Gastro-intestinal system: Abdominal pain, dyspepsia.

Skin: Rash.

Metabolic: Transient elevation of metabolites such as creatinine, haemoglobin, urea and alkaline phosphates.

Musculoskeletal: Arthralgia, arthritis.

Rare: (<0,1%):

General: Acute hypersensitivity.

Haematology: Haemolytic anaemia, increased number of white blood cells, thrombocytopenia.

Central nervous system: Seizures, confusion, psychotic reactions, hallucinations, sleep disorders, depression, paraesthesia, disturbed vision (diplopia) impairment of hearing (particularly at high frequencies), tinnitus, restlessness, impaired taste and smell, symptoms of intracranial hypertension.

Gastrointestinal system: Pseudomembraneous colitis.

Skin: Lyell's syndrome, Stevens-Johnson syndrome, erythema nodosum, vasculitis, erythema multiform (mild).

Liver: Hepatitis, cholestatic jaundice.

Musculoskeletal: Myalgia, tenosynovitis.

Urinary tract: Crystalluria occurs if the urine is alkaline. Haematuria, acute renal failure, interstitial nephritis.

Other: Increased photosensitivity.

4.9 Overdose

In case of overdose, the patient must be examined thoroughly and receive appropriate treatment. The patient should be kept well hydrated. Only a small portion of ciprofloxacin (10%) is excreted from the body by haemodialysis or peritoneal dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC group: J 01 M A 02

Ciprofloxacin is a broad spectrum antibiotic of the quinolone group. The mode of action is not fully known but the drug inhibits DNA-gyrase, which is necessary for bacterial cell division. The drug is active against many species of bacteria, including Gram-negative rods (including pseudomonas aeruginosa, Moraxella catarrhalis). The drug has limited effects on various Gram-positive bacteria, for example pneumococci. The activity against anaerobes is uncertain. Very effective against Neisseria gonorrhoea.

5.2 Pharmacokinetic properties

The bioavailability of the drug is 70-80% after oral administration. Peak plasma concentration is obtained after 2 hours and the plasma half-life is about 4 hours. Approximately 50% of the drug is excreted unchanged in the urine and the rest as metabolites in the urine, bile and faeces.

5.3 Preclinical safety data

No data of relevance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose.
Crospovidone
Anhydrous colloidal silicone
Magnesium stearate
Methylhydroxypropyl cellulose (Hypromellose)
Macrogol 400
Titanium dioxide (E171)

6.2 Incompatibilities

None reported

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Room temperature.

6.5 Nature and contents of container

Plastic bottles:

Siprox 250 mg: 10 tablets and 20 tablets.

Siprox 500 mg: 10 tablets and 20 tablets.

6.6 Instructions for use and handling (and disposal)

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Actavis hf.

Reykjavíkurvegi 76-78

220 Hafnarfjörður

Iceland

8 MARKETING AUTHORISATION NUMBER

Siprox 250 mg: MTnr 910042 (IS)

Siprox 500 mg: MTnr 920264 (IS)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Siprox 250 mg: 01.10.1992, renewal 25.10.2000

Siprox 500 mg: 01.01.1994, renewal 25.10.2000

10 DATE OF REVISION OF THE TEXT

July 13th 2004