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98

SUPERFLOX®

250 mg, 500 mg, 750 mg
Ciprofloxacin
ORAL TABLETS

COMPOSITION

SUPERFLOX® 250
Ciprofloxacin (HCl) Monohydrate equivalent to ciprofloxacin base 250 mg. Excipient: q.s.

SUPERFLOX® 500
Ciprofloxacin (HCl) Monohydrate equivalent to ciprofloxacin base 500 mg. Excipient: q.s.

SUPERFLOX® 750
Ciprofloxacin (HCl) Monohydrate equivalent to ciprofloxacin base 500 mg. Excipient: q.s.

PHARMACOLOGICAL ACTION

Ciprofloxacin is a fluoroquinolone derivative antibacterial agent. There is no cross-resistance between Ciprofloxacin and penicillins, cephalosporins, tetracyclines and aminoglycosids. In general, organisms resistant to these antibiotics are sensitive to Ciprofloxacin. It has been shown that additive effects appear when Ciprofloxacin is given concomitantly with other antibacterial agents.

INDICATIONS

- **Respiratory tract infections:** Acute bronchitis, exacerbation of chronic bronchitis and cystic fibrosis, bronchiectasia, empyema.
- **ORL infections:** Infection of the middle ear, sinuses and eye infections.
- **Genitourinary infections:** Complicated and uncomplicated urethritis, cystitis, pyelonephritis, prostatitis, epididymitis, gonorrhea.
- **Gastrointestinal infections:** Enteric fever, infectious diarrhea and biliary tract infections.
- **Bone and joint infections:** Osseous infections, septic arthritis.
- **Skin and skin structure infections:** Infected ulcers, infected burns.
- **Others:** Septicemia and infections in cases of reduced host defense.

DOSAGE

Doses prescribed by the physician should not be modified or interrupted. The determination of dosage for any particular patient must take into consideration the severity and nature of the infection, the susceptibility of the causative organism, the age, weight and the status of renal function.

Adults:

- Urinary tract infections:
250-500 mg every 12 hours, according to the severity of the infection.

- Respiratory tract infections, bone and joint infections and skin structure infections:
500 mg every 12 hours. For more severe infections, a dosage of 750 mg may be given every 12 hours.

- Altered renal function:
Dosage adjustment is usually not required, except in those patients suffering from severe renal alteration.

Adolescents and children:

Ciprofloxacin may cause alterations in weight bearing joints in immature animals. Although no relationship with man is known, for safety reasons it is recommended not to administer to children or adolescents during growth. However, where the benefit of Ciprofloxacin therapy is considered to outweigh the potential risk (for instance, in cystic fibrosis) the oral dosage should be 7.5-15 mg/kg daily, depending on the severity of the infection and the patient body weight, administered every 12 hours.

The duration of treatment depends upon the severity of infection. The usual duration of therapy is 7 to 14 days, and generally Ciprofloxacin should be continued for 2 days after the signs and symptoms of infection have disappeared.
Bone and joint infections may require treatment for 4 to 6 weeks or longer.
The recommended dosage for infectious Diarrhea is 500 mg every 12 hours from 5 to 7 days.

DIRECTIONS FOR USE

Patients should be advised to take tablets entire with abundant fluids, preferably 2 hours after meals.

CONTRAINDICATIONS

A history of hypersensitivity to Ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of SUPERFLOX®. It is also contraindicated in children, unless when the potential benefits justifies the potential risk.

PRECAUTIONS

Due to the possible appearance of side-effects related to central nervous system, SUPERFLOX® should be only given when the expected benefits outweigh the potential risk. This precaution will be applied to patients with known epileptic crisis or with a history of central nervous system disturbances (such as low convulsive umbral, convulsive disturbances clinical history, reduced cerebral irrigation, cerebral organic alteration or cerebral vascular accident).

Crystalluria related to Ciprofloxacin has been reported only rarely. Patients receiving Ciprofloxacin should be well hydrated and should be advised to drink fluids liberally. Alkalinity of the urine should be avoided.

Use during pregnancy and lactation:

Ciprofloxacin should not be administered during pregnancy or lactation. Therefore, the possible administration to these patients will be appraised and established by the physician.

WARNINGS

SUPERFLOX® administration may alter the capacity to drive or operate machinery. This alteration is increased by alcoholic beverages when taking this product.

INTERACTIONS

This medicament may influence the action of other simultaneously administered drugs, specially theophylline or cyclosporin, so you should advise your physician when undergoing such therapy. It is recommended not to administer SUPERFLOX® within 1-2 hours after taking antiacids containing magnesium hydroxide or aluminium hydroxide since they substantially interfere with the absorption of Ciprofloxacin.

SIDE-EFFECTS

Occasionally, the following adverse effects have been observed:

- **Gastrointestinal disorders:** nausea, vomiting, abdominal pain, diarrhea.
- **Central nervous system alterations:** vertigo, headache, fatigue, insomnia, restlessness, tremor.
- **Hypersensitivity reactions:** cutaneous eruptions and on very rare occasions, muscular and articular pain.

If these reactions occur, you should inform your physician immediately.

OVERDOSAGE

In case of accidental ingestion or overdosage you should immediately inform your physician, indicating the quantity of ingested product.

HOW SUPPLIED

SUPERFLOX® 250: Packages of 10 tablets of 250 mg.
SUPERFLOX® 500: Packages of 10 tablets of 500 mg.
SUPERFLOX® 750: Packages of 10 tablets of 750 mg.

UNDER MEDICAL PRESCRIPTION ONLY

DRUGS SHOULD BE KEPT OUT OF CHILDREN'S REACH

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