SEPCEN 500 mg. ox

CIPROFLOXACIN

Oral - Tablets

COMPOSITION

Each tablet contains:

Ciprofloxacin (clorhydrate monohydrate) 500 mg.

Inactive ingredients:

Corn starch, Primojel, Microcrystalline Cellulose, Precipitated Silica, Magnesium stearate, Hydroxypropyl methyl cellulose, Hydroxypropyl cellulose, Titanium dioxide.

HOW SUPPEIED

Packages of 10 and 20 tablets containing 500 mg of Ciprofloxacin.

PROPERTIES

Ciprofloxacin is a broad spectrum antimicrobial agent with rapid effect, that does not cross react with other antimicrobial agents such as penicillin ,cephalosporin, tetracycline and aminoglycoside. Generally organisms resistant to these drugs may be susceptible to Ciprofloxacin. Ciprofloxacin has shown additive effect when it is combined with other antibacterial agents.

HOLDER AND MANUFACTURER

Laboratories CENTRUM S.A. (A.S.A.C. Pharma)

C/ Sagitario,14 ALICANTE (Spain)

INDICATIONS

Respiratory tract infections: acute bronchitis, re-acute of chronic bronchitis and cystic fibrosis, bronchiestasis,empyema

Genital-urinary tract infections: complicate and no complicate, urethritis, cystitis, pyelonephritis, prostatitis, epidymitis, gonorrhoea.

Gastric intestinal infections: enteric fever, infectious diarrhoea

Bone and joint infections: osteomyelitis, septic arthritis

Skin and skin structure infections: infected ulcers, infected burns

CONTRAINDICATIONS

Ciprofloxacin is contraindicated in person with a history of hypersensitivity to it or any member of the quinolones class, as paediatric patients (less than 18 years of age) children except when potential benefit justifies potential risk.

PRECAUTIONS

Due to the possible side effects related with Central Nervous System, Ciprofloxacin will be only used in those cases where potential benefit justifies potential risk.

This precaution will be applied in patients with a history of epileptic crisis or with known Central Nervous System disorders (such as low seizure threshold, clinical history of convulsive disorders, insufficient cerebral blood flow, organic cerebral alteration ,or cerebral vascular accident).

Crystalluria related to Ciprofloxacin has been reported only rarely in humans. Patients should be well hydrated to prevent the formation of highly concentrated urine. Alkalinity of the urine should be avoided in patients receiving Ciprofloxacin.

INTERACTIONS

This medicament could have influence with other concurrent drug administration, especially teophylline or ciclosporin, so it must be communicated to the physician, if is in the treatment with any of them.

It is not recommended its administration in the period of 1-2 hours after the administration of antacids containing magnesium and /or aluminium hydroxide, as they may substantially interfere with absorption of Ciprofloxacin.

WARNINGS

Use in pregnant and lactating women. It is not recommended its use neither during the pregnancy nor during lactation ,therefore the possible use of this drug in these periods will be stabilised by the physician.

The administration of Ciprofloxacin could alter the capability of driving vehicles or manage machines .This alteration increase with the concomitant ingestion of alcohol.

DOSAGE

The doses prescript by the physician must not or discontinued. The dosage of Ciprofloxacin is determined by the seriousness and kind of infection, the sensitivity of the organisms responsible and also for the age ,weight ,kidney function of the patient.

Adults: urinary tract infections, 250 -500 mg. Every 12 h., it depends the seriousness of the infection; respiratory tract infections, bone and joint, skin and skin structure infections 500 mg every 12 h. ;for more severe or complicated infections, a dosage of 750 mg. may be given every 12 h. Alteration of dosage regimen is not normally necessary for patients with impairment of renal function.

Teenagers and children: Ciprofloxacin may cause alterations in the weight bearing joints in immature animals. Although it does not know its relation with humans it is not recommended to use in children and teenagers who are growing. However, when potential benefit justifies potential risk (ex. Fibrosis cystic) the dose to use could be 7,5-15 mg/kg/ day depending of the seriousness of the infection and patient 's weight every 12 h.

The duration of the treatment depends of the seriousness of the infection. It could be generally from 7 to 14 days and it must be maintained at least two days after the symptoms have completely disappeared.

In case of bone and joint infections the therapy could be extended until 4 or 6 weeks.

The usual treatment for infectious diarrhoea is 500 mg every 12 h. for 5 or 7 days.

ADMINISTRATION FORM

The tablets must be taken as a whole, drinking fluids liberally and preferably two hours after a meal.

OVERDOSAGE

The accidental ingestion of this medicament or the overdose must be immediately communicated to the physician, explaining the quantity of product taken.

For further information, consult your local Toxicological Information Service

SIDE EFFECTS

It has occasionally observed the following side effects.

Gastrointestinal disturbances: nauseous, vomiting, abdominal pain, diarrhoea.

Central Nervous System Álterations: vertigo, migraine, tiredness, insomnia, agitation, and tremor

Hyper sensitivity reactions: skin rash, and rarely muscular articulate pain.

At any of the previous cases the physician must be immediately informed.

If it is observed any other side effect, non described before, consult to the physician or pharmacist.

EXPIRATION DATE

This product must not be used beyond the expiration date that appears in the packaging.

OTHER FORMATS

SEPCEN 250 mg 10 tablets
SEPCEN 250 mg 20 tablets
SEPCEN 500 mg 10 tablets
SEPCEN 500 mg 20 tablets
SEPCEN 750 mg 10 tablets

WITH DOCTOR'S PRESCRIPTION

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

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