ORELOX® 100 mg

cefpodoxime

Film-coated tablet

sanofi aventis

IDENTIFICATION OF THE MEDICINAL PRODUCT

Composition
Cefpodoxime proxetil.....130.45 mg
quantity equivalent to cefpodoxime.....100.00 mg
Excipients: magnesium stearate, carboxymethylcellulose calcium, hydroxypropylcellulose, sodium laurylsulfate, lactose, titanium dioxide, talc, hydroxypropylmethylcellulose for one film-coated tablet.

Pharmaceutical form
Film-coated tablet. (Box of 10).

Pharmaco-therapeutic class
This medicinal product is an antibacterial antibiotic belonging to the betalactam antibiotic group.

Marketing company
sanofi-aventis france
1-13, boulevard Romain Rolland
75014 Paris - France

Manufacturer
Sanofi Winthrop Industrie
56, route de Choisy-au-Bac
60205 Compiègne - France

WHEN SHOULD THIS MEDICINAL PRODUCT BE USED

This medicinal product is indicated in adults for the treatment of certain bacterial infections with sensitive germs.

BE CAREFUL !

When should this medicinal product not be used
This medicinal product SHOULD NOT BE USED in the event of known allergy to antibiotics belonging to cephalosporin group.

IN CASE OF DOUBT, YOU MUST CONSULT YOUR PHYSICIAN OR PHARMACIST.

Special warnings
- Any allergic symptoms (skin rash, itching, ...) during treatment should be immediately reported to your doctor.
- There is a possibility of allergy (5 to 10% of cases) in subjects who are allergic to penicillins.
- Tell your doctor about any allergy or allergic symptoms which have occurred during treatment with penicillin antibiotics.
- A diarrhoea occuring during a treatment with antibiotic should not be treated without medical advice.
- Because of the presence of lactose this medicinal product should not be used in case of galactosemia, glucose and galactose malabsorption syndrome or in case of lactase deficiency (rare metabolic diseases).

Precautions for use
- Because of the need to adapt the treatment, it is important to inform your physician of any kidney disease.
- This medicinal product can cause a wrong positive reaction of certain laboratory analysis (glucose research in the urine, Coombs' test).

KEEP OUT OF THE REACH OF CHILDREN

IN CASE OF DOUBT, DO NOT HESITATE TO ASK FOR THE ADVICE OF YOUR PHYSICIAN OR PHARMACIST.

Interactions with other medicinal products and other interactions
IN ORDER TO AVOID POSSIBLE INTERACTIONS WITH OTHER MEDICINAL PRODUCTS, YOU MUST ALWAYS INFORM YOUR PHYSICIAN OR PHARMACIST ABOUT ANY OTHER CURRENT TREATMENT.

Pregnancy - lactation
Pregnancy :
This medicinal product will be used during pregnancy only on the advice of your physician.
If you discover that you are pregnant during the treatment, consult your physician as he is the only one to know if you can follow up the treatment.

Lactation :
Lactation is possible in case of treatment with this medicinal product.
However, if digestive disorders (diarrhoea, candidosis) or skin rash appear in your child, stop lactation or to take this medicinal product and consult rapidly your physician.

AS A GENERAL RULE, YOU MUST ALWAYS ASK FOR THE ADVICE OF YOUR PHYSICIAN OR PHARMACIST BEFORE TAKING ANY MEDICINAL PRODUCT DURING PREGNANCY AND LACTATION.

Driving vehicles and operating machinery
If you are experiencing dizziness after having taken this medicinal product, you should not drive vehicles or operate machinery.

List of excipients which must be known to allow a safe use in some patients
Lactose.

HOW TO USE THIS MEDICINAL PRODUCT

Dosage
The dosage varies depending on therapeutic indication.
For information only, the usual dosage is 200 to 400 mg per day.
The posology must be fitted in case of renal failure.

IN ALL CASES, STRICTLY FOLLOW YOUR PHYSICIAN'S PRESCRIPTION.

Mode and route of administartion
Oral use.

Frequency and time of administration
Two intakes daily during meals.

Treatment duration
To be effective, this antibiotic must be taken regularly at the doses prescribed and for as long as your physician has advised.

The disappearance of fever or any other symptoms does not mean that you are completely cured. Any sensations of fatigue are not due to the antibiotic therapy but to the infection itself. Reducing or suspending your treatment will have no effect on these sensations and will only delay your recovery.
Specific case : the duration of treatment for certain sinusitis and for certain tonsillitis is of 5 days.

Action to be taken in case of overdosage
ALERT YOUR DOCTOR IMMEDIATELY.

UNWANTED AND UNPLEASANT EFFECTS

Essentially :
- digestive symptoms : diarrhoea, nausea, vomiting, belly aches.

More rarely :
- digestive symptoms : as with other broad spectrum antibiotics, rare cases of enterocolitis (intestine inflammation) with bloody diarrhoea and of pseudomembranous colitis (disease of the large intestine characterized by the evacuation of false membranes or mucus, accompanied by constipation and belly aches) have been reported,
- slight increase in liver enzyme levels,
- allergic symptoms : cutaneous eruption, itching, rash, angioneurotic oedema, (abrupt face and neck swelling of allergic origin) and allergic shock,
- cutaneous events : varied eruptions, localised bullous eruption, multiform erythema (disease with cutaneous erythema), Stevens-Johnson's syndrome and Lyell's syndrome (detachment of the skin which can quickly and seriously spread over the body),
- headaches,
- feeling of dizziness,
- slight increase in urea and creatinine levels in blood,
- hematological events : decrease or increase in rate of platelets and in white blood cells, significant but exceptional fall in number of certain white blood cells (granulocyte).

REPORT TO YOUR PHYSICIAN OR YOUR PHARMACIST ANY UNWANTED AND UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT USE LATER THAN THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.

SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C.

DATE OF LEAFLET REVISION

July 2008.