Zeefra 500 mg

Cephradine (INN)

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

a) NAME : Zeefra 500 mg.

b) QUALITATIVE AND QUANTITATIVE COMPOSITION

Cefradine ..... 500 mg

Excipients : talc, magnesium stearate, lactose.

Capsule shell : gelatin, indigotine, titanium dioxide, erythrosine, yellow ferric oxide.

c) PHARMACEUTICAL FORM : 12 capsules.

d) PHARMACO-THERAPEUTIC CLASS : Beta-lactam antibacterial antibiotics of the first-generation cephalosporin group.

(J : anti-infective agent).

e) NAME AND ADDRESS OF MARKETING AUTHORISATION HOLDER : Laboratoires DOMS-ADRIAN - 4, rue Ficatier - 92400 COURBEVOIE - FRANCE.

NAME AND ADDRESS OF THE MANUFACTURER : Laboratoires MACORS - Z.I. La Plaine des Isles Rue des Caillottes - 89000 AUXERRE - FRANCE

2. WHEN TO USE THIS MEDICINE (THERAPEUTIC INDICATIONS)

This medicine is suitable for the treatment of certain infections caused by sensistive bacteria.

3. WARNING !

a) WHEN NOT TO USE THIS MEDICINE (CONTRA-INDICATIONS) : – This medicine MUST NOT BE USED if you are allergic to cephalosporin antibiotics, – In child below 6 years, because of the pharmaceutical form. *IF IN DOUBT, ASK YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE.*

b) SPECIAL WARNINGS : Tell your doctor immediately if you experience any allergic reaction (skin rash, itching, etc.) while taking this treatment.

Before beginning this treatment, tell your doctor if you have ever experienced an allergic reaction with antibiotics in the past : urticaria or other skin rashes, itching, angioneurotic œdema (a type of urticaria with rapid swelling on the face and neck).

c) PRECAUTIONS FOR USE : TELL YOUR DOCTOR if any of the following apply : – renal insufficiency, – previous history of allergy, particularly to antibiotics. *IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE.*

d) INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION : *YOU MUST TELL YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING ANY OTHER TREATMENTS IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN DIFFERENT MEDICINES.*

e) PREGNANCY AND LACTATION : This medicine may be taken during pregnancy if required. Breast-feeding is possible while taking this medicine. If the infant presents disorders such as diarrhoea, skin rash, thrush (a condition caused by certain microscopic fungi), immediately tell your doctor who will recommend the course of action to be taken, as these effects may be due to this medicine. AS A GENERAL RULE, IT IS ALWAYS ADVISABLE TO CONSULT YOUR DOCTOR OR PHARMACIST BEFORE USING A MEDICINE WHEN PREGNANT OR BREAST-FEEDING.

4. HOW TO USE THIS MEDICINE

a) DOSAGE : As a reference, the usual dosage is as follows : • adults : 2 g per day, • children over 6 years: 50 to 100 mg/kg per day. The dosage should be modified for patients with renal insufficiency.

b) METHOD AND ROUTE OF ADMINISTRATION : Oral route. The capsules should be swallowed with half a glass of water.

c) WHEN AND HOW OFTEN TO TAKE YOUR MEDICINE : To be taken with meals.

d) DURATION OF TREATMENT : For this antibiotic to be effective, it must be taken regularly at the prescribed doses for as long as your doctor advises.

The disappearance of fever or any other symptom does not mean that you are completely cured. Any feeling of tiredness that you may experience is not caused by the treatment but by the infection itself. Reducing or stopping your treatment would have no effect on this feeling but would slow down your recovery.

e) WHAT TO DO IF YOU TAKE TOO MUCH OF YOUR MEDICINE : Tell you doctor immediately.

f) WHAT TO DO IF YOU FORGET TO TAKE ONE OR MORE DOSES OF YOUR MEDICINE : Tell your doctor.

5. UNDESIRABLE AND UNPLEASANT EFFECTS (ADVERSE EFFECTS)

AS WITH ALL ACTIVE PRODUCTS, THIS MEDICINE CAN CAUSE UNPLEASANT EFFECTS OF VARYING SEVERITY IN SOME PEOPLE : – Gastrointestinal effects : nausea, vomiting, diarrhoea, constipation, abdominal pains, – Allergic reactions : pruritis (itching), skin rashes, urticaria (skin rashes identical to those caused by nettle stings), – Haematological effects : eosinophilia, thrombocythaemia (increased amonts of certain components of the blood), – Transient increase in the level of certain liver enzymes in the blood (transaminases), – Effects on the kidneys, particularly when taken in association with aminoglycosides (antibiotics) or diuretics.

TELL YOU DOCTOR IF YOU EXPERIENCE ANY UNWANTED OR UNPLEASANT EFFECTS WHICH ARE NOT MENTIONED IN THIS LEAFLET.

6. STORAGE

DO NOT USE AFTER THE EXPIRY DATE PRINTED ON THE BOX.

7. DATE OF LAST REVISION OF THE LEAFLET : October 1998

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