PATIENT INFORMATION LEAFLET

PAROTICIN

EA. SOL.
(FLUDROCORTISONE ACETATE,
POLYMYXIN B SULFATE, LIDOCAINE HCl)

1. DEFINITION OF THE PHARMACEUTICAL PRODUCT

1.1 PRODUCT NAME

Paroticin

1.2 COMPOSITION

Active ingredients: Fludrocortisone Acetate, Polymyxin B Sulfate, Lidocaine Hydrochloride
Excipients: Acetic acid, Propylene glycol, Distilled water

1.3 PHARMECEUTICAL FORM

Ear drops, solution

1.4 ACTIVE INGREDIENTS CONTENT

Each ml of the solution contains:

- Fludrocortisone Acetate 1mg
- Polymyxin B Sulfate 1.30 mg (equivalent to Polymyxin B 10,000 I.U.)
- Lidocaine HCl 50 mg

1.5 DESCRIPTION-PACKAGING

PAROTICIN ear drops, solution is a clear, slightly yellowish liquid of characteristic odour, contained in a plastic bottle of 10ml.

1.6 PHARMACOTHERAPEUTICAL CATEGORY

Fludrocortisone and antiinfectives

1.7 MARKETING AUTHORIZATION HOLDER-MANUFACTURER

ADELCO – CHROMATOURGIA ATHINON E. COLOCOTRONIS BROS S.A.,
37 PIREOS STR., 183 46 MOSCHATO, ATHENS-GREECE
TEL.: (0030) 210 4819 311- 4, FAX: (0030) 210 4816790

1.8 EXCEPTIONAL MARKETING AUTHORIZATION HOLDER IN CYPRUS

ADELCO – CHROMATOURGIA ATHINON E. COLOCOTRONIS BROS S.A.,
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Exceptional Marketing Authorizaton No in Cyprus: S00778

2. WHAT YOU SHOULD KNOW ABOUT THE DRUG PRESCRIBED BY YOUR PHYSICIAN

2.1 GENERAL INFORMATION

PAROTICIN contains fludrocortisone acetate which is used topically on the skin, the eye and the ear for the management of several problems. It also contains polymixin B which is used in topical antibacterial pharmaceutical products and lidocaine hydrochloride, solutions of which are used topically for the surface anesthesia of the mucosa (e.g. oral mucosa, throat mucosa and in laryngoscopy).

2.2 INDICATIONS

PAROTICIN is indicated for the treatment of inflammations and microbial infections of the ear.

2.3 CONTRAINDICATIONS

PAROTICIN is contraindicated:

- In patients with chickenpox (varicella)
- In patients with vaccinia or herpes simplex.
- In patients who have presented an allergic reaction to any of the ingredients of the product.

2.4 SPECIAL PRECAUTIONS AND WARNINGS DURING USE

2.4.1 General

Do not use PAROTICIN for more than 10 days.

- If the inflammation does not subside after one week, consult your doctor who may propose a modification of the treatment.
- During the application of the product, the dropper should not get in contact with the hands and the ear in order to avoid the risk of an infection.
- After the instillation of the drops, you should stay lying down for at least 5 minutes.
- If a topical irritation occurs during the application of the product, inform your doctor.

2.4.2 Pregnancy

Do not use PAROTICIN without consulting your doctor first.

2.4.3 Lactation

Some of the ingredients of this medicinal product are excreted in human milk. Before starting lactation, consult your doctor first.

2.4.4 Children

Consult section 2.6 “Dosage”.

2.4.5 Effects on the ability to drive and use machines

PAROTICIN does not affect the ability to drive and use machines.

2.4.6 Special warnings for the excipients

PAROTICIN contains propylene glycol which may cause topical irritation of the skin and the mucosa.

2.5 INTERACTIONS WITH OTHER MEDICINAL PRODUCTS OR SUBSTANCES

The action of the drug may be modified if it is used concomitantly with other drugs. Before starting treatment with PAROTICIN, inform your doctor if you are taking other drugs e.g. other antibiotics (kanamycin, streptomycin, gentamycin) or chloramphenicol, tetracycline, sulphonamides and trimethoprim.

2.6 DOSAGE

Dosage should be individualized according to the needs of the patient. The usual dosage is the following:
Adults-Elderly: 2-4 drops inside the ear canal, 3-4 times a day.
Children: 2-3 drops inside the ear canal, 3-4 times a day.

After the instillation of the drops, you should stay lying down for at least 5 minutes.

2.7 OVERDOSE-MANAGEMENT

The topical use of PAROTICIN is not accompanied by undesirable effects in case of overdose. If you drink the solution, a vomiting tendency may appear. Inform your doctor immediately and visit the nearest hospital.

2.8 WHAT YOU SHOULD KNOW IN CASE YOU MISS A DOSE

The ear drops should be instilled in the ear canal according to the dosage instructions. If you miss to use the drops as recommended, you should use them as soon as possible according to the instructions.

2.9 UNDESIRABLE EFFECTS

Long-term topical use of the ear drops may cause hypersensitivity reactions or other undesirable effects. In this case, you should inform your doctor immediately. Possible undesirable effects are the following:

- Hypothalamo-pituitary-adrenal axis suppression, decrease of plasma cortisol level, Cushing's syndrome,
- Topical after long-term use: development of microbial and fungal infections, inhibition of injuries healing, atrophy and linear striations in the skin, topical hypersensitivity, topical hirsutism, acme or vesication, couperose, hypopigmentation, perioral dermatitis.
  The use of corticosteroids is contraindicated in cases of infectious diseases, without management and treatment with antibiotics, during vaccinations and in the case of severe renal disease.
- After the instillation of lidocaine and adrenaline in the middle ear, severe dizziness has been reported.
- Polymixine, due to its pure absorption, does not cause systemic reactions when applied on intact skin, apart from rare cases of allergy. During systemic parenteral use, neurological symptoms have been reported (paresthesia, peripheral neuropathy, confusion, psychosis, neuromuscular block, toxicity).

2.10 PRODUCT EXPIRATION DATE

The product expiration date is written on the internal and external packaging.
In case this date has elapsed, do not use the drug.
Throw away the bottle 30 days after you first opened it.

2.11 SPECIAL STORAGE PRECAUTIONS

Keep at temperature below 25°C in a dry place, protected from light, out of reach and sight of children.

2.12 DATE OF LAST REVISION OF THE TEXT

05 /2011

3. INFORMATION ON THE PROPER USE OF DRUGS

- This drug was prescribed to you by your doctor only for your particular medical problem. You should not give it to others or use it for some other condition, without having consulted your doctor first.
- If during treatment a problem related to the drug occurs, inform your doctor or pharmacist immediately.
- If you have any questions regarding the information about the drug you are taking or you need to be better informed on your medical problem, do not hesitate to request such information from your physician or pharmacist.
- In order for the drug that was prescribed to you to be effective and safe, you should use it according to the instructions provided.
- For your safety and well-being, it is necessary to read carefully all information about the drug prescribed to you.
- Do not store drugs in bathroom cabinets because the heat and the humidity may spoil the drugs making them harmful to your health.
- Do not keep drugs you no longer need or that have expired.
- For safety reasons, keep all drugs out of the reach of children.

4. WAY OF SUPPLY

This drug is administered only by a physician's prescription.

adelco

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