Paroticin

Fludrocortizone Acetate
Polymyxin B Sulfate
Lidocaine hydrochloride

Combination of 3 active ingredients:

- **Polymyxin B sulfate:** It develops anti-microbial action against most of the *Gram* bacteria and particularly effective against *Pseudomonas aeruginosa*.
- **Fludrocortizone acetate:** With glucocorticoid action 10 times more potent than that of hydrocortisone and mineralocorticoid action more than 100 times more potent.
- **Lidocaine hydrochloride:** Topical anesthetic with a fast onset and medium duration of action.

Paroticin

Fludrocortizone Acetate
Polymyxin B Sulfate
Lidocaine hydrochloride

Is indicated for the treatment of inflammations and microbial infections of the ear, such as otitis externa, eczema, mycoses, furuncle of auditory canal.

Name of the medicinal product:	Paroticin
Active ingredients:	Fludrocortizone Acetate Polymyxin B Sulfate Lidocaine hydrochloride
Pharmaceutical form:	Ear drops, solution
Packaging:	Dropper bottle of 10 ml
Therapeutic indications:	For the treatment of inflammations and microbial infections of the ear
Method of administration:	Before the instillation of the drops, is recommended cleaning of the ear canal with sterile cotton. Keep the head with the ear to be treated turned upwards and this position should be kept for 5 minutes after the instillation of the drops. Alternatively, with the introduction of a plug into the ear canal and its impregnation.
Posology:	Adults: 2 - 4 drops, 3 - 4 times daily Children: 3 drops, 3 - 4 times daily
Marketing authorization holder & manufacturer:	ADELCO S.A.

Under prescription only medicine

For more information please refer to the Summary of Product Characteristics

Help to the safety of the products. Fill the **«YELLOW CARD».**
REPORT:
- ALL adverse reactions for ALL drugs

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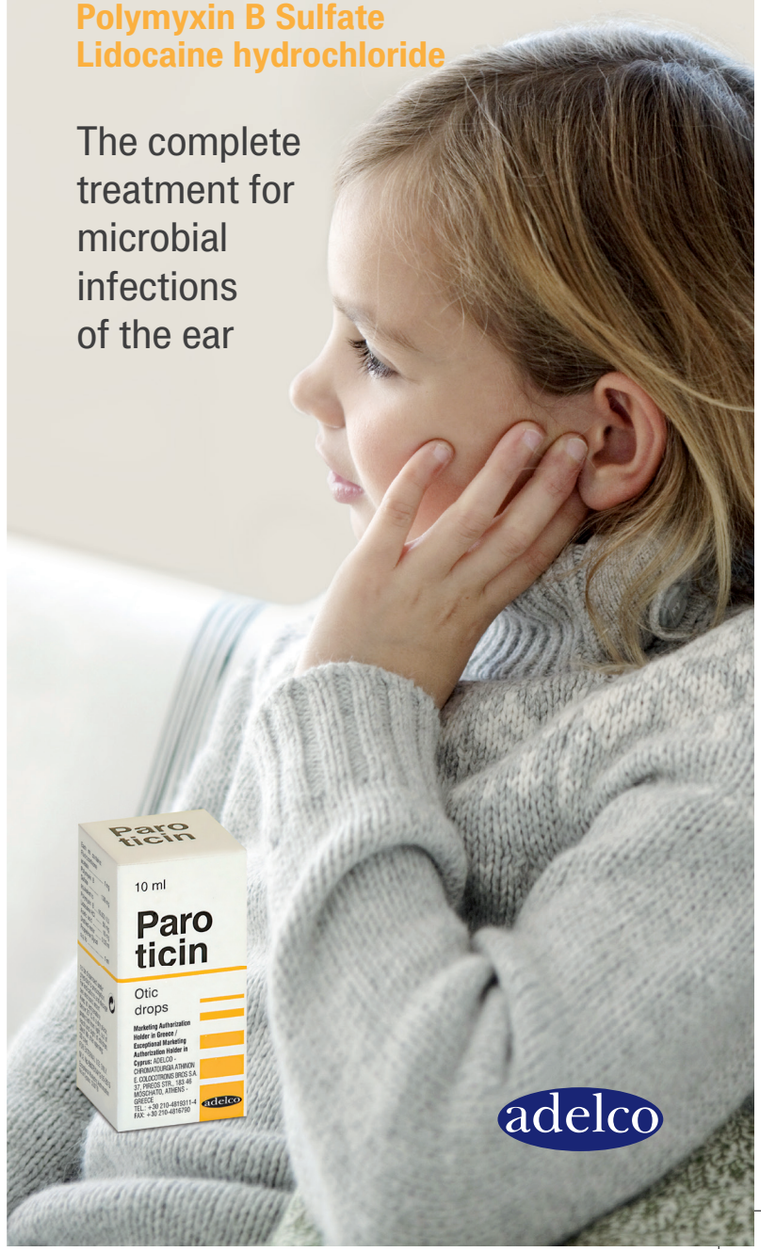
Paroticin

Fludrocortizone Acetate
Polymyxin B Sulfate
Lidocaine hydrochloride

The complete treatment for microbial infections of the ear



Paroticin

Fludrocortizone Acetate
Polymyxin B Sulfate
Lidocaine hydrochloride

- Ear drops for topical use of Paroticin have a potent anti-microbial and glucocorticoid action, but also anesthetic action for pain relief.

PAROTICIN contains as excipients:

- Acetic acid, which has antibacterial - antifungal properties, well tolerated that does not cause sensitization and does not create resistant strains.
- Propylene glycol which facilitates diffusion and penetration of the drug.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT: PAROTICIN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION in active ingredients

Each ml of the solution contains:

- Fludrocortisone acetate 1 mg
- Polymyxin B sulfate 1.30 mg = 10,000 IU Polymyxin B
- Lidocaine HCl 50 mg

3. PHARMACEUTICAL FORM

Ear drops, solution

4. CLINICAL PARTICULARS:

4.1. Therapeutic indications:

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

4.2. Dosage and method of administration:

The dosage and the method of administration of PAROTICIN for all ages is 2-4 drops inside the ear canal, 3-4 times a day. In children, the instillation of only 3 drops is recommended given the small capacity of the ear canal.

Method of administration: Before the instillation of the drops, cleaning of the ear canal with sterile cotton is recommended in order for the canal to be dry. It is also necessary to keep the head of the patient steady with the ear to be treated turned upwards, and this position should be kept for 5 minutes after the instillation of the drops. An alternative method of administration of PAROTICIN is the introduction of a plug into the ear canal and its impregnation with the drops 3-4 times daily. The plug should be changed at least every 24 hours.

4.3. Contraindications:

There are very few contraindications. PAROTICIN is contraindicated for patients with known history of hypersensitivity to any of its ingredients and for cases in which herpes simplex, chicken-pox and cowpox coexist.

4.4. Special warnings and precautions for use:

Chronic use of PAROTICIN could result in the development of micro-organisms and fungi resistant to Polymyxin. If the inflammation does not subside within one week, it is recommended to repeat the culture and to determine the sensitivity of the microorganisms in order to modify or not the treatment.

The treatment should not continue for a period longer than ten days, particularly in the case of no medical surveillance.

To avoid the risk of an infection, it is recommended to avoid contact of the dropper with the hands, the skin or the ear.

Should a topical irritation or allergic reaction occurs, the treatment must stop and medical advice must be asked.

4.5. Interaction with other medicinal products and other forms of interaction:

Concurrent use and topical treatment together with another antibiotic preparation, such as neomycin, could cause a cross reaction against a series of other antibiotics such as kanamycin, streptomycin, gentamicin, paromomycin the use of which is likely to become complicated in the long – run.

Polymyxin has been reported to act in synergy with a variety of other agents such as chloramphenicol, tetracycline, sulfonamides and trimethoprim. Its action is reduced by cations such as Ca++ and Mg ++ and so its in vivo action is smaller than the in vitro one.

4.6. Pregnancy and lactation:

Pregnancy: Corticosteroids should not be administered during pregnancy except in the case of absolute indication and when the benefits from the treatment outweigh the corticosteroids effects on the foetus. Do not use PAROTICIN without consulting your doctor first.

Lactation: Hydrocortisone is excreted in breast milk. Given that the topical use of corticosteroids is accompanied by absorption and detection of the drug in breast milk, the topical use of corticosteroids should be performed with special caution and surveillance of the nursing mother.

4.7. Effects on the ability to drive and use machines:

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

4.8. Undesirable effects:

General undesirable effects after long-term use of corticosteroids 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 topical 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.
- Polymixin, 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).

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Greek National Organization for Medicines: 284 Mesogeion Av., GR-15562 Xolargos, Athens, Greece. Tel: + 30 21 32040380/337, Fax: + 30 21 06549585, Website: http://www.eof.gr

4.9. Overdose:

The topical use of PAROTICIN is not accompanied by undesirable effects in case of overdose.

If PAROTICIN is ingested and depending on the quantity, it may cause gastric discomfort (vomiting) and possible undesirable effects owed to the absorption of its ingredients. For this reason, medical care is recommended for the management of overdose.

5. PHARMACOLOGICAL PROPERTIES: ATC code: S02CA07

5.1. Pharmacodynamic properties:

- Polymyxin: It acts mainly by binding with the phospholipids of membranes and by interrupting the cytoplasmic membrane of bacteria. It develops anti-microbial action against most of the Gram– bacteria with the exception of Proteus spp. It is particularly effective against Pseudomonas aeruginosa. The same stands for other Gram- bacteria, such as Escherichia coli, Enterobacter, Klebsiella spp., Haemophilus Influenza, Bordetella pertussis, Salmonella, Shigella spp.
- Lidocaine: It is a topical anaesthetic (amide), with a fast onset and medium duration of action.
- Fludrocortisone acetate: It has glucocorticoid action, 10 times more potent than that of hydrocortisone and mineralocorticoid action more than 100 times more potent (to which undesirable effects are owed).
- PAROTICIN contains acetic acid as an excipient which has been used as antibacterial and antifungal in mild infections of the ear canal.

5.2. Pharmacokinetic properties:

- Fludrocortisone: It is easily absorbed from the gastrointestinal tract. Like all corticosteroids, it is also absorbed through topical application, mostly through damaged skin. It is rapidly distributed to all tissues. It crosses the placenta and can be traced in small quantities in breast milk. Most of corticosteroids are bound with plasma proteins, mainly with globulins and at a smaller extent with albumin.
- Polymyxin: Polymyxin B sulfate is the sulfate salt of polymyxin B1 and B2 which is produced by bacillus polymyxa. Polymyxin B is not absorbed by the gastrointestinal tract (except for that of the newborns) and by healthy skin. It is easily absorbed by skin which has been damaged and there is a risk of systemic absorption. After intra- muscular administration, maximum plasma concentration is usually achieved within 2 hours. It is widely distributed throughout the tissues and the cell membranes of the tissues. The elimination half- life is 6 hours. It is excreted mainly by the kidneys (up to 60%). It is detected in the urine after 12-24 hours.
- Lidocaine: It is easily absorbed by the gastrointestinal tract, the mucous membranes and the damaged skin. The absorption by healthy skin is poor. After intravenous administration, plasma concentrations are rapidly decreased with an initial elimination half-life less than 30 min. The elimination time is 1-2 hours. It goes through a metabolism of first passage in the liver and bio - availability is 35% after oral administration. The liver metabolism is rapid and nearly 90% of the dose administered is dealcylated. It crosses the placenta and the blood- brain barrier. It is detected in breast milk.

5.3. Preclinical safety data:

Toxicological side effects of topically acting medicinal products are associated with the topical reaction to the product' s ingredients (polymixin, lidocaine, fludrocortisone) and the side effects that may be observed due to the absorption in the cases of long-term use of the product or overdose.

- Acute Toxicity: topically it is owed to idiocrasis or topical reaction.
- Chronic toxicity: it is owed to topical reactions to the product' s ingredients.
- Mutagenic action-Oncogenesis: it refers to the undesirable effects caused to the mother or the foetus due to the steroids skin absorption.
- Reproduction toxicity: steroids effect on the pregnant mother and the foetus during long-term use.

6. PHARMACEUTICAL DATA:

6.1. List of excipients:

PAROTICIN Ear Solution contains:

1. Acetic acid
2. Propylene glycol
3. Distilled water

6.2. Incompatibilities:

None known.

6.3. Shelf life:

2 years. After the opening of the container it should be consumed within 30 days.

6.4. Special storage precautions:

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

6.5. Nature and contents of the container:

FL x 10ML. Dropper bottle of 10 ml made by polyethylene.

6.6. Instructions for use/handling:

See section 4.2 "Dosage and method of administration".

6.7. 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

6.8. Exceptional Marketing Authorization Holder in Cyprus:

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

7. MARKETING AUTHORIZATION NUMBER: 66078/14/12-05-2015

Exceptional Marketing Authorization Number in Cyprus: S00778

8. DATE OF FIRST AUTHORIZATION: 10-12-1968

9. DATE OF (PARTIAL) REVISION OF THE TEXT: 06-2015