

# parotycin

**Ear drops**

for the



**immediate  
relief**

and

**treatment of  
inflammation**



*Science Signs  
Quality*

**ADELCO S.A.**  
PHARMACEUTICALS AND COSMETICS

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### SUMMARY OF THE PRODUCT CHARACTERISTICS (SPC)

**TRADE NAME OF THE PHARMACEUTICAL PRODUCT**  
PAROTICIN

#### QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE COMPONENTS

Each 1 ml of the solution contains:  
FLUDROCORTISONE ACETATE 1 MG  
POLYMYXIN B SULFATE 1,30 mg = 10.000 IU POLYMYXIN B  
LIDOCAINE HCL 50 MG

#### PHARMACOTECHNICAL FORM

Ear Solution ( ea.Sol.)

#### CLINICAL ELEMENTS

##### Therapeutic indications

Inflammation and microbial infections of the external ear canal.

##### Dosage and way of administration (adults, children, aged people)

The dosage and the ways of administration of PAROTICIN for all ages is 2-4 drops in the external auditory canal 3-4 times a day. For children it is advisable to instill only 3 drops given the small capacity of their external ear canal.

Way of administration: Before the instillation of the drops, it is advisable to clean the auditory tract with a sterilised cotton, so that the tract would be dry. It is also necessary to keep the head of the patient steady with the ear to be treated turned upwards, and this posture should be kept for 5 minutes after the instillation of the drops. An alternative way of administering the PAROTICIN is to introduce a wad into the external ear canal and impregnate it with the drops 3-4 times a day. The change of the wad should to be done at least every 24 hours.

##### Side - effects

Few. Parotycin is contra indicated for people having a known record of hypersensitivity to any of the medicament' s components, and in cases where simple herpes, chicken - pox and smallpox coexist.

##### Specific warnings and precaution during the treatment

Chronic use of Parotycin could result in the development of micro-organisms and fungi resisting to Polymyxin . If the inflammation does not regress within one week. It is recommended to repeat the culture and to determine the sensitivity of the microorganisms in order to modify the treatment.

The treatment should not continue for a period longer than ten days, particularly in the case of no medical surveillance. To keep the solution sterilised, it is recommended to avoid the infection of the dropping - tube by the hands, the skin or otherwise. Should a local irritation or allergic reaction occur, the treatment must stop and medical consultation must be asked.

##### Interaction with other medicament and other forms of interaction

Simultaneous use and local treatment together with another antibiotic preparation, such as neomycin, could cause a crossed reaction against a series of other antibiotics such as kamamycin, streptomycin, gentamycin, 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 factors such as chloramphenicol, tetracyclin, sulfonamids and trimethoprim. Its action is reduced by cations such as Ca++ and Mg ++ and so its in vivo action is lesser than in vitro action.

##### Administration through pregnancy and nursing

Corticosteroids should not be administered during pregnancy except in the case of absolute indications and when the advantages of the treatment surpass those of the effect of the corticosteroids on the foetus. Hydrocortisone is secreted in the breast milk. Given that a local use of corticosteroids comes together with absorption and detection of the medicament to breast milk, the use of corticosteroids locally should be conducted with utmost care and surveillance of the nursing mother.

##### Effect on the capacity to drive and handle machinery

No contra - indication in the administration of Parotycin during the handling of machines and driving exists.

##### Unwanted action (frequency and importance)

General side effects after a chronic local administration of corticosteroids which are the following :

- Suppression of the cortex - central nervous system - suprarenal axis, fall of the cortisol level in the plasma, the development of Cushing syndrome.
- Localised side effects after chronic use : Development of microbial and fungous local infectious diseases, inhibition of trauma healing, atrophy and linear striping of the skin, local hypersensitivity, local excessive hair-growing, acme lesions or vesicles, varicose veins discoloration, mouth dermatitis. The use of corticosteroids is contraindicated during infectious diseases, without surveillance and coverage by antibiotic administration, during vaccination, in the case of serious renal disease.
- Serious vertigo has been described by instillation of lidocain and adranaline in the middle ear.
- Due to poor absorption polymyxin does not cause systemic reactions when applied to normal skin, with the exception of rare cases of allergy. At a systemic parenteral administration there have been descriptions of neurological symptoms ( illusion, peripheral neuropathy, confusion, psychosis, neuromuscular dysfunction, neurotoxicity).

##### Symptoms of overdose, measures of treatment and antidotes

Local use of Parotycin is not accompanied by any side - effects in case of overdose.

When administered from the mouth and depending on the quantity intaken it is likely to cause gastric discomfort and possibly unwanted side effects due to the absorption of its components. Medical care to treat overdose is mainly symptomatic.

### PHARMACOLOGICAL PROPERTIES

#### Pharmacodynamic properties

- **Polymyxine** : it acts mostly when associated with the phospholipids of the membranes, interrupting the cytoplasmic membrane of the bacteria. It develops an anti-microbial action against most of the Gram - bacteria with the exception of Proteus spp. It is particularly effective against Pseudomonas aeruginose. The same stands for other Gram- bacteria, such as Escherichia coli, Enterobacter, Klebsiella spp., Haemophilus Influenza, Bordetella pertussis, Salmonela, Shigella spp.
- **Lidocaine** : It is a local anaesthetic ( amine ) , with a fast onset and medium duration of action.
- **Fludrocortisone acetate** : It has a glyocortisone action, 10 times stronger than that of hydrocortisone and a saltocortisone action more than 100 times stronger.
- It contains as excipient acetic acid which has been used as a bactericide and fungicide in cases of mild infections of the outer auditory canal.

#### Pharmacokinetic properties

- **Fludrocortisone**: It is easily absorbed from the gastrointestinal tract. Like all cortisones, it is also absorbed through local application, mostly through damaged skin. It is rapidly distributed to all tissues. It passes through the placenta and can easily be found in breast milk. Most of the cortisones are bound with plasma proteins, mostly globulines and at a lesser degree with albumines.
- **Polymyxin**: Polymyxin sulfate is the sulphate salt of polymyxin B1 and B2 which is produced by bacillus polymyxa. Polymyxin is not absorbed by the gastrointestinal tract except for the new borns and by healthy skin. It is easily absorbed by skin which has been damaged and there is a risk of systemic absorption. After intramuscular administration, a maximum plasma concentration is usually obtained within 2 hours. It is largely distributed throughout the tissues and the cytomembranes of the tissues. The half- life span is 6 hours . It is excreted from the body through the kidneys ( up to 60%) It is detected in the urine after 12-14 hours.
- **Lidocaine**: It is easily absorbed by the gastrointestinal tract, mucous membranes and damaged skin. The absorption by healthy skin is poor. After intravenous administration, the plasma concentration is rapidly decreased with an initial half - life span less than 30 m. The elimination time is 1-2 hours. It goes through a metabolism of first passage to the liver and the bio - availability disposability is 35% after per os administration. The metabolism at the liver is rapid and nearly 90% of the dose administered is de-acetylated. It goes through placenta and the blood-brain barrier. It is detected in breast milk.

#### Pre-Clinical evidence regarding safety (toxicological evidence)

Toxic local side effects of Parotycin are manifestation of the actual ingredients and individual medication of the preparation following chronic use of overdoses.

- **Acute Toxicity**: The above local mentioned toxicity due to idiosyncrasy of local reaction.
- **Chronic toxicity**: The above mentioned toxicity. Local reactions may appear and are due to the ingredients of the product.
- **Mutational action - Oncogenesis**: Possibly a side - effect due to the absorption of the steroids through the skin by the mother and the foetus.
- **Toxicity during reproduction**: The effect of the steroids to the pregnant and the foetus after long use.

### PHARMACEUTICAL INFORMATION

#### Qualitative composition in excipients

The solution contains: Acetic Acid, Propylene glycol, Distilled water

#### Incompatibilities

None known

#### Shelf - Life

2 years for the ready - made product , after dilution or reconstitution according to the instructions. After the opening of the container it should be consumed within 30 days.

#### Specific precaution during the keeping of the product

Keep the product in a cool place out of the reach of children.

#### Nature and components of the container

Dropping - tube phial made by soft polypropylene 10 ml.

## Solution for the treatment of inflammation of the exterior ear and the painful symptoms of media otitis

### One

### (1) ml Parotycin Solution contains:

<b>Fludrocortisone acetate</b>	<b>1 mg</b>
<b>Polymyxine B sulfate</b>	<b>10.000 units</b>
<b>Lidocaine hydrochloride</b>	<b>50 mg</b>
<b>Acetic acid</b>	<b>10 mg</b>
<b>Water</b>	<b>20 mg</b>
<b>Propylene glycol</b>	<b>Q.S.</b>

### The above ingredients give a suitable formula that:

✓ **Facilitates the penetration of the active ingredients into the affected area**

✓ **Direct action of the bactericidal agent and fluorocortisone in the tissues**

✓ **Fast relief of symptoms**

✓ **Treats inflammation**

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