SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINALPRODUCT

Oto-med® Ear Drop

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml contains:

Fludrocortsone	0.10%
Neomycin Sulphate	0.44%
Polymyxin B Sulphate	0.12%
Lidocaine HCl	4.00%

{For a full list of excipients, see section 6.1}

3. Pharmaceutical form

Topical (Ear Drops). A clear colourless liquid with a characteristic odour.

4. Clinical particulars

4.1 Therapeutic indications

Oto-med is indicated in the treatment of acute and chronic otitis externa, otitis media, flurunculosis of the auricular tube, allergic dermatosis of the auricular area and otalgia of various aetiology.

4.2 Posology and method of administration

4-5 drops, 2-4 times daily according to the seriousness of the morbid form.

Method of administration

Oto-med® ear drop is to be instilled with the dropper into the external auricular tube.

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4.3 Contraindications

Oto-med ear® drop is contra-indicated in patients with a known history of allergy to it.

It also contra-indicated in patients with perforated ear drum or tympanic membrane.

4.4 Special warnings and precautions for use

Occasionally, delayed hypersensitivity to corticosteriods may occur.

Treatment with topical steroid antibiotic combinations should not be continued for more than seven days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infection due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation and the emergence of resistant organisms.

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; neomycin and polymyxin B sulphate have nephrotoxic potential and polymyxin B sulphate has neurotoxic potential.

All topically active corticosteroids possess the potential to suppress the pituitary-adrenal axis following systemic absorption. Development of adverse systemic effects due to the fludrocortisone component of Oto-med Ear Drops is considered to be unlikely, although the recommended dosage should not be exceeded, particularly in infants.

Fludrocortisone may mask the allergic effects produced by any components of Oto-med ear drops.

Oto-med ear drops should only be used in the ear and are not suitable for use in the eye. Particular care should be taken to ensure that the correct formulation has been provided and administered. If ear drops are accidentally introduced into the eye, the eye should be rinsed thoroughly with water.

Oto-med ear drops should be kept out of the reach of children.

Prolonged, unsupervised, use should be avoided as it may lead to irreversible partial or total deafness, especially in the elderly and in patients with impaired renal function. In renal impairment the plasma clearance of neomycin is reduced (see Dosage in Renal Impairment).

Use in the immediate pre- and post- operative period is not advised as neomycin may rarely cause neuro-muscular block; because it potentiates skeletal muscle relaxant drugs, it may cause respiratory depression and arrest.

There have been observed cases of an increased risk of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations, particularly the m.1555A>G mutation, including cases where the patient's aminoglycoside serum levels were within the recommended range. Some cases were associated with a maternal history of deafness and/or mitochondrial mutation. While no cases were identified with neomycin, based on a shared mechanism of action there is the potential for a similar effect with neomycin.

These mitochondrial mutations are rare, and the penetrance of this observed effect is unknown.

4.5 Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption, both Neomycin Sulphate and Polymixin B Sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

4.6 Pregnancy and Lactation

There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity thus use of Oto-med Ear Drops is not recommended in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

none known

4.8 Undesirable effects

Oto-med produce reversible and irreversible cumulative ototoxicity affecting both

Cochlear System (manifested as dizziness or vertigo)

4.9 Overdose

Symptoms and signs

Possible symptoms or signs associated with excessive use of Oto-med Ear Drops are nephrotoxicity and neurotoxicity.

Treatment

Use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

In overdose, blood concentrations of neomycin sulphate, and polymyxin B sulphate, fludrocortisones sulphate and lidocaine should be determined. Haemodialysis may reduce the serum level of neomycin sulphate

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Mechanism of action:

Neomycin sulphate – is an aminoglycoside. This antibiotic has broad spectrum of anti-bacteria activity. It acts by binding to components in the bacteria cell, causing the production of abnormal proteins.

Polymyxin B sulphate – belongs to a class of antibiotic called Polymyxins.

It acts by interfering with the functioning of part of the bacteria's cell wall.

These results in leaking of the content of the cell.

Fludrocortisone Acetate - is an anti-Inflammatory and anti-Allergic agent.
Lidocaine Hydrochloride is a local anesthetic agent. This helps to reduce pain at the site of inflammation.

5.2 Pharmacokinetic properties

No data are available regarding the pharmacokinetics of this product. However since this is a topical preparation and significant systemic absorption is unlikely to occur, the data are irrelevant.

Systemically absorbed neomycin is predominantly excreted by the kidney and the total amount excreted in the urine varies between 30% and 50%. The pharmacokinetics of systemically absorbed polymixin B has been described.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Propylene glycol
Acetic acid
Sodium acetate trihydrate
Di-sodium edetate
Benzalkonium chloride
Glycerine

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

8ml white plastic dropper bottle.

6.6 Special precautions for disposal

No special requirements

7. APPLICANT/MANUFACTURER

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