Otosporin Ear Drops

QUALITATIVE AND QUANTITATIVE COMPOSITION
Polymyxin B Sulphate EP 10,000 units per ml
Neomycin Sulphate EP 3,400 units per ml
Hydrocortisone EP 1.0% w/v
EXCIPIENTS
Cetostearyl Alcohol, Sorbitan Monolaurate, Polysorbate20, Nipagin M, Dilute Sulphuric Acid, Purified Water
INDICATIONS
Otosporin Ear Drops are indicated for the treatment of otitis externa due to, or complicated by, bacterial infection.
Route of Administration
Topical
In Vitro Activity
Otosporin Ear Drops are active against a wide range of bacterial pathogens. The range of activity includes:-
Gram-Positive Organisms:
Staphylococcus Epidermis and *Staphylococcus Aureus:*
Gram-Negative Organisms:
Enterobacter Spp., Escherichia Spp., Haemophilus Spp., Klebsiella Spp., *Proteus Spp., Pseudomonas Aeruginosa*
Otosporin Ear Drops are not expected to be active against streptococci, including *Streptococcus Pyogenes*
Hydrocortisone possesses anti-inflammatory, anti-allergic and antipruritic activity
DOSAGE AND ADMINISTRATION
Adults
Following cleansing and drying of the external auditory meatus and canal as appropriate, three drops should be instilled into the affected ear three or four times daily. Alternatively, a gauze wick may be introduced into the external auditory canal and kept saturated with the solution; the wick may be left in place for 24 to 48 hours.
Treatment should not be continued for more than 7 days without medical supervision.
Soap should not be used for cleansing of the external auditory meatus and canal as it may inactivate the antibiotics.
Children
Otosporin Ear Drops are suitable for use in children (3 years and over) at the same dose as adults. A possibility of increased absorption exists in very young children, thus Otosporin Ear Drops are not recommended in neonates and infants (<3 years). (See 4.3 Contra-indications, 4.4 Special Warnings and Precautions for Use).
Elderly
As for adults. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur (see 4.4 Special Warnings and Precautions for Use).
Renal Impairment
Dosage should be reduced in patients with reduced renal function (see 4.4 Special Warnings and Precautions for Use).
CONTRAINDICATIONS
Contra-indicated in patients in whom perforation of the tympanic membrane is known or suspected.
Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, the use of Otosporin Ear Drops in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.
Contra-indicated in patients who have demonstrated allergic hypersensitivity to any of the components of the preparation or to cross-sensitising substances such as framycetin, kanamycin, gentamicin and other related antibiotics.
Contra-indicated in the presence of untreated viral, fungal and tubercular infections.
A possibility of increased absorption exists in very young children, thus Otosporin Ear Drops are not recommended for use in neonates and infants (up to 3years). In neonates and infants, absorption by immature skin may be enhanced and renal function may be immature.
WARNINGS AND PRECAUTIONS
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 hydrocortisone component of Otosporin Ear Drops is considered to be unlikely, although the recommended dosage should not be exceeded, particularly in infants.
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
INTERACTIONS
Following significant systemic absorption, both neomycin sulphate and polymyxin b sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.
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 Otosporin Ear Drops is not recommended in pregnancy or lactation.
ABILITY TO PERFORM TASKS THAT REQUIRE JUDGEMENT, MOTOR OR COGNITIVE SKILLS
None known
ADVERSE REACTIONS
The incidence of allergic hypersensitivity reactions to neomycin sulphate in the general population is low. There is, however, an increased incidence of hypersensitivity to neomycin in certain selected groups of patients in dermatological practice, particularly those with venous stasis eczema and ulceration, and chronic otitis externa.
Allergic hypersensitivity reactions following topical application of polymyxin B sulphate and hydrocortisone are rare.
Allergic hypersensitivity to neomycin following topical use may manifest itself as an eczematous exacerbation with reddening, scaling, swelling and itching or as a failure of the lesion to heal.
Stinging and burning have occasionally been reported when Otosporin Ear Drops gained access to the middle ear.
Otosporin Ear Drops should only be used in the ear and are not suitable for use in the eye
OVERDOSE
Symptoms and signs: Possible symptoms or signs associated with excessive use of Otosporin Ear Drops are those due to significant systemic absorption (see Special Warnings and Precautions for Use).
Management: 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 should be determined. Haemodialysis may reduce the serum level of neomycin sulphate.
Shelf-life
36 months
Storage
Store below 25°C, away from sun light

Nature & Content of Packaging
5ml in Plastic Squeeze bottle

MANUFACTURED BY:
GlaxoSmithKline Bangladesh Limited
Fouzderhat Industrial Area, Chittagong

Ref:

http://www.medicines.org.uk/emc/medicine/2181/SPC/Otosporin+Ear+Drops (last accessed on 30 March, 2014)