Otosporin™

Ear Drops

To the Medical and Pharmaceutical professions

Presentation

Each ml of milky-white liquid contains 10,000 Units Polymyxin B Sulphate BP. 3.400 Units Neomycin Sulphate BP, and 1 % w/v Hydrocortisone BP. in an aqueous base.

Uses

Otosporin Ear Drops are indicated for the treatment of otitis externa due to, or complicated by, bacterial infection.
The use of **Otosporin** Ear Drops does not exclude concomitant systemic therapy with antibiotics where appropriate (see Precautions).
In vitro activity: **Otosporin** Ear Drops are active against a wide range of bacterial pathogens. The range of activity includes:-

Gram-positive organisms

Staphylococcus spp. including *Staphylococcus aureus;*

Gram-negative organisms

Enterobacter spp.
Escherichia spp.
Haemophilus spp.
Klebsiella spp.
Proteus spp.
Pseudomonas spp. Including *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.
Soap should not be used for cleansing the external auditory meatus and canal as it may inactivate the antibiotics.

Children

As for adults.

Use in the elderly

As for adults.

Contra-indications. warnings. etc.

Contra-indications

The use of **Otosporin** Ear Drops is contra-indicated inpatients in whom perforation of the tympanic membrane is known or suspected.
The use of **Otosporin** Ear Drops is 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.
The use of **Otosporin** Ear Drops is contra-indicated in the presence of untreated viral, fungal and tubercular infections.

Precautions

Occasionally, delayed hypersensitivity to corticosteroids 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.

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.

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

Side-and adverse effects

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 extern. 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.

Use in pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal, development, including cleft palate and intra-uterine growth retardation. There may be a very small risk of such effects in the human foetus.

As well as suppression of the neonatal HPA axis, there is a risk of foetal toxicity if aminoglycoside antibiotic preparations are administered during pregnancy.

No information is available regarding the excretion of polymyxin B sulphate and neomycin or their metabolites in human breast milk, following the use of **Otosporin** Ear Drops.

There is no information available on the levels of hydrocortisone which may appear in human breast milk following topical administration. When **Otosporin** Ear Drops are used as recommended, it is unlikely that sufficient hydrocortisone would be absorbed to produce detectable levels in breast milk.

Toxicity and treatment of overdosage

There is no experience of overdosage with **Otosporin.**

Pharmaceutical precautions

Store below 25°C. Protect from light.

Shake before use

Otosporin is a Trademark

GlaxoWellcome

Manufactured by:
Glaxo Wellcome Inc
Mississauga, Ontario, Canada