Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Otosporin Ear Drops Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Polymyxin B Sulphate	10,000	Units.
Neomycin Sulphate	3,400	Units.
Hydrocortisone	1	% w/v.

Excipients with known effect: Each ml contains 0.005g of cetostearyl alcohol and 0.001g of methyl parahydroxybenzoate (E218).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops, suspension
A creamy-white aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Otosporin Ear Drops are indicated for the prophylaxis and management 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 Special Warnings and Special Precautions for Use*).

4.2 Posology and method of administration

Otosporin Ear Drops are for topical administration into the ear only.

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 of the external auditory meatus and canal as it may inactivate the antibiotics.

Treatment should not be continued for more than 7 days without medical supervision.

Use in children:
Otosporin Ear Drops is suitable for use in children (2 years and over) at the same dose as adults. A possibility of increased absorption exists in very young children, thus Otosporin Ear Drops is not recommended for use in neonates and infants (less than 2 years) (see *4.3 Contraindications* and *4.4 Special Warnings and Special Precautions for Use).*

Use in the elderly:
Otosporin Ear Drops is suitable for use in the elderly. 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 Special Precautions for Use).*

Dosage in renal impairment:
Dosage should be reduced in patients with reduced renal function (see *4.4 Special Warnings and Special Precautions for Use).*

4.3 Contraindications

The use of Otosporin Ear Drops is contraindicated 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 in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

The use of Otosporin Ear Drops is contraindicated 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 contraindicated in the presence of untreated Herpes simplex, Herpes zoster, fungal infections 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 2 years). In neonates and infants, absorption by immature skin may be enhanced and renal function may be immature.

4.4 Special warnings and precautions for use

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.

As with other combined antibacterial/corticosteroid preparations, prolonged use may result in the overgrowth of non-susceptible organisms, including fungi.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. Although this is unlikely to occur with topically applied antibiotics, if prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Hydrocortisone may mask the allergic effects produced by any components of Otosporin Ear Drops.

Accidental maladministration, prescription and dispensing errors have been reported. Otosporin 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 cold water.

Otosporin Ear Drops should be kept out of the sight and reach of children.

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.

Neomycin may cause irreversible partial or total deafness when given systemically or when applied to open wounds or damaged skin.

In renal impairment the plasma clearance of neomycin is reduced (see *4.2 Dosage in Renal Impairment).*

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption both neomycin sulphate and polymyxin B sulphate can intensify and prolong the respiratory depressant effect of neuromuscular blocking agents.

4.6 Fertility, pregnancy and lactation

No specific studies have been conducted in pregnant patients although the product has been used for many years without any evidence of adverse effects in pregnancy. The expected clinical benefit of treatment to the patient must be balanced against any possible, but unknown, hazards to the developing foetus.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. Relevance of this finding to human beings has not been established, however, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

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.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The incidence of allergic hypersensitivity reactions to neomycin sulphate in the general population is low. There is, however, an increased incidence of hypersensivity 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.

Postmarketing Data

Immune System Disorders
Rare: Application site hypersensitivity

General Disorders and Administration Site Conditions
Rare: Headache, application site reaction including: pain, irritation, oedema, burning sensation, rash

Skin and Subcutaneous Tissue Disorders
Rare: Local exfoliative dermatitia, skin atrophy, telangietasia, striae, exacerbation of underlying skin condition,

including eczema

4.9 Overdose

Symptoms and signs:-
No specific symptoms or signs have been associated with excessive use of Otosporin Ear Drops. However, consideration should be given to significant systemic absorption (see *4.4 Special Warnings and Special 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone possesses anti-inflammatory, anti-allergic and anti-pruritic activity.

In vitro activity*:* Otosporin Ear Drops are active against a wide range of bacterial pathogens.

Otosporin Ear Drops are not expected to be active against streptococci, including *Streptococcus pyogenes.*

5.2 Pharmacokinetic properties

No data.

5.3 Preclinical safety data

No data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Sorbitan laurate
Polysorbate 20
Methyl parahydroxybenzoate (E218)
Dilute sulphuric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years
Discard within one month of first opening the container

6.4 Special precautions for storage

Do not store above 25°C.
Keep container in the outer carton to protect from light.

6.5 Nature and contents of container

Polypropylene dropper bottles with screw caps containing a creamy-white aqueous suspension.

Pack sizes: Bottles of 5 ml and 10 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Otosporin Ear Drops should be shaken gently prior to use.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
Stonemasons Way
Rathfarnham
Dublin 16

8 MARKETING AUTHORISATION NUMBER

PA 1077/73/1

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Date of last renewal: 01 April 2007

10 DATE OF REVISION OF THE TEXT

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