

[GlaxoSmithKline Logo]

**Package Leaflet: Information for the user**  
**Otosporin™ Ear Drops, Suspension**  
**polymyxin B sulphate, neomycin sulphate and hydrocortisone**

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet:**

- 1 What Otosporin is and what it is used for
- 2 What you need to know before you use Otosporin
- 3 How to use Otosporin
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**1 What Otosporin is and what it is used for**

The name of your ear drops is Otosporin™ Ear Drops, Suspension. It is used to treat ear infections and swelling of the external ear.

- Otosporin contains three medicines called: polymyxin B sulphate, neomycin sulphate and hydrocortisone.
- Polymyxin B sulphate and neomycin sulphate belong to a group of medicines called antibiotics. They kill the germs that can cause ear infections.
- Hydrocortisone belongs to a group of medicines called steroids. It helps to reduce the swelling and irritation caused by the infection.

**2 What you need to know before you use Otosporin**

**Do not use Otosporin:**

- if you are allergic (hypersensitive) to polymyxin B sulphate, neomycin sulphate, hydrocortisone or any of the other ingredients of Otosporin (See section 6: Further information)
- if you are allergic (hypersensitive) to aminoglycoside antibiotics such as framycetin, kanamycin or gentamicin
- if you have a perforated ear drum
- if you have either a viral, fungal or tubercular (TB) infection
- for a child under 2 years old

in large quantities or on large areas of the body for prolonged periods of time. Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Otosporin.

**Warnings and precautions**

Talk to your doctor or pharmacist before using Otosporin if:

- you have kidney problems. Your doctor may change how often you use Otosporin

As with all other topical corticosteroids, Otosporin may affect the body's production of the hormone cortisol, which controls many of the body's functions such as growth & blood sugar levels.

Do not use more than the recommended dose.

Prolonged use may result in this medicine becoming less effective in treating the infection. This is because the bacteria causing the infection become resistant to the antibiotic in Otosporin.

If you experience prolonged diarrhoea or stomach cramps stop the treatment and contact your doctor or pharmacist.

Otosporin should only be used in the ear and is not suitable for use in the eye. If ear drops accidentally come into contact with the eye, rinse thoroughly with cold water.

If you use Otosporin in large quantities, it can affect your hearing, nerves and kidneys. This is unlikely when you use the normal dose of the ear drops.

Avoid contact with open wounds or damaged skin as it may result in partial or total deafness.

Otosporin Ear Drops should be kept out of reach of children.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Otosporin.

### **Children**

Do not use on children under 2 years old, as there is a possibility of increased absorption of the medicine.

### **Other medicines and Otosporin**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

If Otosporin is absorbed into the body in large amounts, the effects of medicines used to relax muscles during surgery can last longer or these effects could be stronger.

### **Pregnancy and breast-feeding**

Do not use Otosporin if you are pregnant or plan to get pregnant.

Do not breast-feed while using Otosporin.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

### **Otosporin contains cetostearyl alcohol and methyl parahydroxybenzoate**

- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

- Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed)

### 3 How to use Otosporin

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### When using Otosporin

- shake the closed bottle gently before each use
- clean and dry the ears
- do not use soap, it may stop the medicine working
- **do not put the drops in your eyes. Otosporin is for topical administration to the ear only.**

#### Adults and children 2 years of age and older

- apply 3 drops into the affected ear up to four times a day, for up to 7 days
- make sure you finish the course of Otosporin which your doctor has prescribed.

#### If you are due to have surgery

Tell your doctor you have used Otosporin if you are due to have surgery. If Otosporin is absorbed into the body in large amounts, the effects of medicines used to relax muscles during surgery can last longer or these effects could be stronger.

#### If you use more Otosporin than you should

If you think you have been using too much Otosporin, tell your doctor or pharmacist.

#### If you forget to use Otosporin

If you forget a treatment, apply 3 drops to the affected ear as soon as you remember. Then go on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4 Possible side effects

Like all medicines, Otosporin can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Rarely, an allergic reaction to Otosporin can occur. Your ear infection may:
  - seem to get worse instead of better
  - become red, scaly, itchy and swollen.

#### **You should stop using the drops and talk to your doctor**

- You may get a stinging or burning sensation when using the drops. This could mean you have a perforated ear drum. **You should stop using the drops and talk to your doctor**

Other rare side effects include:

- Headache
- application site reaction including: pain, irritation, swelling, burning sensation, rash
- redness and scaling
- skin thinning

- the appearance of blood vessels under the surface of your skin
- stretch marks
- worsening of skin condition, including eczema

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5 How to store Otosporin**

- Keep this medicine out of the sight and reach of children.
- Do not use Otosporin after the expiry date which is stated on the carton and the bottle label. This expiry date (Exp.) refers to the last day of that month.
- Do not store above 25°C.
- Otosporin should be stored in the outer carton in order to protect it from light.
- Do not use the drops for longer than one month after first opening the bottle.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6 Further information**

### **What Otosporin contains**

- The active substances per ml are polymyxin B sulphate 10,000 IU, neomycin sulphate 3,400 IU and hydrocortisone 1% w/v.
- The other ingredients are cetostearyl alcohol (see section 2), sorbitan monolaurate, polysorbate 20, methyl parahydroxybenzoate (see section 2), dilute sulphuric acid and purified water.

### **What Otosporin looks like and contents of the pack**

Each carton has a plastic bottle with a nozzle and a screw cap, which contains either 5 ml or 10 ml of a creamy-white liquid.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

GlaxoSmithKline (Ireland) Limited, Stonemason's Way, Rathfarnham, Dublin 16.

Manufacturer: Aspen Bad Oldesloe GmbH, Industriestrasse 32 – 36, 23843\_Bad Oldesloe, Germany

### **This leaflet was last revised in**

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