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Package Leaflet: Information for the user

Otosporin® Ear Drops

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

- 1 What Otosporin is and what it is used for
- 2 Before you use Otosporin
- 3 How to use Otosporin
- 4 Possible side effects
- 5 How to store Otosporin
- 6 Further information

1 What Otosporin is and what it is used for

The name of your ear drops is Otosporin. It is used to treat ear infections.

- 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 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 3 years old.

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.

Take special care with Otosporin

Check with your doctor or pharmacist before using your medicine if:

- you have kidney problems. Your doctor may change how often you use Otosporin
- you have a long-standing infection of your outer ear.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not use Otosporin with antibiotics such as framycetin, kanamycin or gentamicin, or other aminoglycosides. Using them at the same time may increase the risk of hearing, nerve and kidney damage.

Pregnancy and breast-feeding

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

Do not breast-feed while using Otosporin.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

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Artwork Information
Panel

RSC A/W
Version:
2

Item Number:
1000000092655

Manufacturing Site:
GSK-CAN-Mississauga-CAMIS

Market or Pack Owner:
United Kingdom-GBR

Market Trade Name:
Otosporin

No. of Colours: 1
(does NOT include Varnish, if applicable)

List Colours:
(include sample in fields provided below;
 e.g. spot / spot-CMYK equivalent)

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Technical Reference No(s):
A140210L
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Mississauga - Additional Artwork Information Panel

Specification Number:
(Does NOT include Specification version number)

GSLFLT050

Replaces Item Code:

A047412

Component Basic Dimensions:
(in mm)

140.0 x 210.0

3 How to use Otosporin

Always use Otosporin exactly as your doctor has told you. You should 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.**

Adults and children over 3 years old

- 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 and itchy.

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**
- 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.

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 out of the reach and sight 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 carton to protect it from light.
- 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, sorbitan laurate, polysorbate 20, methyl hydroxybenzoate, 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 milky-white liquid.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: The Wellcome Foundation Ltd, trading as GlaxoSmithKline UK Stockley Park West, Uxbridge, Middlesex UB11 1BT. Manufacturer: Aspen Bad Oldesloe GmbH Bad Oldesloe, Germany

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Otosporin Ear Drops
Reference number 00003/5106R

This is a service provided by the Royal National Institute of the Blind.

Leaflet date: July 2011

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