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PHOENIX LABS

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 because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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
- 4 Possible side effects
- 5 How to store Otosporin
- 6 Contents of the pack and other 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. 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 this medicine (see section 6)
- 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.

Conditions you need to look out for

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Contact your doctor as soon as possible if you get these symptoms.

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.
- You know (or think you have) a mitochondrial disease (mutations in the parts of your cells which help make energy); certain mitochondrial diseases may increase your risk of hearing loss with this product.

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

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.

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.

Otosporin ear drops contain cetostearyl alcohol and methyl hydroxybenzoate, E218
Otosporin ear drops contains cetostearyl alcohol which may cause local skin reactions (e.g. local dermatitis) and methyl hydroxybenzoate, E218 which may cause allergic reactions (possibly delayed).

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3. How to use Otosporin

Always use this medicine exactly as your doctor or pharmacist 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.** If you accidentally get the drops in your eyes, rinse thoroughly with cold water.

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 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, this medicine 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 with swelling. This may be due to your skin not healing properly.**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.

Some patients have also reported experiencing the following rare side effects (may affect up to 1 in 1,000 people):

- headache
- flaking skin in areas where you have applied Otosporin
- thinning of the skin, which may bruise easily
- red spots on your skin that may appear "spidery"

- lines on your skin that look like stretch marks
- existing skin conditions such as eczema getting worse

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otosporin

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine 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.
- Store below 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. Contents of the pack and other 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 monolaurate, polysorbate 20, methyl hydroxybenzoate, E218, 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: Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland

Manufacturer: FAMAR A.V.E, 49th National Road Athens-Lamia, Avlon Attiki, 19011, Greece

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