

## **Panotile, ear drops**

Polymyxin B sulfate, Neomycin sulfate, Fludrocortisone acetate,

Lidocaine hydrochloride

### **What is panotile and what is it used for?**

What are Panotile ear drops?

Panotile is a medication that contains four active ingredients. Polymyxin B and neomycin are antibiotics used to treat certain infections. Together, they have a bactericidal effect on the most common causes of inflammation in the external ear canal.

Fludrocortisone is a corticosteroid hormone that works as an anti-inflammatory, reducing pain and itching.

Lidocaine is a local anesthetic that relieves pain.

**Use:** The ear drops are used to treat infections of the external ear canal (otitis externa) in adults and children aged 2 years and older, caused by bacteria sensitive to the active ingredients, and provided the eardrum is intact.

Panotile helps to heal the ear infection. Symptoms (pain and itching) will decrease after a few days of treatment, and further damage to the ear will be prevented.

### **When should you not use this medication or be extra careful?**

When should you not use this medication?

- You are allergic to any of the ingredients in this medication.
- You are hypersensitive to substances related to the ingredients of this medication, such as polymyxins or antibiotics from the group of aminoglycosides, including framycetin, kanamycin, and gentamicin.
- You have a perforated eardrum or it is suspected that you have one.
- In very young children (under the age of 2 years), there is a risk that the substance neomycin will penetrate through the still young skin and enter the bloodstream. Also, the kidneys are not yet fully developed. This increased uptake can lead to damage to the hearing or kidneys. Therefore, Panotile ear drops should not be used by children under the age of 2.
- You have an (untreated) virus or fungal infection, which requires a different treatment method.
- You should not use this medication for more than 10 consecutive days.

### **When should you be extra careful with this medication?**

In addition to using Panotile, your doctor may decide to prescribe other antibiotics. If you have used Panotile for a long time or frequently, hypersensitivity may occur. If you experience a hypersensitivity reaction, your doctor will tell you to stop using Panotile. There is also a risk of permanent hearing loss.

### **Are you using other medications?**

Are you using other medications in addition to Panotile, or have you done so recently, or is there a possibility that you will use other medications in the near future? Then tell your doctor or pharmacist.

### **Pregnancy, breastfeeding, and fertility**

**Pregnancy:** It is not recommended to use Panotile during pregnancy.

**Breastfeeding:** When breastfeeding, you may use Panotile only briefly after consulting with your doctor.

**Fertility:** No effect on fertility is expected from Panotile.

Are you pregnant, think you may be pregnant, want to become pregnant, or are you breastfeeding?

Then contact your doctor or pharmacist before using this medication.

**Driving and using machines:** There is no evidence that Panotile adversely affects driving or machine use, but one should be aware of the adverse effect on hearing caused by the ear condition.

Panotile ear drops contain 0.002 mg benzalkonium chloride and 11 mg polypropylene glycol in each drop.

Benzalkonium chloride and polypropylene glycol can cause skin irritation.

### **How to use this medication?**

Always use this medication exactly as your doctor or pharmacist has told you.

The usual dosage is: Unless otherwise prescribed by the doctor: Adults: 2-4 times a day 4-5 drops

**Children from 2 years:** 3-4 times a day 2-3 drops

In patients with reduced kidney function, your doctor may prescribe a lower dosage. Panotile ear drops are intended for administration in the ear. One can also place a gauze or cotton swab in the ear canal and saturate it with Panotile. The tampon should remain in the ear canal for 24 hours

and be regularly saturated with Panotile. The duration of treatment depends on the severity of the infection but never longer than 10 consecutive days.

**Instructions for use:**

- Warm the bottle to body temperature before use.
- Panotile ear drops are instilled in the ear as indicated below.
- Pull off the tab and remove the protective cap, revealing the dropper.
- When instilling into the external ear canal, keep the head slightly tilted to the other side.
- Press on the drop counter until the desired number of drops is reached.
- Replace the protective cap on the dropper and raise the head.

**Have you used too much of this medication?:** In case of overdose, contact your doctor or pharmacist as soon as possible.

**If you forget to use this medication?**

Then instill the missed dose in your ear and continue with the prescribed schedule. Do not instill a double dose of drops in your ear to make up for the missed dose.

**If you stop using this medication:** Panotile kills the bacteria in your external ear canal. This takes some time. Your doctor has indicated how long you should use Panotile. If you stop using it before this period has elapsed, the symptoms may return. The bacteria may also have become resistant to Panotile.

**Possible side effects**

Like any medicine, this medicine can have side effects, although not everyone experiences them. Infections and parasitic diseases Long-term use can result in overgrowth of non-sensitive organisms, including fungi. Skin and subcutaneous tissue disorders Sometimes itching or mild irritation or burning sensation. Hypersensitivity may also occur. If Panotile is used in an ear with a damaged or perforated eardrum, stinging or burning sensations may occur. In this case, Panotile should not be used anymore.

When this medicine enters the bloodstream, it can lead to permanent hearing damage.

**How to store this medicine?**

Store below 25°C.