

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### OTOL H

(1.0 + 0.1 + 10.0) mg / g, ear drops, solution

PREDNISOLONE, TYROTHRIN, TETRACAINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What OTOL H is and what it is used for
2. Before you take OTOL H
3. How to take OTOL H
4. Possible side effects
5. How to store OTOL H
6. Further information

#### 1. WHAT OTOL H IS AND WHAT IS IT USED FOR

OTOL H is medicine comprising the three active substances, antibiotic (tyrothricin), corticosteroid (Prednisolone) and local anesthetic (tetracaine). It is used only locally in the external ear canal, and only when the eardrum is not damaged.

#### How OTOL H works

OTOL H is a combined preparation that works by reducing the inflammation, pain and itching in the outer ear canal and it reduces the sense of tension and pain in the case of inflammation of the middle ear.

#### When is OT OL H USED?

OTOL H, ear drops are used to suppress pain and inflammatory reactions in the outer ear canal, which are the symptoms of the acute inflammation of the outer ear (otitis externa acuta).

If after two days of using this medicine your condition does not improve, stop the further use of this product and immediately consult your doctor.

#### 2. BEFORE YOU TAKE OTOL H

**Do not take OTOL H**

- If you are allergic to Prednisolone, tyrothricin, tetracaine hydrochloride or other ingredients of this medicine
- If you have or are suspected to have ruptured (damaged) eardrum
- if it is meant for a child under the age of 2

**Take special care with OTOL H**

If you notice redness, itching, stinging and burning feeling in the outer ear canal while using OTOL H, stop using this product and contact your doctor.

This medicine should never be used as the sole remedy for inflammation of the middle ear, nor should it be used without consulting a doctor first.

**Taking other medicines**

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

**Pregnancy and breastfeeding**

Before you start taking some medicine, consult your doctor or pharmacist.

There is no data on the use of this drug during pregnancy and breastfeeding.

**Driving and using machines**

No specific precautions are required.

**Important information**

No significant information on additional substances contained in this medicine.

**3. HOW TO TAKE OTOL H**

Always use **OTOL H** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you think that Sept **OTOL H** has too weak or too strong effect on you, you should contact a doctor.

The usual dose in children above the age of 2 is 2-4 drops every hour. Drops should be instilled directly into the affected ear or on sterile gauze that than should be placed into the affected ear. In adults 5-6 drops should be instilled every hour. If after two days of using this medicine your condition does not improve, stop the further use of this product and immediately consult your doctor.

Before you apply these drops, it is necessary to clean affected ear and wait until it is completely dry. Then lie on your bed so that you affected ear is made available for use of these drops. Drops are thick and you will need to be careful and patient during the instillation. When you have instilled OTOL H drops, you should stay lying down for another 15 minutes.

**If you take more OTOL H than you should**

If you have taken higher dose than recommended or if someone else accidentally took your medicine, contact your doctor, pharmacist or nearest hospital!

**If you forget to take OTOL H**

Do not take a double dose to make up for a forgotten dose.

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

#### 4. POSSIBLE SIDE EFFECTS

Besides the possibility of local hypersensitivity to any component of this medicine, other side effects were not recorded.

#### **Reporting of suspected 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.

#### 5. HOW TO STORE OTOL H

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Store below 25 °C.

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 OTOL H contains**

Active ingredients:

One (1) g of solution contains:

Prednisolone 1.00 mg

tyrothricin 0.10 mg

tetracaine hydrochloride 10.00 mg.

Excipient:

Glycerol.

##### **What OTOL H looks like and contents of the pack**

Clear, colorless to light yellow syrupy solution.

Glass bottle with 10 g of ear drops, solution.

##### **Regime of dispensing**

The medicine is issued on prescription.

##### **Manufacturer**

Hemofarm d.o.o. Banja Luka, Novakovići b.b. Banja Luka, Bosna i Hercegovina