

 **PACKAGE LEAFLET:**
Information for the patient

OTOL

Ear drops, solution

(30 mg + 20 mg + 50 mg) / ml

(Procaine hydrochloride, Phenol, Phenazone)

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 question, ask your doctor or pharmacist.
- This medication 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 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.

What is in this leaflet:

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

1. WHAT OTOL IS AND WHAT IT IS USED FOR

Otol contains three active substances in its composition as follows:

- procaine (novocaine) hydrochloride, which exerts local anesthetic effect;
- phenol, which acts as disinfectant against vegetative forms of gram - positive and gram - negative bacteria and against many viruses;
- phenazone, has local analgesic astringent and hemostatic properties.

Otol is used in acute congestive media and catarrhal otitis.

It is used as antiseptic and analgesic in otology. Ask your doctor if you want to know why Otol has been given to you.

2. BEFORE YOU USE OTOL

Do not use Otol:

- if you have a known hypersensitivity to the active substances (procaine hydrochloride, phenol, phenazone) that compose the drug or inactive ingredient of the drug, glycerin;
- if you have tympanic perforation of chronic otitis media and otitis media with complications.

If you think you have any of the situations mentioned above, do not use the drug, talk to your doctor first and follow the given advice.

Warnings and precautions

When drug side effects appear, the treatment should be discontinued.
In these cases, when the drug is stopped, you should contact your doctor or pharmacist.

Taking other medicines

Tell your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription.

There are no data for Otol interaction with other drugs that should be taken into consideration.

Using Otol with food and drinks

There are not enough data available.

Pregnancy

Tell your doctor or pharmacist if you are pregnant, think you may be pregnant or are planning to have a baby. Otol may be used during pregnancy if your doctor considers it necessary.

Breast-feeding

Tell your doctor or pharmacist if you are breast-feeding. It is not known yet whether Otol components, active and inactive pass into breast milk. As most of the drugs pass into breastmilk, caution is required when breast-feeding mothers are using Otol. You should always consult your doctor before using Otol.

Driving and using machines

No data available.

3. HOW TO USE OTOL

Otol is used as follows:

Acute otitis

Instill some drops of solution in the sick ear and then moisten a cotton plug with Otol and insert it into the ear canal. Repeat after 1 to 2 hours until pain and congestion are relieved and then decrease the frequency of instillation at an interval of several hours.

Children: up to 6 months 2 drops every 2 hours into the affected ear.

Removal of cerumen

Instill Otol 3 times daily for 2 or 3 days to help detach cerumen from wall of canal and facilitate removal.

After cerumen is removed, Otol is used also for drying out the canal or relieving discomfort. Before and after removal of cerumen, a cotton plug moistened with Otol should be inserted into the ear canal.

Always use Otol ear drops solution only as your doctor has told you. If you feel that its effects are too strong or too weak, talk to your doctor or pharmacist.

Your doctor may ask you to use Otol for a longer time. Ask your doctor for advice if you are not

sure for how long it should be used.

If you use more Otol

If you use more Otol than you should, or if the children use it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to use Otol

If you forget to use one dose, use the next dose in its usual time.

Do not use a double dose to make up a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time they are not.

One known side effect is hypersensitivity to the active or inactive ingredients of Otol.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OTOL

Keep this medicine out of the sight and reach of children.

Do not use Otol after the expiry date which is stated on the pack (label or box).

Do not store above 25°C!

6. FURTHER INFORMATION

What Otol contains

The active substances are: procaine hydrochloride, phenol, phenazone.

1 ml solution contains 30 mg procaine hydrochloride, 20 mg phenol, 50 mg phenazone.

The other excipient is glycerin.

Contents of the pack

Box with 1 vial with dropper 5 ml.

Explanatory of the illustration icons on the packaging:



According to medical prescription.



Content.



Warning.



Ear drops.

Marketing Authorisation Holder (MAH) and Manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
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Tirana - ALBANIA

This leaflet was last revised in July 2015.

