

PACKAGE LEAFLET

AURICULARUM, powder and solvent for suspension for ear instillation

Oxytetracycline hydrochloride, Polymyxin B sulphate, Dexamethasone sodium phosphate, Nystatin

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, if you have any doubt, ask your doctor or pharmacist
- . This medicine has been prescribed for you. Never 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 AURICULARUM, powder and solvent for suspension for ear instillation IS AND WHAT IT IS USED FOR?
2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING AURICULARUM, powder and solvent for suspension for ear instillation?
3. HOW TO USE AURICULARUM, powder and solvent for suspension for ear instillation?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS?
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1. WHAT AURICULARUM, powder and solvent for suspension for ear instillation IS AND WHEN IT IS USED FOR?

This medicine is a combination of a steroidal anti-inflammatory (dexamethasone), two antibiotics (oxytetracycline and polymyxin B) and an antifungal [treatment for fungal infections] (nystatin). Oxytetracycline is an antibiotic of the cycline series. Polymyxin B is an antibiotic of the polypeptide series.

This medicine is indicated in the local treatment of certain forms of otitis.

2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING AURICULARUM, powder and solvent for suspension for ear instillation?

Never use AURICULARUM, powder and solvent for suspension for ear instillation:

- if you are allergic to oxytetracycline or another medicine of the cycline series,
- if you are allergic to polymyxin B,
- if you are allergic to nystatin,
- if you are allergic to dexamethasone or any other ingredient of the solution,
- if you have tympanum perforation without any discharge (see Special warnings),
- if you have a viral infection of the ear (varicella, herpes, etc.).

IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with AURICULARUM, powder and solvent for suspension for ear instillation:
Special warnings

Your doctor is to check the state of your tympanum before any prescription.

Stop treatment if skin rash or any other local or generalised allergic reaction occurs. Consult your doctor.

Brownish residues may persist in the auditory canal. They are not dangerous but may require cleaning by your doctor at the end of treatment.

Special attention is to be paid to patients with hearing aids. The persistence of the deposit may interfere with the operation of the hearing aid.

You are advised not to administer other medicines in the ear at the same time.

Do not inject or swallow this medicine.

At the time of use, avoid contact of the nozzle with the ear or fingers in order to limit the risks of contamination.

Precautions for use

If symptoms persist after 10 days, or even 15 days in the event of fungal infection, consult your doctor again.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Taking or using 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.

Pregnancy and lactation

This medicine is only to be used during pregnancy if necessary. This medicine may be prescribed during lactation.

Ask your doctor or pharmacist for advice before taking any medicine.

Sportsmen

This product contains an active substance (dexamethasone) that may induce a positive reaction in illicit drug screens.

3. HOW TO USE AURICULARUM, powder and solvent for suspension for ear instillation?

Posology

This medicine has been prescribed for you personally in a precise situation:

- it may not be suitable for another case;
- do not reuse it without a medical opinion;
- do not advise anyone else to use it.

As an indication, the usual dosage is as follows:

1)- In powder form: diagram No. 4

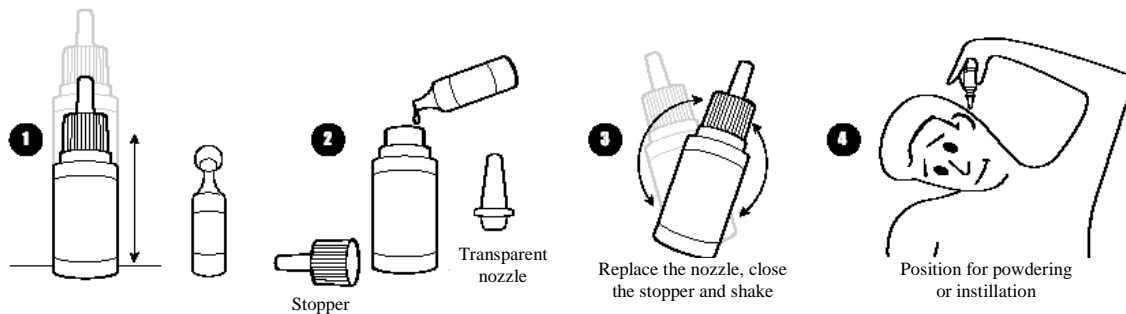
- Hold the flexible bottle, head down and with the stopper; pack all of the powder in the neck.
- Open the bottle, head downwards, and hold it as shown in diagram No. 4.
- Press the bottle to obtain a dose of product.
- Repeat the operation once or twice daily or every 2 to 3 days.

2)- In the form of a suspension: diagrams No. 1 through No. 4

- In certain particular cases, it is possible to use the powder suspended in the contents of the ampoule of solvent.
- Hold the flexible bottle, head up, and pack the powder in the bottom of the bottle.

- Open the bottle.
- Remove the transparent nozzle from the bottle.
- Open the solvent ampoule.
- Transfer the contents of the solvent ampoule into the bottle.
- Replace the transparent nozzle on the bottle, close the bottle and shake vigorously.
- From the suspension thus obtained, instill 5 to 10 drops into the auditory canal of the affected ear once or twice daily.

Always use the product as your doctor has told you.



Method of administration

Local auricular route.

For the suspension form

The auricular suspension prepared at the time of use retains its activity for 8 days **at between 2 and 8°C (in the refrigerator)**.

Warm the bottle at the time of use by holding it in the palm of the hand for several minutes in order to prevent the unpleasant contact of the cold solution with the ear. Shake vigorously before use.

Inserting the drops into the ear and conducting an ear wash:

- First tilt your head to the side opposite to the affected ear so that the affected ear is uppermost.
- Instill the drops into the affected ear.
- Pull the outer ear several times so that the drops flow into the bottom of the ear.
- Wait about 5 minutes with the head tilted.
- When you straighten your head the drops may leak out a little. Wipe with absorbent paper, which does not need to be sterile.

It is important to comply with this recommendation in order to ensure the efficacy of your treatment. The head must be maintained tilted for a sufficiently long time to ensure satisfactory penetration of the medicine into the ear. Straightening the head too early will result in loss of the medicine since drops will flow down your face and not into the ear. This will reduce the efficacy of treatment.

Close the bottle immediately after use.

At the end of treatment, the remainder of the bottle is to be discarded and must not be retained for reuse.

Frequency of administration

One or two administrations daily (powder or suspension) or 1 administration every 2 to 3 days (powder).

Treatment duration

The treatment duration is usually 7 days and may be up to 15 days in the event of fungal infection.

In order to be effective, the antibiotic is to be used regularly at the prescribed dosage and for as long as your doctor has advised you.

The resolution of symptoms does not mean that you have been completely cured. Any impression of tiredness is not due to the antibiotic treatment but to the infection itself. Reducing or suspending your treatment will have no effect on the impression of tiredness and will delay your recovery.

If you use more AURICULARUM, powder and solvent for suspension for ear instillation, than you should:

Consult your doctor or pharmacist.

If you forget to use AURICULARUM, powder and solvent for suspension for ear instillation:

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

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, AURICULARUM, powder and solvent for suspension for ear instillation, can cause side effects, although not everybody gets them.

- Exceptionally: hot sensation or itching at the start of treatment, local allergy, dizziness.
- Persistence of brownish residues in the auditory canal (see Special warnings)
- Selection of resistant germs.

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Web site: www.signalement-sante.gouv.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE AURICULARUM, powder and solvent for suspension for ear instillation?

Keep out of the reach and sight of children.

Do not use AURICULARUM, powder and solvent for suspension for ear instillation, after the expiry date which is stated on the box.

Before reconstitution: do not store above 25°C.

After reconstitution: the suspension for auricular instillation is to be stored at between 2°C and 8°C (in the refrigerator) for a maximum of 8 days.

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What does AURICULARUM, powder and solvent for suspension for ear instillation, contain?

The active substances are:

Oxytetracycline hydrochloride	100.0 mg
Polymyxin B sulphate	12.3 mg
Dexamethasone sodium phosphate	10.0 mg
Nystatin	1,000,000 IU
	per bottle.

The other ingredients are:

Sodium laurylsulphate.

Solvent composition: sodium chloride, purified water.

What is AURICULARUM, powder and solvent for suspension for ear instillation and contents of the outer pack?

This medicine is a powder and solvent for suspension for auricular instillation. Box of 1.

Marketing Authorisation Holder: Laboratoires GRIMBERG SA – 44 avenue Georges Pompidou – 92300 Levallois-Perret - FRANCE

Manufacturer:

Laboratoires GRIMBERG SA - ZA des Boutries - rue Vermont - 78704 Conflans Sainte Honorine cedex– FRANCE

This leaflet was last revised in January 2019.

HEALTH ADVICE / EDUCATION

WHAT DO YOU NEED TO KNOW ABOUT ANTIBIOTICS?

Antibiotics are effective in combating infections due to bacteria. They are not effective against infections due to viruses.

Accordingly, your doctor has chosen to prescribe this antibiotic for you because it is precisely suitable for your case and your current disease.

Bacteria are able to survive and reproduce despite the action of an antibiotic. This phenomenon is known as resistance: it makes certain antibiotic treatments inactive.

Resistance is increased by the misuse or inappropriate use of antibiotics.

You may promote the emergence of resistant bacteria and thus delay your recovery or even make this medicine inactive if you do not comply with:

- the dose to be taken,
- the times of dosing,
- and the duration of treatment.

In consequence, in order to maintain the efficacy of this medicine:

- 1- Only use an antibiotic when your doctor has prescribed it.**
- 2- Strictly comply with your prescription.**
- 3- Do not reuse an antibiotic without a medical prescription even if you think the disease is apparently similar.**
- 4- Never give your antibiotic to anyone else, it may not be suitable for his/her disease.**
- 5- When you have completed your treatment, take all the remaining boxes back to your pharmacist for correct and appropriate destruction of this medicine.**