

Package leaflet: information for the patient
AURICULARUM, powder and solvent for suspension for ear instillation

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, 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT AURICULARUM, powder and solvent for suspension for ear instillation IS AND WHAT IT IS USED FOR?
2. WHAT YOU NEED TO KNOW BEFORE YOU USE AURICULARUM, powder and solvent for suspension for ear instillation?
3. HOW TO USE AURICULARUM, powder and solvent for suspension for ear instillation?
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1. WHAT AURICULARUM, powder and solvent for suspension for ear instillation IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: otological drugs; corticosteroids and anti-infectives in combination dexamethasone and anti-infectives – ATC code: S02CA06

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.

You should contact your doctor if you do not feel any improvement or if you feel worse after 10 days, or even 15 days in case of infection due to a fungus.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AURICULARUM, powder and solvent for suspension for ear instillation?

Do not use AURICULARUM, powder and solvent for suspension for ear instillation:

- if you are allergic (hypersensitive) to oxytetracycline or another medicine of the cycline series,
- if you are allergic (hypersensitive) to polymyxin B,
- if you are allergic (hypersensitive) to nystatin,
- if you are allergic (hypersensitive) to dexamethasone or any other ingredient of the solution, see section 6
- if you have tympanum perforation without any discharge (due to trauma),
- if you have a viral infection of the ear (varicella, herpes, etc.).

Warning and precautions

Talk to your doctor or pharmacist before using AURICULARUM, powder and solvent for suspension for ear instillation.

Your doctor should 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.

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.

Other medicines and AURICULARUM, powder and solvent for suspension for ear instillation?

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Pregnancy and breast-feeding

This medicine is only to be used during pregnancy if necessary. This medicine may be prescribed during breast-feeding.

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

AURICULARUM, powder and solvent for suspension for ear instillation contains sodium laurilsulfate.

This medicine contains 3.25 mg sodium laurilsulfate in each bottle.

Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Auricular use

For information purposes, the recommended dosage is as follows:

1)- *In powder form*: One dose 1 to 2 times a day, or every 2 to 3 days depending on the following administration (diagram No. 4).

Direct the soft bottle, upside down with the stopper; pack the entire powder back in the neck area.

Open the bottle, head downwards, and position it as shown in diagram No. 4.

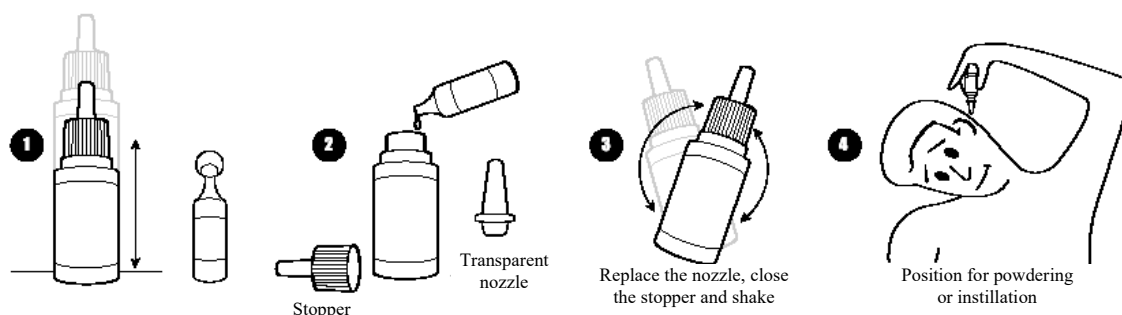
Press the bottle to obtain a dose of the product.

2)- *In the form of a suspension*: 5 to 10 drops 1 to 2 times a day depending on the following administration (diagram No 1 to No. 4).

In certain particular cases, it is possible to use the powder suspended in the contents of the ampoule of solvent.

- Hold the soft 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.
- Incorporate the contents of the solvent ampoule into the bottle.
- Replace the transparent nozzle on the bottle, close the bottle and shake vigorously.

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.



For putting the drops into the ear and conducting an ear wash:

First, the head should be tilted to the opposite side of the affected ear so that the affected ear is at the top.

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 run your face down 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 (see section 5).

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 immediately.

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

Do not take a double dose to make up for the dose you forgot.

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

4. POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine 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 Warning and precautions)
- Selection of resistant germs.

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system.

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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.

Before reconstitution: do not store above 25°C.

After reconstitution: the suspension for auricular instillation keeps its activity for 8 days when stored **between + 2°C and + 8°C (in the refrigerator).**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What AURICULARUM, powder and solvent for suspension for ear instillation, contains?

- 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 AURICULARUM, powder and solvent for suspension for ear instillation looks like and contents of the 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 September 2020.

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 you 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.