

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Cetraxal Plus 3 mg/ml + 0.25 mg/ml
ear drops solution in single-dose container
 Ciprofloxacin/ Fluocinolone acetonide

30 mm PLEGADO

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 further questions, please 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 effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cetraxal Plus is and what it is used for
2. What you need to know before you use Cetraxal Plus
3. How to use Cetraxal Plus
4. Possible side effects
5. How to store Cetraxal Plus
6. Contents of the pack and other information

1. What Cetraxal Plus is and what it is used for

Cetraxal Plus is a solution for auricular use (in the ear). It contains:

- Ciprofloxacin, an antibiotic belonging to the group known as the fluoroquinolones. Ciprofloxacin works by killing bacteria that cause infections,
- and fluocinolone acetonide, a corticosteroid with anti-inflammatory and analgesic properties for treatment of swelling and pain.

It is used in adults and in children aged 6 months and older to treat acute otitis externa (infection of the outer ear) and otitis media (infection of the middle ear) with draining ear tubes (tympanostomy tubes) of bacterial origin.

You must talk to a doctor if you do not feel better or if you feel worse once the treatment has ended.

2. What you need to know before you use Cetraxal Plus

Do not use Cetraxal Plus

- if you are allergic (hypersensitive) to ciprofloxacin, other quinolones, fluocinolone acetonide or any of the other ingredients of this medicine (listed in section 6).
- if you have an ear infection caused by virus or fungus.

Warnings and precautions

- This preparation should only be applied to the ear. It should not be swallowed, injected or inhaled. It should not be used in the eye.
- Once treatment has begun, if you develop urticaria (hives), skin rash or any other allergic symptoms (e.g. sudden swelling of face, throat or eyelids, respiratory difficulty), you must stop treatment immediately and you should consult with your doctor. Serious hypersensitivity reactions may need immediate emergency treatment.
- Talk to your doctor if the symptoms do not improve before the end of the treatment. As with other antibiotic preparations, sometimes additional infections may occur caused by organisms which are not affected by ciprofloxacin. In case of such infection appropriate treatment should be started by your doctor.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children

There is insufficient clinical experience available on the use of Cetraxal Plus in children below 6 months, so talk to your doctor before giving this medicine if your child has this age.

Other medicines and Cetraxal Plus

Tell your doctor or pharmacist if you are taking/using or have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription. The use in conjunction with other ear medicines is not recommended.

Pregnancy, breast-feeding and fertility

There are no adequate and well-controlled studies with Cetraxal Plus in pregnant women. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Caution should be exercised when Cetraxal Plus is used during breastfeeding since it is not known whether Cetraxal Plus is excreted in human milk.

Driving and using machines

Given the characteristics and administration route of this medicine, Cetraxal Plus does not affect the ability to drive vehicles or operate dangerous machinery.

3. How to use Cetraxal Plus

Cetraxal Plus is intended to be administered into the ear only (auricular use).

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

The recommended dose in adults and children is the contents of 1 single-dose container in the affected ear twice a day for 7 days.

Only use Cetraxal Plus in both ears if your doctor told you to do so.

Your doctor will tell you how long your treatment with Cetraxal Plus will last. To make sure that the infection does not return, do not stop treatment early even if your ear(s) feel better.

Instructions of administration

1. The person giving Cetraxal Plus should wash his or her hands with soap and water.
2. Gently clean any discharge that can be removed easily from the outer ear. Do not insert any object or swab into the ear canal.
3. Detach the single-dose container from the pack.
4. Warm the ear drops by holding the single-dose container in your hands for 1 or 2 minutes.
5. Twist off the single-dose container cap.
6. Tilt your/your child's head to one side to keep the affected ear up.
7. Place all the content of 1 single-dose container in the ear.
- 8a. For patients with outer ear canal infection, gently pull the outer ear lobe upward and outward. This will allow the ear drops to flow down into the ear canal.
- 8b. For patients with middle ear infection, pump the tragus (the small piece of cartilage found in front of the ear canal) 4 times by pushing inward to allow the medicine to penetrate the middle ear. This will allow the drops to pass through the tube in the eardrum and into the middle ear.
9. Keep the patient's head tilted sideways for approximately 1 minute to allow the medicine time to penetrate the ear. When instilling ear drops, raising the head to the vertical position or moving too rapidly may cause part of the medicine to leak out of the ear canal. This should be avoided as it may prevent the medicine from reaching the full depth of the ear canal. Discard the single-dose container after the administration.
10. Repeat all steps, if necessary, for the opposite ear.

It is of the most importance to follow this instruction to have a good efficacy of the drug in your ear.

If you use more Cetraxal Plus than you should

Symptoms of overdose are unknown. In case of overdose or if the medicine is accidentally swallowed, contact your doctor or pharmacist immediately or go to the closest medical service.

If you forget to use Cetraxal Plus

Do not take a double dose to make up for a missed dose. Just continue your next dose.

If you stop using Cetraxal Plus

Do not stop using Cetraxal Plus without telling your doctor or pharmacist. It is very important to use these ear drops for as long as the doctor has instructed, even if the symptoms improve. If you stop using the medicine sooner, the infection may not disappear and the symptoms may reappear again or even worsen. Antibiotic resistance may also be produced.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following, stop taking this medicine and tell your doctor immediately: swelling of hands, feet, ankles, face, lips, mouth or throat, difficulty in swallowing or breathing, rash or hives, sores, ulcers.

Common: May affect up to 1 in 10 people

Effects in the ear: Discomfort, pain, itching.
General side effects: Abnormal taste.

Uncommon: May affect up to 1 in 100 people

Effects in the ear: Ringing, residue of medication, blockage of tube draining the ear, tingling, congestion, reduced hearing, rash, redness, fungal infection of outer ear, discharge, swelling, tympanic membrane disorder, granulation tissue, contralateral otitis media.
General side effects: Candida infection, irritability, crying, dizziness, flushing of skin, headache, vomiting, fatigue.

Not known (frequency cannot be estimated by available data):

Eye disorders: Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (See section 6). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetraxal Plus

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

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

Store below 30°C. Store the pouch in the original packaging in order to protect from light. Discard 7 days after first opening of the pouch.

After first opening of a single-dose container: use immediately and discard the single-dose container after use.

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

6. Contents of the pack and other information

What Cetraxal Plus contains

- The active substances are ciprofloxacin in the form of ciprofloxacin hydrochloride and fluocinolone acetonide.

Each millilitre of Cetraxal Plus contains 3 mg of ciprofloxacin (as hydrochloride) and 0.25 mg of fluocinolone acetonide. Each single-dose container (0.25 ml) delivers 0.75 mg of ciprofloxacin and 0.0625 mg of fluocinolone acetonide.

- The other ingredients are polysorbate 80, glycerin, povidone and purified water.

What Cetraxal Plus looks like and contents of the pack

Cetraxal Plus is a colourless or slightly yellow, clear ear drops solution for auricular use contained in single-dose containers. The single-dose containers are packed in an aluminium foil overwrap pouch for protection. Each pack contains 15 single-dose containers.

Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections. If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosages,
- schedules,
- duration of treatment.

Consequently, to preserve the efficacy of this drug:

1. Use antibiotics only when prescribed.
2. Strictly follow the prescription.
3. Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
4. Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
5. After completion of treatment, return all unused drugs to your pharmacy to ensure they will be disposed of correctly.

Marketing Authorisation Holder and Manufacturer

Laboratorios Salvat, S.A.
 C/ Gall 30-36
 08950 - Esplugues de Llobregat
 Barcelona
 Spain

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To report any side effects

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)
 Fax: +966-11-205-7662
 Call NPC at +966-11-2038222,
 Exts: 2317-2356-2340.
 Reporting hotline: 19999
 E-mail: npc.drug@sfd.gov.sa
 Website: www.sfd.gov.sa/npc

United Arab of Emirates:

Pharmacovigilance & Medical Device Section
 P.O.Box: 1853
 Tel: 80011111
 Email: pv@moh.gov.ae
 Drug Department
 Ministry of Health & Prevention
 Dubai, UAE

Other GCC States:

Please contact the relevant competent authority.


Council of Arab Health Ministers

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
 Union of Arab Pharmacists

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Características Técnicas 	H.P.: 12103	C. Barras: 204 Medidas Plegado: 130 x 30 mm	C.I.: 84415
	C. Cliente: LAB. SALVAT, S.A. Producto: CETRAXAL PLUS SD AE-KW LUNATUS Código: 427050-01 Papel: PRIMABRITE Medidas: 130 x 540 mm Tipografía: TRAZADA Colores: I + I NEGRO		
		Fecha y Firma <div style="border: 1px solid black; width: 100px; height: 20px; margin: 0 auto;"></div>	
		Fecha: 11 / 03 / 2021	

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