

Package leaflet: Information for the user
Cetraxal Plus 3 mg/ml + 0.25 mg/ml ear drops solution
in single-dose container
Ciprofloxacin/ Flucinolone acetonide

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 flucinolone 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, flucinolone acetonide or any of the other ingredients of this medicine (listed in section 6).
- if you have an ear infection caused by a 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.
- Tell 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 is this age.

Other medicines and Cetraxal Plus

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

Use in conjunction with other ear medicines is not recommended.

Pregnancy and breast-feeding

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 breast-feeding 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).

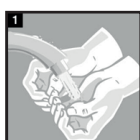
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

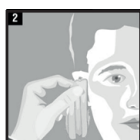
Only use Cetraxal Plus in both ears if your doctor told you to do so.

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 for administration



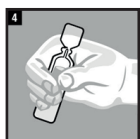
1. The person giving Cetraxal Plus should wash his or her hands with soap and water.



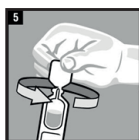
2. Gently clean any discharge that can be removed easily from the outer ear. Do not insert any object or swab into the ear canal.



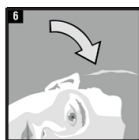
3. Detach the single-dose container from the pack.



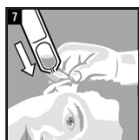
4. Warm the ear drops by holding the single-dose container in your hands for 1 or 2 minutes.



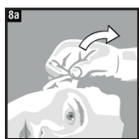
5. Twist off the single-dose container cap.



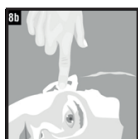
6. Tilt your/your child's head to one side to keep the affected ear up.



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 some 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 important to follow these instructions to make sure this medicine works.

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 nearest hospital.

If you forget to use Cetraxal Plus

Do not take a double dose to make up for a missed dose. Just continue with 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 eardrops for as long as the doctor has instructed, even if the symptoms improve. If you stop using the medicine sooner, you may not get better and the symptoms may come back or get worse. Antibiotic resistance may also occur.

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.

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 via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). 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 reach of children.

Do not use this medicine after the expiry date which is stated on the label after 'Exp'. 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 the pouch.

After first opening 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 aqueous 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 medicine:

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

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

This leaflet was last revised in 04/2019