

PACKAGE LEAFLET: INFORMATION FOR THE USER

CetraXal 2mg/ml ear drops, solution single-dose container

Ciprofloxacin

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, 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT CETRAXAL IS AND WHAT IT IS USED FOR

CetraXal 2mg/ml ear drops solution is a solution for auricular use (in the ear) that contains ciprofloxacin, the active substance which is an antibacterial agent belonging to the group of fluoroquinolones. Ciprofloxacin works by killing bacteria that cause infections. CetraXal 2mg/ml ear drops solution is indicated for the treatment of acute external otitis of bacterial origin in adults and children older than 1 year where the eardrum is still intact (see section 2. *What you need to know before you use CetraXal*).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CETRAXAL

Do not use CetraXal:

- if you are allergic (hypersensitive) to ciprofloxacin, to any member of the quinolone class of antimicrobial agents or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions

- 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.
- 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.
- Tell the doctor if the symptoms do not improve within one week of starting treatment.
- As with all antibiotics, 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.
- CetraXal 2mg/ml ear drops solution should be used with caution in patients with known or suspected perforation, or where there is a risk of perforation of the tympanic membrane.

Other medicines and CetraXal

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

Pregnancy, breast-feeding and fertility

CetraXal can be used during pregnancy and during breast-feeding.

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 taking this medicine.

Driving and using machines

CetraXal does not affect the ability to drive vehicles or operate dangerous machinery.

3. HOW TO USE CETRAXAL

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

This medicine is intended to be administered into the ear. It should not be swallowed, injected or inhaled.

Dosage

The recommended dose is for children (age 1 year and older) and adults, the contents of 1 single ampoule should be instilled into the affected ear twice daily for seven days.

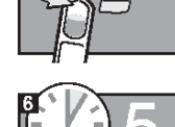
Administration

Warm the solution, by holding the ampoule in the hand for several minutes, to avoid the dizziness that may result from the instillation of a cold solution into the ear canal. Lie with the affected ear upward and then instil the drops pulling several times on the auricle. Maintain the position for around 5 minutes, to facilitate penetration of the drops into the ear. When you stand up again, some drops can fall out. You can dry them with a non-sterile absorbent paper. Repeat, if necessary, for the opposite ear.

If the auditory canal is narrow, the medicine can be made to reach the eardrum by pulling the ear upwards.

It is of the most importance to follow this instruction to have a good efficacy of the drug in your ear. When you instil ear drops, maintaining your head vertically or moving your head too rapidly will cause you to lose a part of the drug because drops are going to run down on your face and do not go into the depth of the auditory canal.

Discard the single-dose container after the use. Do not keep it for subsequent use.



If you use more Cetraxal than you should

Since this is a single-dose preparation, an accidental overdose is unlikely. In any case you should contact your doctor or pharmacist for advice.

If you forget to use Cetraxal

Do not use a double dose to make up for a missed one.

If you forget to apply your drops, apply the correct dose when you remember or if it is close to your next application then wait until this time.

If you stop using Cetraxal

It is very important to use these eardrops for as long as the doctor has instructed, even if the symptoms improve. Do not interrupt your treatment before time, as the infection could return.

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.

Uncommon: may affect up to 1 in 100 people:

- Ear pruritus (itching), ringing in the ears
- Headache
- Dizziness
- Local skin reactions or irritation (Dermatitis)
- Pain in the application site

Very rare: may affect up to 1 in 10,000 people:

- Rash
- Blistering and tissue break down (Toxic epidermolysis)
- Redness and scaling of the skin (Exfoliative dermatitis)
- Serious allergic reaction with fever, red patches, joint pain and/or eye problems (Stevens-Johnson syndrome)
- Skin allergy with development of itchiness and wheals (Urticaria)

If you consider that any of the side effects you suffer are serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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). By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CETRAXAL

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 package. The expiry date refers to the last day of that month.

Store below 30°C in the original package, in order to protect from light.

The ampoule contents should be used immediately after opening the single dose ampoule. Any unused contents should be discarded.

Once the pouch is opened, use within 8 days.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cetraxal contains

- The active substance is ciprofloxacin as hydrochloride.
1ml solution contains 2mg of ciprofloxacin as hydrochloride. Each ampoule delivers 0.25ml of solution that contains 0.58mg of ciprofloxacin hydrochloride corresponding to 0.50mg of ciprofloxacin.
- The other ingredients are povidone-K-90-F (E1201), glycerol (E422), purified water and sodium hydroxide (E524) and/or lactic acid (E270) for pH-adjustment.

What Cetraxal looks like and contents of the pack

Cetraxal is a clear ear drops solution contained in ampoules. The ampoules are packed in an aluminium foil overwrap pouch for protection. Each pack contains 15 ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Rd, 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 10/2017.

Artwork for:	Aspire Pharma Limited
Product name:	Cetralax 2mg/ml ear drops solution
Size:	
PL/PA no:	
Type:	Leaflet
Artwork dimensions:	375mm x 130mm
Profile supplied:	Dimensions and style supplied
Date of first artwork:	4 May 2017
Reason for request:	COO-minor amends
Version no:	2.3
Date of revision:	4.10.17
Colours:	As swatch(es)
Font(s):	8 on 9pt Times New Roman
Artwork software:	InDesign CC
BAC ref:	U173

