PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Cetraxal Ear drops

Active ingredients:

Ciprofloxacin (as HCl)	3 mg/ml
Fluocinolone Acetonide	0.25 mg/ml

For information regarding inactive ingredients and allergens, see section 2 – "Important information about some ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for local treatment of an acute inflammation of the outer ear (acute otitis externa) and an inflammation of the middle ear (otitis media) following ear tube surgery, caused by bacteria.

The medicine is intended for adults and children over 6 months of age.

Therapeutic class:

Ciprofloxacin – a fluoroquinolone antibiotic. Ciprofloxacin works by killing infection-causing bacteria.

Fluocinolone acetonide – a corticosteroid with anti-inflammatory and pain-relieving properties for treatment of swelling and pain.

2. Before using the medicine

☒ Do not use this medicine if:

- You are sensitive to fluocinolone acetonide, ciprofloxacin, other quinolones, or to any of the additional ingredients the medicine contains (see section 6).
- In case of an ear infection caused by a virus or fungus.

❗ Special warnings regarding the use of the medicine

- If during treatment you develop signs of urticaria (hives), skin rash or other allergy signs (e.g., sudden swelling of the face, throat or eyelids, trouble breathing), you must discontinue treatment immediately and contact your doctor. An immediate emergency treatment may be required if you suffer from severe reactions of hypersensitivity.
- The preparation is only intended for local administration in the ear – do not swallow, inject or inhale the solution. The preparation is not intended to be used in the eyes.
- If the symptoms do not improve before the end of the treatment, inform the doctor. As with other antibiotic preparations, sometimes another infection may occur, caused by organisms that are not affected by ciprofloxacin. In case of such an infection, an appropriate treatment should be started as instructed by your doctor.
- Tell the doctor if you experience blurred vision or any visual disturbances.

❗ Children and adolescents

This medicine is intended for children over 6 months of age.

❗ Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and dietary supplements, tell the doctor or the pharmacist. Combination with other ear medications is not recommended.

❗ Pregnancy and breastfeeding

No proper and appropriately-controlled studies have been conducted on Cetraxal in pregnant women. If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Caution should be exercised when using Cetraxal while breastfeeding, since it is unknown whether Cetraxal passes into breastmilk.

❗ Driving and operating machinery

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

❗ Important information about some ingredients of the medicine

The preparation contains preservatives: propyl parahydroxybenzoate and methyl parahydroxybenzoate, which may cause an allergic reaction (delayed allergic reaction is also possible).

3. How should you use the medicine?

Cetraxal is intended to be used in the ear only.

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage for adults and children over 6 months of age is: 6-8 drops into the affected ear twice a day, for 7 days.

Do not exceed the recommended dose.

Use Cetraxal in both ears only if the doctor told you to do so. The duration of treatment with Cetraxal will be determined by the doctor. To make sure the infection will not return, do not stop the treatment earlier than prescribed, even if your ear(s) feel(s) better.

Do not swallow nor inject the medicine. The preparation is intended for external use only.

How to use the preparation:

The person administering Cetraxal must wash their hands.

1. Warm the bottle between your palms for a few minutes before administration until it reaches body temperature, in order to prevent dizziness which may occur as a result of administering cold solution into the ear canal. (figure 1).
2. Lie down or tilt your head such that the ear to be treated faces upwards. (figure 2).
3. Administer the drops into the ear using the dropper. To avoid contamination of the solution, do not allow the tip of the bottle to come into contact with any surface (including the ear and the fingers). (figure 3).
4. After administering the drops, follow the instructions below according to the type of infection.
   In patients with an inflammation of the middle ear following ear tube surgery: while the patient is lying on his side, the person administering Cetraxal should gently press the flap of skin at the entrance to the ear canal (figure 4a) 4 times using a pumping motion. This will enable the drops to penetrate through the tympanostomy tubes into the middle ear.
   In patients with an acute inflammation of the outer ear: while the patient is lying on his side, the person administering Cetraxal should gently pull the ear lobe upwards and backwards (figure 4b). This will enable the ear drops to flow into the ear canal.
5. Keep the ear facing upwards for one minute following administration of the solution, to allow the medicine to go down into the ear canal.
6. Repeat the process if the other ear also requires treatment.

It is highly important to follow these instructions for the medicine to work effectively in the ear. During administration of the ear drops, vertical position of the head or moving the head too fast may cause partial loss of the medicine, since the drops will run down on your face and not go deep into the ear canal.

Keep the bottle until the end of the treatment. Do not keep it for future use.

If you accidentally administer a higher dose or if a child accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you have forgotten to administer this medicine at the required time, do not administer a double dose. Administer the next dose at the regular time and consult a doctor.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

Do not stop treatment with the medicine without consulting the doctor or pharmacist. It is highly important to use these ear drops for the entire duration of treatment prescribed by the doctor, even if the symptoms improve. If you stop using the medicine earlier than that, the infection may not go away and the symptoms may return or even worsen. Resistance to antibiotics may also develop.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, use of Cetraxal may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using this medicine and refer to a doctor immediately:

If you have a serious allergic reaction or any of the following: swelling of the hands, feet, ankles, face, lips, mouth or throat, swallowing or breathing difficulties, rash or hives, sores, ulcers.

Additional side effects

Common side effects - side effects that occur in 1-10 out of 100 users

Side effects in the ear: discomfort, pain, itching

General side effects: unusual taste

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users

Side effects in the ear: ringing, feeling residue of the medicine in the ear, blockage of the ear's draining tube, tingling, congestion, hearing deterioration, rash, redness, fungal infection of the outer ear, secretion, swelling, tympanic membrane impairment, granular tissue, middle ear inflammation (otitis media) in the other ear.

General side effects: candida infection, nervousness, crying, dizziness, skin flushing, headache, vomiting, fatigue.

Side effects with unknown frequency

Eye disturbances: blurred vision

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (EXP) appearing on the package/bottle. The expiry date refers to the last day of that month.

Storage:

Store at a temperature lower than 30°C.

May be used up to one month after opening.

6. Additional information

In addition to the active ingredients the medicine also contains:

Diethylene glycol monoethyleter, Glycereth-26 (compound of glycerine and ethylene oxide), Povidone, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Hydrochloric Acid, Purified Water.

What does the medicine look like and what are the contents of the package

A clear solution, packed in a white plastic bottle with a dropper. Each bottle contains 10 ml of solution.

License holder and address: CTS Ltd., 4 Haharash St., Hod Hasharon.

Name and address of the manufacturer:

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

This leaflet was revised in January 2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1481333374