

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ciprofloxacin ABR 3 mg/ml eye and ear drops, solution

Ciprofloxacin

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ciprofloxacin ABR is and what it is used for
2. Before you use Ciprofloxacin ABR
3. How to use Ciprofloxacin ABR
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5. How to store Ciprofloxacin ABR
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1. WHAT CIPROFLOXACIN ABR IS AND WHAT IT IS USED FOR

Ciprofloxacin ABR belongs to a group of medicines, called quinolone antibiotics. These are active against a large number of microorganisms causing infections and inflammations of the eye and the ear.

Ciprofloxacin ABR is indicated for:

- Treatment of corneal ulcers;
- Treatment of other inflammations of the ocular surface (conjunctivitis) and adjacent areas;

- Treatment of inflammations of the external ear (commonly observed in swimmers) and the middle ear, with discharge due to a perforation (rupture) of the ear drum.

2. BEFORE YOU USE CIPROFLOXACIN ABR

Do not use Ciprofloxacin ABR

- if you are allergic (hypersensitive) to ciprofloxacin or any of the other ingredients of Ciprofloxacin ABR;
- if you are allergic (hypersensitive) to other medicine of the group of quinolone antibiotics.

Take special care with Ciprofloxacin ABR

- If you experience itching and swelling of the eyelids, reddening of the eye, swelling of the face or throat, skin rash or any other symptom of an allergic reaction, stop using Ciprofloxacin ABR and contact your attending physician.
- You may become more sensitive to sunlight while using Ciprofloxacin ABR. Avoid exposure to intensive sunlight during this period.
- Prolonged use of Ciprofloxacin ABR, as well as other antibiotic products, may result in development of a superinfection with bacteria or fungi, non-susceptible to the antibiotic. Apply Ciprofloxacin ABR as long as prescribed.
- The use of Ciprofloxacin ABR is not recommended in newborns with neonatal conjunctivitis (a type of eye infection).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Quinolone antibiotics may interfere with some medicines, containing theophylline (for the treatment of asthma), caffeine or warfarin (a product preventing coagulation).

Taking Ciprofloxacin ABR with food and drink

No interactions have been established.

Pregnancy and breast-feeding

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

If you are pregnant, making attempts to get pregnant or breast-feeding at present, Ciprofloxacin ABR should be administered with caution and by your attending physician's prescription only.

Driving and using machines

As with all products for ocular use, transient blurring of vision or other disturbances may affect the ability to drive and use machines. After insertion of Ciprofloxacin ABR, you should wait until your vision clears, before you start operating machines or driving.

There are no known effects of Ciprofloxacin ABR on the ability to drive and use machines after its application in the ear. It is unlikely to have an effect.

Important information about some of the ingredients of Ciprofloxacin ABR

Ciprofloxacin ABR contains a preservative (benzalkonium chloride), which may induce irritation of the eyes. If you wear contact lenses, it may precipitate on the lens surface or decolourise it. Therefore, prior to applying Ciprofloxacin ABR, the contact lenses should be removed and an interval of at least 15 minutes should be allowed before they are inserted again.

It is important to know, that you should not wear contact lenses in case of available eye infection.

3. HOW TO USE CIPROFLOXACIN ABR

Always use Ciprofloxacin ABR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Ocular use:

Adults, newborns (0 - 27 days), breast-fed and young children (28 days - 23 months), children (2 - 11 years) and adolescents (12 - 16 years):

Corneal ulcers:

Ciprofloxacin ABR should be applied at the following intervals, even during the night:

Day 1: 2 drops are instilled in the conjunctival sac of the affected eye/eyes every 15 minutes for the first 6 hours; then, until the end of the day, 2 drops are instilled every 30 minutes.

Day 2: 2 drops are instilled in the conjunctival sac of the affected eye/eyes every hour.

From Day 3 to Day 14: 2 drops are instilled in the conjunctival sac of the affected eye/eyes every 4 hours. If a course of treatment longer than 14 days is required, the dosing regimen should be determined by the attending physician.

Superficial infections of the eye and adjacent areas:

The usual dose is 1 - 2 drops in the conjunctival sac of the affected eye/eyes 4 times daily (at 6-hour intervals).

In more severe infections, the dose for the first two days is: 1 - 2 drops in the conjunctival sac of the affected eye/eyes, every 2 hours during the day.

Use in the elderly (over 65 years of age): there is no need of dose adjustment.

The usual duration of the treatment with Ciprofloxacin ABR is 7 - 14 days. The duration of treatment is determined by the attending physician.

During simultaneous application with any other product for ocular use, the interval between the applications of the two products should be at least 10 minutes.

Keeping hygiene during the instillation of the drops is of importance. Avoid the contact between the tip of the vial and the eye or surrounding objects, since the tip may be contaminated, thus leading to development of eye infection with serious sequels for the eye, even to loss of vision. Always wash your hands before using the vial!

If you think that your vial is contaminated, contact your doctor before continuing the application of this eye drops.



Instructions for use

1. Before you start using the vial, make sure that the protective strip between the cap and the vial is not broken. Wash your hands and unscrew the cap.
2. Tilt your head slightly backwards and pull the lower eyelid downwards. Thus, a pouch is formed between the eyelid and the eye. The eye drop will fall just into this place.
3. Hold the vial downwards. Put its tip close to the eye. Use a mirror, if helpful.
4. Pay attention not to touch the tip of the vial to the eye, eyelid or adjacent surfaces. Press carefully the vial base to let fall a drop of Ciprofloxacin ABR. Only a slight pressure on the vial bottom is needed.
5. After you have instilled Ciprofoxacin ABR, close the eyelid and by using your finger, press at the corner of your eye near your nose. This will prevent Ciprofloxacin ABR from passing into the nose or running out.
6. If it is necessary to apply the eye drops in both eyes, repeat all previously described steps for the other eye.

If the eye drop fails to fall in the eye, try again.

Use this vial of Ciprofloxacin ABR for your eyes only!

Auricular use

Use in adults, including the elderly (over 65 years of age):

The dose is 4 drops of Ciprofloxacin ABR, instilled 2 times daily in the ear canal.

Use in children at and over 1 year of age:

The dose is 3 drops, instilled 2 times daily in the ear canal.

In patients requiring the use of *ear tampons*, the dose can be doubled only for the first instillation (i.e. 6 drops for children and 8 drops for adult patients).

The total duration of therapy should not exceed 5 - 10 days. The prolongation of treatment is determined by the attending physician.

In case of application of more than one product for auricular use, an interval of 10 – 15 minutes should be allowed between the individual instillations.

Instructions for use

1. Before you start using the vial, make sure that the protective strip between the cap and the vial is not broken.
2. The person, who will instill Ciprofloxacin ABR should wash her/his hands with water and soap.
3. Clean carefully any discharge that may be removed easily from the external ear. Do not insert any object or tampon in the internal canal of the ear. Hold the bottle with Ciprofloxacin ABR in your hand for one – two minutes, to warm up the solution.
4. The person, who will be instilled with Ciprofloxacin ABR, should lie on one side, with her/his inflamed ear upwards.



5. Unscrew carefully the cap and hold the vial downwards, between the thumb and the middle finger.

6. Put the tip of the vial close to the ear canal. Pay attention not to touch the lobe of the ear, ear canal, adjacent tissues or surfaces with the tip of the vial! This may contaminate the ear drops.



7. By using your index finger, press the bottom of the downturned vial, to let fall a drop of Ciprofloxacin ABR, when necessary.

8. In infections of the middle ear, whilst the patient is in a lying position, the person who will instill the drops, should press the tragus (the ear projection just in front of the ear canal) very gently 4-5 times by applying pumpig movements. This will allow the drop to pass through the canal to the ear drum and in the middle ear.



9. In infections of the external ear, whilst the patient is in a lying position, the person who will instill the drops, should pull

the lobe of the ear carefully downwards and backwards. This will allow the drops to pass through the ear canal.

10. The patient should remain in a lying position for at least 5 minutes.

11. If it is necessary to apply the drops in the other ear, repeat the steps from 3 to 9.

Use this vial of Ciprofloxacin ABR for your ears only!

If the ear drop fails to fall in the ear, try again.

If you use more Ciprofloxacin ABR than you should

Ciprofloxacin ABR can be rinsed out from the eye/eyes or ear/ears with tempered water. If you have instilled an excessive amount in the ear, turn your head in a way to let the excessive liquid run out of the ear.

If you forget to use Ciprofloxacin ABR

Apply the dose as soon as you remember. If it is almost the time for your next dose, continue according to your usual regimen. Do not apply a double dose to make up for a forgotten application.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ciprofloxacin ABR can cause side effects, although not everybody gets them.

The side effects are listed in order of their frequencies, as the following classification has been adopted: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Ocular use:

The side effects that may develop during the application of Ciprofloxacin ABR are mild and alleviate rapidly after treatment discontinuation.

Eye disorders

Common – itching, sensation of a foreign body, formation of crusts and scales on the eyelid margin, reddening of the eye, occurrence of white stains on the cornea;

Uncommon – colouration of the cornea, inflammation of the cornea, depositions on the cornea, allergic reactions, swelling of the eyelid, excessive tear discharge and photosensitivity;

Not known – blurred vision, reduced vision, residues of the medicinal product.

Gastrointestinal disorders

Common – changes in sensation of taste;

Rare – nausea.

Immune system disorders

Very rare – skin rash, urticaria, toxic epidermolysis (a severe disease, accompanied by formation of blisters in the skin), exfoliative dermatitis (a skin disease with reddening and readily exfoliating of the skin), *Stevens-Johnson* syndrome (a severe disease, accompanied by formation of blisters in the skin, mouth, eyes and genitalia).

Auricular use:

Ear and labyrinth disorders

Common – itching in the ear;

Uncommon – ringing in the ears.

Skin and subcutaneous tissue disorders

Uncommon – redness, burning and itching of the skin.

General disorders and administration site conditions

Uncommon – headache.

Immune system disorders

Very rare – skin rash, urticaria, toxic epidermolysis (a severe disease, accompanied by formation of blisters in the skin), exfoliative dermatitis (a skin

disease with reddening and readily exfoliating of the skin), *Stevens-Johnson* syndrome (a severe disease, accompanied by formation of blisters in the skin, mouth, eyes and genitalia).

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

5. HOW TO STORE CIPROFLOXACIN ABR

Store below 25°C.

Keep out of the reach and sight of children.

Keep the vial tightly closed.

Do not freeze.

Dispose of the vial in 4 weeks after opening, to avoid eventual infections and contaminations.

Do not use Ciprofloxacin ABR after the expiry date which is stated on the carton.

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

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Ciprofloxacin ABR contains

- The active substance is ciprofloxacin of 3 mg/ml (as ciprofloxacin hydrochloride).
- The other ingredients are benzalkonium chloride; disodium edetate; sodium acetate trihydrate; acetic acid solution (1 mol/l); mannitol; water for injections.

What Ciprofloxacin ABR looks like and contents of the pack

Eye and ear drops, solution.

Clear liquid.

Ciprofloxacin ABR is packed in sterile, white plastic vials, closed with a plastic dropper applicator and hermetised with a sterile screw cap fitted with a “tamper-evident” ring.

1 (one) vial with a patient leaflet is inserted in a cardboard carton.

Marketing Authorisation Holder

Antibitic-Razgrad AD

Office 201, 68 “Aprilsko vastanie” Blvd

Razgrad 7200, Bulgaria

Manufacturer

Balkanpharma-Razgrad AD

68 “Aprilsko vastanie” Blvd

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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