

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

OTIXAL 3 mg/0,25 mg per 1 ml ear drops solution

**3 mg of ciprofloxacin (as hydrochloride monohydrate), 0,25 mg of fluocinolone
acetoneide**

Read all of this leaflet carefully before you start using OTIXAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- OTIXAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What OTIXAL is and what it is used for

OTIXAL is an ear drop solution and is intended for use in the ear. It contains two active ingredients:

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

It is used in patients from the age of 6 months and older to treat infections caused by bacteria affecting

- the outer ear (acute otitis externa) and
- the middle ear (otitis media) with draining ear tubes (tympanostomy tubes).

2. What you need to know before you use OTIXAL

Do not use OTIXAL:

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

Warnings and precautions

Take special care with OTIXAL:

OTIXAL should only be instilled in 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 healthcare provider. 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 medicines, sometimes additional infections may occur caused by

organisms which are not affected by OTIXAL. 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 and adolescents

There is no experience with OTIXAL in children younger than 6 months old.

Other medicines and OTIXAL

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Warfarin, a 'blood thinner', medicine used to keep blood flowing smoothly in your body.
- Other ear preparations, if you need to use more than one ear preparation it is advised to administer them apart.

Pregnancy, breastfeeding and fertility

As there is very little systemic absorption, OTIXAL may be used during pregnancy and breastfeeding.

Driving and using machines

OTIXAL may cause dizziness which may influence your ability to drive and operate machinery. You should not drive, use machinery or perform any tasks that require concentration until you are certain that OTIXAL does not adversely affect your ability to do so safely (see section 4).

3. How to use OTIXAL

Do not share medicines prescribed for you with any other person.

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


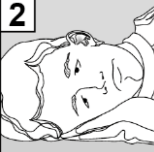
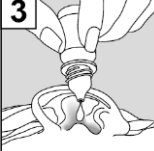

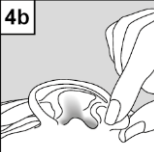
The usual dose of OTIXAL is:

Adults and children aged 6 months and older

Instil 6 to 8 drops in the affected ear twice a day for 7 days.

Your doctor will tell you how long your treatment with OTIXAL will last. Do not stop treatment early. If you have the impression that the effect of OTIXAL is too strong or too weak, tell your doctor or pharmacist.

Instructions for use

	<p>1. The person administering the OTIXAL should wash their hands. Warm the drops by holding the bottle in your hands for several minutes, to avoid dizziness that may result from the instillation of a cold solution into the ear canal.</p>
	<p>2. Tilt your head to one side to keep the affected ear up.</p>
	<p>3. Place the drops in the ear with the dropper. Avoid touching the dropper against the ear or your fingers to prevent contamination.</p>
	<p>4. After putting in the drops follow the instructions below for the patient's specific ear infection: For patients with middle ear infection with draining ear tubes: While the patient lies on his / her side, the person giving OTIXAL should gently press the flap of skin at the entrance to the ear canal (picture 4a) 4 times in a pumping motion. This will allow the drops to pass through the tube in the eardrum and into the middle ear.</p>
	<p>5. For patients with outer ear infection: While the patient lies on his / her side, the person giving OTIXAL should gently pull the outer ear lobe upward and backward (picture 4b). This will allow the ear drops to flow down into the ear canal.</p>

	6. Keep your head tilted up for around 1 minute to give the medicine time to penetrate the ear. 7. Repeat, if necessary, for the opposite ear.
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If you use more OTIXAL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use OTIXAL

Do not use a double dose to make up for forgotten individual doses.

If you have missed a dose of OTIXAL, instil the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to instil several doses, contact your doctor without delay.

4. Possible side effects

OTIXAL can have side effects.

Not all side effects reported for OTIXAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using OTIXAL, please consult your healthcare provider for advice.

If any of the following happens, stop using OTIXAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to OTIXAL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Altered or impaired sense of taste (dysgeusia),
- ear pain, ear discomfort, ear itching (pruritus).

Less frequent side effects:

- Fungus infection on the skin (candidiasis), ear infection fungal, infection of the middle ear (contralateral otitis media),
- paraesthesia (tingling in ears), dizziness, headache, crying,
- hearing loss (hypoacusis), ringing or buzzing in the ears (tinnitus), ear drainage (otorrhoea), ear congestion, inflamed eardrum (tympanic membrane disorder), ear cartilage (auricular) swelling,
- flushing,
- vomiting,
- skin exfoliation, redness of the skin (rash erythematous), rash, granulation tissue,
- irritability, fatigue,
- medicine residue,
- obstruction of the tympanostomy tube, in the ear.

Side effects with an unknown frequency:

- Blurry vision (see also section 4.4).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store OTIXAL

Store all medicines out of reach of children.

Store at or below 30 °C.

After first opening: Store at or below 25 °C and discard after 1 month.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What OTIXAL contains**

The active substances are 3 mg of ciprofloxacin (as hydrochloride monohydrate) and 0,25 mg of fluocinolone acetonide per 1 ml.

The other ingredients are compound of glycerine and ethylene oxide, diethylene glycol monoethylether, hydrochloric acid (as pH adjuster), methyl parahydroxybenzoate, povidone, propyl parahydroxybenzoate, purified water, sodium hydroxide (as pH adjuster).

Preservatives:

Methyl parahydroxybenzoate 0,06 % *m/v*

Propyl parahydroxybenzoate 0,03 % *m/v*

What OTIXAL looks like and contents of the pack

OTIXAL is a colourless or slightly yellow, clear aqueous solution without visible particulate matter.

1 x 10 ml white, low density polyethylene (LDPE) bottle fitted with a low density polyethylene dropper. The bottle is closed with a white, high density polyethylene (HDPE) cap, labelled, and packed into a cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088