

N1225U6L02/0821

Package Leaflet: Information for the patient

Azyter 15 mg/g, eye drops, solution in single-dose container

Azithromycin dihydrate

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 the doctor treating your child, or pharmacist or nurse.
- This medicine has been prescribed for you or for your child 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What AZYTER is and what it is used for

Azyter contains azithromycin, which is an antibiotic (macrolide class).

Azyter is used to treat some eye infections that are caused by bacteria in adults (including the elderly) and in children from birth to 17 years of age.

- purulent bacterial conjunctivitis,
- trachoma conjunctivitis (a particular infection of the eye caused by bacteria called *Chlamydia trachomatis*, which is usually found in developing countries).

2. What you need to know before you use AZYTER

Do not use Azyter:

- If you are allergic to azithromycin, to any other antibiotic from the macrolide class or to medium-chain triglycerides.

Warnings and precautions

Talk to your doctor, or the doctor treating your child, or your pharmacist or nurse before using Azyter.

- If you or your child have an allergic reaction, stop the treatment and tell your doctor or the doctor treating your child.
- If your or your child's eye infection does not get better after three days using the drops, or if you notice anything unusual, tell your doctor or the doctor treating your child.
- Do not wear contact lenses when you or your child have an eye infection.

Use your drops only in your eyes.
Do not inject or swallow your drops.

Other medicines and Azyter

If you are using any other eye medicine, you should:

- ① use the other eye medicine first,
- ② wait for 15 minutes,
- ③ then use Azyter last.

Tell your doctor, or the doctor treating your child, or pharmacist if you are using or have recently used or might use any other medicines.

Pregnancy

If you are pregnant, tell your doctor before using Azyter. If he or she considers it to be necessary; he or she may still give this medicine to you.

Breast feeding

You can use these drops if you are 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

You may have blurred vision for a short time after using your drops. Wait until your vision is normal before driving or using any machine.

3. How to use AZYTER

This medicine is only to be used in the eye (ocular use).

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

Dosage

The recommended dose for adults (including the elderly) and children from birth to 17 years of age is one drop twice a day in the eye(s) to be treated: one drop in the morning and one drop in the evening.

The course of treatment is three days.

Azyter eye drops have a prolonged action and will continue to work after the three day course. Do not use your drops for more than three days even if you still have some residual signs of your eye infection.

How to use Azyter

For a proper administration of Azyter:

- wash your hands well before and after using your drops,
- look up and pull down the lower eyelid,
- apply one drop into each affected eye,
- take care not to touch the eye and eyelids with the dropper tip of the single-dose container,
- **throw away the single-dose container after use. Do not keep it to use again.**

DO NOT INJECT, DO NOT SWALLOW

If you forget to use Azyter

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

If you stop using Azyter

Always tell your doctor if you want to stop the treatment.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after using this medicine as the symptoms can be severe.

Uncommon: may affect 1 in 100 people:

- serious allergic reaction which causes swelling of the face or throat (angioedema).

Not known: frequency cannot be estimated from the available data

- serious skin reactions: skin rash, skin eruption, blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN)), skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell), rash appearance as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)), generalised erythema with scaling over large areas of the body (Dermatitis Exfoliative), skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP)).

Stop taking azithromycin if you develop these skin symptoms and contact your doctor or seek medical attention immediately.

The following side effects have been observed upon using these eye drops:

Very common: may affect more than 1 in 10 people:

- itching, burning or stinging when you use the drops. This will soon pass.

Common: may affect up to 1 in 10 people:

- blurred vision,
- a feeling of sticky eye,
- a feeling there is something in your eye.

Uncommon: may affect up to 1 in 100 people:

- allergic reaction (hypersensitivity),
- inflammation of the conjunctiva (could be due to infection or allergy) (conjunctivitis),
- allergic inflammation of the conjunctiva (allergic conjunctivitis),
- inflammation of the cornea (keratitis),
- itchy skin on the eyelids (eczema eyelids),
- dry, red, swelling of the eyelids (eyelid oedema),
- eye allergy,
- eye watering,
- redness of the eyelids (erythema of eyelids),
- redness of the conjunctiva (conjunctival hyperaemia).

Reporting of side effects

If you get any side effects, talk to your doctor or the doctor treating your child, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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

5. How to store AZYTER

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 outer carton and single-dose container. The expiry date refers to the last day of that month.

- Do not store above 25°C.
- Keep the single-dose containers **in the sachet** to protect them from light.

Throw away the opened single-dose container immediately after you have used it, even if it has some solution left. Do not keep it to use again.

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 Azyter contains

- The active substance is azithromycin dihydrate. Each gram of solution contains 15 mg of azithromycin dihydrate equivalent to 14.3 mg of azithromycin. Each single-dose container of 250 mg solution contains 3.75 mg of azithromycin dihydrate.
- The other ingredient is triglycerides, medium-chain.

What Azyter looks like and contents of the pack

Azyter is an eye drops solution supplied in single-dose containers, each containing 0.25 g of the product. It is a clear, colourless to slightly yellow, oily liquid.

The pack contains six single-dose containers in a sachet, which are for one course of treatment.

Marketing Authorisation Holder

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