Package Leaflet - Information for the User

ALOMIDE® 0.1% w/v eye drops, solution Lodoxamide

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

IN THIS LEAFLET

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

1. What ALOMIDE is and what it is used for

ALOMIDE belongs to a group of medicines called anti-allergics.

It is used to treat the symptoms of allergic conjunctivitis such as red, itchy, puffy and watery eyes.

2. What you need to know before you use ALOMIDE

Do not use ALOMIDE...

- If you are allergic to lodoxamide or any of the other ingredients listed in section 6.
- In CHILDREN below 4 years of age.

Take special care...

- Only use ALOMIDE in your eye(s).
- You may experience eye discomfort, such as burning or stinging, at the beginning of treatment
 with ALOMIDE. These symptoms should wear off, however if they persist, ask your doctor for
 advice.

If any of these apply, ask your doctor for advice.

Pregnancy and breast-feeding

If you are pregnant or might get pregnant, or if you are breast-feeding a baby, **talk to your doctor** before you use ALOMIDE.

Driving and using machines

You may experience blurred vision after using ALOMIDE. Do not drive or use any machines unless your vision is clear.

Other medicines and ALOMIDE

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

If you are using more than one type of eye medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

Important information if you wear Contact Lenses

Wearing **contact lenses** is not advisable if you have allergic conjunctivitis as it may make your condition worse.

Do not use the drops while wearing **contact lenses.** Wait at least 15 minutes after use before putting your lenses back in. There is a preservative in ALOMIDE (benzalkonium chloride) that can discolour soft contact lenses.

This medicine contains 0.7mg of benzalkonium chloride in each 10ml which is equivalent to 0.07mg/ml.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor

3. How to use ALOMIDE

The recommended dose

The recommended dose is 1 or 2 drops into the affected eye 4 times a day at regular intervals.

You should notice an improvement in your symptoms within a few days, but longer treatment for up to 4 weeks is sometimes required.

Remove the loose collar from the cap when you open the bottle.

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

How to use

- Wash your hands before you start.
- Twist off the bottle cap.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).



- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- **Do not touch your eye or eyelid,** surrounding areas or other surfaces with the dropper. It could infect the drops.
- **Gently press on the base** of the bottle to release one drop at a time (picture 2).



- Release the lower eyelid and keep closed for 2 minutes.
- **Press the corner of your eye** nearest to your nose with a finger for at least **2 minutes** immediately after use. This will reduce the amount of the medicine getting to the rest of your body.
- **Do not squeeze the bottle,** only a gentle press on the bottom is needed.

• If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.

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- If a drop misses your eye, try again.
- If you forget to take ALOMIDE, do not worry, just take it as soon as possible. Do not take a double dose to make up.
- If you use more ALOMIDE than you should it can be washed out of your eye with warm water.
- If you accidentally swallow ALOMIDE consult your doctor immediately.

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

4. Possible side effects

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

• You may experience some or all of the following effects in your eye(s):

Very common (affects more than 1 user in 10): discomfort

Common (affects 1 to 10 users in 100): blurred vision, dryness, itching, increased tear production, redness.

Uncommon (affects 1 to 10 users in 1,000): pain, swelling, tired eyes, white deposits on the eye surface (cornea), feeling of something in the eye, discharge, irritation, eyelid scales.

Rare (affects 1 to 10 users in 10,000): damage or scarring to eye surface (cornea), inflammation, eye allergy, impaired vision, eyelid swelling.

You may also experience effects in other areas of your body including:

Uncommon: dizziness, headache, nausea, a feeling of warmth or flushing.

Rare: drowsiness, bad taste, dryness of the nose, sneezing, stomach discomfort, rash.

Not known (cannot be estimated from the available data): abnormal increase in heart rate.

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 national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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

5. How to store ALOMIDE

- Keep out of the reach and sight of children.
- Do not store above 25° C.
- Store upright.
- Keep the bottle tightly closed.
- Do not use the drops after the expiry date (marked 'Exp') on the bottle and the carton. The expiry date refers to the last day of that month.
- Stop using the bottle 4 weeks after first opening, to prevent infections.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- **Do not pass this medicine on to others.** It may harm them even if their symptoms are the same as yours.

6. Contents of the pack and other information

What ALOMIDE contains

- The active substance lodoxamide 0.1% w/v (as lodoxamide trometamol).
- The other ingredients are mannitol, hypromellose, sodium citrate, citric acid monohydrate, tyloxapol, disodium edetate, benzalkonium chloride, concentrated hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

What ALOMIDE looks like and contents of the pack

ALOMIDE eye drops, solution is a clear, colourless liquid supplied in a pack containing a 10 ml plastic bottle with a screw cap.

Do not use ALOMIDE if it has changed colour or become cloudy.

Marketing authorisation holder

Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ United Kingdom.

Manufacturer:

Alcon-Couvreur NV Rijksweg 14, 2870 Puurs, Belgium. DUNS: 370205429

Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ, United Kingdom.

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