LOMIDE®

Eye Drops 0.1%

Lodoxamide trometamol

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use Lomide Eye Drops.

This leaflet answers some common questions about Lomide Eye Drops. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.novartis.com.au

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using Lomide Eye Drops against the risks this medicine could have for you.

The information in this leaflet applies to Lomide only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOMIDE is used for

Lomide contains the active ingredient, lodoxamide, which is a "mast cell stabiliser" which works by preventing the allergic response to stimulants (e.g. pollen, dust) that cause conjunctivitis.

This medicine is used for the treatment of the symptoms of seasonal allergic conjunctivitis (itchy, watery or swollen eyes and/or eyelids). It is also used to treat a severe allergic condition of the eye called vernal keratoconjunctivitis or spring catarrh.

Ask your pharmacist or doctor if you have any questions about why this medicine has been given to you.

Your pharmacist or doctor may have given it for another reason.

This medicine is not addictive.

It is available from your pharmacy.

Use in children

Lomide is not recommended for use in children under 4 years.

The safety and effectiveness of Lomide in this age group have not been established.

Before you use LOMIDE

Do not use Lomide Eye Drops if you have an allergy to:

• Lodoxamide

 Other ingredients in Lomide that are listed at the end of this leaflet under "Product description" at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine if the expiry date has passed, the packaging is torn or the seal around the neck area is broken.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you use this medicine after the expiry date has passed, it may not

If you are not sure whether you should start using Lomide talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if:

- You have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes
- You are pregnant, or intend to become pregnant Your doctor will discuss the possible risks and benefits of using Lomide during pregnancy
- You are breastfeeding or intend to breastfeed
 Your doctor will discuss the possible risks and benefits of

using Lomide when you are breastfeeding.

If you have not told your doctor about any of the above, tell them before you use Lomide Eye Drops.

Do not put Lomide Eye Drops into your eye(s) while you are wearing contact lenses.

The preservative in Lomide Eye Drops, benzalkonium chloride, may be deposited in contact lenses that may cause irritation to your eyes.

You can put your contact lenses back into your eyes 15 minutes after you have used Lomide Eye Drops.

Taking or using other medicines

Tell your doctor if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Lomide Eye Drops may interfere with each other.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to use LOMIDE

Carefully follow all directions given to you by your doctor and pharmacist.

Use Lomide Eye Drops only as prescribed by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to use

The usual dose for Lomide Eye Drops for adults and children over 4 years of age is one drop in the affected eye(s) four times a day at regular intervals. After using Lomide Eye Drops wait at least 10 minutes before putting any other eye drops in your eye(s).

If you wear soft contact lenses, remove them before using this medicine. Wait for 15 minutes after using Lomide before reinserting the contact lenses.

The preservative in Lomide Eye Drops can affect the contact lenses.

Follow these steps to use the eye drops:

- 1. Wash your hands thoroughly with soap and water.
- Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- 3. Shake the bottle.
- 4. Remove the cap from the bottle.
- 5. Hold the bottle upside down in one hand between your thumb and middle finger.
- 6. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- 7. Place the tip of the bottle close to your eye. Do not let it touch your eye.
- Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger.
- 9. Close your eye. Do not blink or rub your eye.
- 10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body.
- 11. If necessary, repeat the above steps for the other eye.
- 12. Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your

- cheek. You should wipe away any spillage with a tissue.
- 13. Replace the cap on the bottle, closing it tightly.
- 14. Wash your hand again. If you have been using Lomide Eye drops in a child's eye(s) make sure that you wash the child's hands as well.

You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else.

This will help prevent the drops becoming dirty or contaminated.

When to use it

Use Lomide Eye Drops at about the same time every day unless your doctor or pharmacist tells you otherwise.

Using your eye drops at the same time each day will have the best effect in treating your allergic conjunctivitis. It will also help you remember when to use the eye drops.

How long to use it

Continue using your medicine for as long as your doctor or pharmacist tells you.

If you are unsure about when, or how, to stop using Lomide Eye Drops you should talk to your doctor or pharmacist.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use the drops as soon as you remember, and then go back to using your medicine as you would normally.

Do not use double the amount to make up for the dose that you

missed. Using multiple doses may cause unwanted side effects.

If you are not sure what to do ask your pharmacist.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

Some of the symptoms of accidently swallowing lodoxamide in doses of 0.1 mg to 10.0 mg include feeling warm, flushing, nausea, vomiting, sweating and abdominal cramps.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of Lomide, immediately telephone your doctor or the Poisons Information Centre on 13 1126 for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using Lomide

Things you must do

Tell your pharmacist or doctor immediately if you become pregnant while using Lomide.

If you are about to be started on any new medicine, remind your pharmacist or doctor that you are using Lomide.

Tell any other doctors, dentists or pharmacists who treat you that you are using this medicine.

Things you must not do

Do not use Lomide to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give it to anyone else, even if they have the same condition as you. Things to be careful of

Be careful driving or operating machinery until you know how Lomide affects you.

This medicine may cause blurred vision in some people.

If you have this symptom do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are using Lomide.

This medicine helps most people with allergic conjunctivitis but may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- · Burning, stinging or discomfort
- Itching of the eye
- · Blurred vision or dimmed vision
- Crusting of the eye lid margins
- · Dry eyes
- Tearing
- · Redness of the eye
- Discomfort or a feeling of having something in your eye
- · Pain in the eye
- Discharge from the eye
- Swelling of the eye or eye lid
- · Dim vision
- Tired eyes

• Inflammation of the eye.

These are the most common side effects of your medicine. They are usually mild and short lived.

Occasionally some people notice unwanted effects in the rest of their body as a result of using Lomide Eye Drops.

These effects may include:

- · Feeling warm
- · Headache
- Nausea
- A feeling of discomfort in the stomach
- Dizziness
- Sleepiness
- · Dry nose
- Sneezing
- Rash

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Lomide

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C. Do not freeze the eye drops.

Do not store Lomide Eye Drops or any other medicine in the car, bathroom, window sill or in other warm, damp places.

Heat and dampness can destroy some medicines.

Keep it out of the sight or reach of children.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

This eye drop contains a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection.

If you need to continue treatment get a new bottle of drops, even if there is some left in the old bottle.

Put the top back on the bottle right away after use to avoid contaminating the eye drops. Do not leave the top off the bottle for any length of time as the drops may not keep well.

Disposal

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

Lomide is a sterile solution containing lodoxamide and is available in a 10 mL Drop-tainer bottle.

Ingredients

Lomide contains the active ingredient lodoxamide (as trometamol) 1.06 mg in 1 mL.

Lomide also contains:

- Benzalkonium chloride (as a preservative)
- Mannitol
- Hypromellose
- · Sodium citrate
- · Citric acid monohydrate
- · Tyloxapol
- · Disodium edetate
- Sodium hydroxide and hydrochloric acid to adjust pH
- Purified water

Supplier

Lomide is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited ABN 18 004 244 16054 Waterloo Road Macquarie Park NSW 2113 Telephone: 1-800-671-203 Web site: www.novartis.com.au

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