

LOMIDE®

Eye Drops 0.1%

Iodoxamide trometamol

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Lomide?

Lomide contains the active ingredient Iodoxamide trometamol. Lomide eye drops are used to treat certain eye problems such as seasonal allergic conjunctivitis and vernal keratoconjunctivitis or spring catarrh.

For more information, see Section [1. Why am I using Lomide?](#) in the full CMI.

2. What should I know before I use Lomide?

Do not use if you have ever had an allergic reaction to Lomide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Lomide?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lomide and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Lomide?

- Use one drop in each eye, four times a day at regular intervals.
- Follow the instructions provided and use Lomide eye drops until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use Lomide?](#) in the full CMI.

5. What should I know while using Lomide?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or optometrist you visit that
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	<p>you are using Lomide eye drops.</p> <ul style="list-style-type: none"> ● Call your doctor immediately if you develop any signs of allergic reactions such as swelling of the face, lips, tongue or other parts of the body, rash, hives. ● Do not touch the dropper tip to any surface to avoid contamination.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly. ● Do not put Lomide eye drops in your eyes if you are wearing contact lenses as it may cause irritation to your eyes and discolor the soft contact lenses ● Do not give Lomide eye drops to anyone else, even if they seem to have the same condition as you.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Precaution should be taken before you drive

	<p>or use any machines or tools.</p> <ul style="list-style-type: none"> ● Lomide eye drops may cause temporary blurred vision or other eye problems in some people. ● Wait until vision clears before driving or using machinery.
Looking after your medicine	<ul style="list-style-type: none"> ● Store below 25°C. ● Do not freeze the eye drops. ● Discard any remaining eye drops after 28 days after opening it.

For more information, see Section [5. What should I know while using Lomide?](#) in the full CMI.

6. Are there any side effects?

Common side effects include blurred vision, eye pain, dry or itchy eye(s), feeling of temporary burning sensation or sharp, painful sensation in eye(s), swelling around the eye(s) or eyelids, eye irritation.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LOMIDE®

Eye Drops 0.1%

Iodoxamide trometamol

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lomide. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Lomide.**

Where to find information in this leaflet:

- [1. Why am I using Lomide?](#)
- [2. What should I know before I use Lomide?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Lomide?](#)
- [5. What should I know while using Lomide?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Lomide?

Lomide eye drops contains the active ingredient Iodoxamide trometamol.

Lodoxamide trometamol belongs to a class of drugs called " Mast Cell Stabilisers." It works directly on mast cells and prevents allergic reaction to stimulants (e.g. pollen, dust) that cause conjunctivitis.

Lomide is used to treat seasonal allergic conjunctivitis, an eye problem which causes red, watery, and itchy eyes and/or eyelids. It is also used to treat vernal keratoconjunctivitis or spring catarrh (a severe allergic swelling of the eye with symptoms such as severe itching in eyes, sensitivity to light, eye discharge). It can be used as a preventive treatment against a seasonal allergic conjunctivitis.

2. What should I know before I use Lomide?

Warnings

Do not use Lomide if:

- you are allergic to lodoxamide trometamol, or any of the ingredients listed at the end of this leaflet.
- the expiry date has passed, the packaging is torn or the seal around the neck area is broken.

Do not use Lomide eye drops in children less than four years of age.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- take any medicines for any condition.

Do not put Lomide eye drops in your eyes if you are wearing contact lenses as it may cause irritation to your eyes and discolor soft contact lenses.

Remove your contact lenses before putting Lomide eye drops and wait at least 15 minutes before you reinsert your contact Lense in your eyes.

Lomide eye drops are for Ophthalmic use only. Do not use for oral use or for the injection use.

Talk to your doctor if you are unsure about using Lomide eye drops.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will advise you regarding the potential possible risks and benefits of using Lomide eye drops during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will advise you regarding the potential possible risks and benefits of using Lomide eye drops during breast feeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with Lomide eye drops and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lomide eye drops.

4. How do I use Lomide?

How much to use

- Your doctor will advise you the appropriate dose.
- Use one drop in each eye, four times a day at regular intervals.
- Follow the instructions provided and use Lomide eye drops until your doctor tells you to stop.
- **If you want to use any other eye drops, wait for 10 minutes after using Lomide eye drops.**
- **Consult your doctor or pharmacist if your eye problem increases or symptoms do not improve within a few days after starting Lomide eye drops.**

- Lomide eye drops can be used as a preventive treatment against a seasonal allergic conjunctivitis (eye problem with symptoms such as red, watery, and itchy eyes and/or eyelids).
- Your doctor will advise you regarding the treatment duration for the allergy season.

When to use Lomide

- Lomide eye drops should be used at about the same time every day unless your doctor or pharmacist tells you otherwise.
- Use Lomide eye drops at regular intervals to have the maximum effect.

How to use Lomide eye drops

- Sitting or lying down might make putting your eye drops process simpler.
- Remove contact lenses if you are wearing them before putting the eye drops in.
- Shake the bottle well prior to use.

Follow below steps to use Lomide eye drops:

- Wash your hands thoroughly with soap and water.
- Before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Remove the cap from the bottle.

- Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

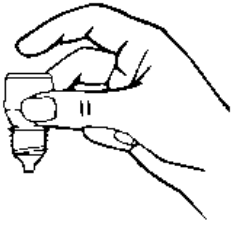


Diagram 1

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to the eye
- **Do not touch the dropper tip to any surface to avoid contamination.**
- 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 (see Diagrams 2 and 3).

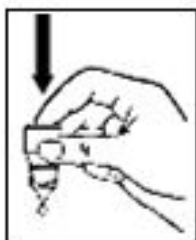


Diagram 2



Diagram 3

- Close your eye. Do not blink or rub your eye.
- When 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 prevent 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.
- If necessary, repeat the above steps for the other eye.
- It is normal for a small amount of the eye drop to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle, closing it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Wash the child's hands, if you are using Lomide eye drops in a child's eye(s)
- You may feel a temporary burning sensation or sharp, painful sensation or discomfort in the eye(s) shortly after using Lomide eye drops.
- Contact your doctor, optometrist or pharmacist immediately if the symptoms persist for a long time.

- If you want to wear your contact lenses, wait 15 minutes after instilling the dose before reinserting the contact lenses.
- If you want to use any other eye drops, wait for 10 minutes after using Lomide eye drops.
- **Discard the eye drops after 28 days after opening it.**

If you forget to use Lomide

Lomide eye drops should be used regularly at the same time each day. If you miss your dose at the usual time, use the eye drops as soon as you remember and then go back to using your eye drops as you would normally do.

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

Do not take a double dose to make up for the dose you missed.

If you use too much Lomide

If you think that you have used too much Lomide eye drops, you may need urgent medical attention.

If you have accidentally put several drops in your eyes, immediately wash your eyes with warm water and consult your doctor.

If you have accidentally swallowed Lomide eye drops you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Lomide?

Things you should do

Call your doctor straight away if you:

- develop any signs of allergic reactions.
- become pregnant while using Lomide eye drops.
- feel any persisting burning sensation or painful sensation in your eyes or feel uncomfortable after putting eye drops in.
- have increased eye problems or symptoms do not improve within a few days after starting Lomide eye drops.

Remind any doctor, dentist or pharmacist or optometrist you visit that you are using Lomide eye drops.

Things you should not do

- Do not stop using this medicine suddenly.

- Do not put Lomide eye drops in your eyes if you are wearing contact lenses as it may cause irritation to your eyes and discolor soft contact lenses.
- Do not use Lomide eye drops in children less than four years of age.
- Do not give Lomide eye drops to anyone else, even if they seem to have the same condition as you.
- Do not use Lomide eye drops to treat other problems unless your doctor or pharmacist tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lomide affects you.

Lomide eye drops may cause temporary blurred vision or other eye problems in some people.

Wait until the vision clears before driving or using machinery.

Looking after your medicine

- Store below 25°C
- Do not freeze the eye drops.
- Do not leave the top off the bottle for any time. Put the top back on the bottle immediately after use to avoid any contamination.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool, dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any remaining eye drops after 28 days after opening it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Eye problems:</p> <ul style="list-style-type: none">• Allergic reaction having symptoms such as shortness of breath, difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, rash.• Feeling of temporary burning sensation or sharp, painful sensation or uncomfortable feeling in eye(s) after using Lomide eye drops.• Itchy eye(s)• Blurred vision• Dry eye• Feeling of tiredness in eye(s)• Eye pain• Eye irritation• Eye discharge• Swelling around the eye(s) or eyelids.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Excessive secretion of tears from the eye(s) <p>General problems:</p> <ul style="list-style-type: none"> ● Headache ● Feeling sick ● Dizziness ● Drowsiness ● Dry nose ● Sneezing 	

Serious side effects

Serious side effects	What to do
<p>Eye problems:</p> <ul style="list-style-type: none"> ● Excessive production of tears. ● Swelling of the thin membrane (conjunctiva) that covers the white part of the eye (sclera) ● Anterior chamber cells epitheliopathy (An eye problem characterized by multiple yellowish white or light-colored lesions that form in the retina) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Keratopathy (diseases of cornea/eyeball), keratitis (a disease of the cornea having symptoms such as eye pain, eye redness, blurred vision) ● Blepharitis (eye condition causing swollen eyelid, eye irritation, crusting, eye redness) ● Excessive opening of blood vessels of eye causing reddening of white portion of the eye (sclera) (ocular hyperaemia) ● Sticky sensation in eye(s) ● Corneal erosion, corneal abrasion (eye disorder having symptoms such as pain, irritation, redness in eye(s), blurred vision) ● Corneal deposits (an eye condition that may cause decrease in vision) 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● Feeling that something is in your eye(s) (foreign body sensation) <p>Other problems:</p> <ul style="list-style-type: none"> ● Taste disturbance or loss of taste ● Fast or irregular heartbeat. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Lomide contains

Active ingredient (main ingredient)	Iodoxamide trometamol
Other ingredients (inactive ingredients)	Mannitol, hypromellose, sodium citrate, citric acid monohydrate, tyloxapol, disodium edetate, benzalkonium chloride, hydrochloric acid, sodium hydroxide and water purified.
Potential allergens	benzalkonium chloride as a preservative

Do not take this medicine if you are allergic to any of these ingredients.

What Lomide looks like

Lomide Eye Drops are a clear, colourless sterile solution in an LDPE 10 mL dispenser bottle

Who distributes Lomide

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1-800-671-203

Web site: www.novartis.com.au

Australian registration numbers

Aust R No. 54275

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