

ILEVRO®

Eye Drops Suspension

Nepafenac 0.3%

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

This leaflet answers some common questions about Ilevro Eye Drops. It does not contain all 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 Ilevro Eye Drops against the risks this medicine could have for you.

The information in this leaflet applies to Ilevro 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 ILEVRO is used for

Ilevro is used to:

- prevent and treat pain and inflammation of the eye associated with cataract surgery
- reduce risk of postoperative macular oedema associated with cataract surgery in patients with non proliferative diabetic retinopathy.

Ilevro contains the active substance nepafenac. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

NSAIDs relieve pain and reduce inflammation (e.g. swelling, redness and throbbing).

Your doctor may have prescribed Ilevro for another reason. Ask your doctor if you have any questions about why Ilevro has been prescribed for you.

There is no evidence that Ilevro is addictive.

Use in children

Ilevro Eye Drops are not recommended in children and young adults aged under the age of 18 years as the safety and efficacy in children has not been established.

Use in pregnancy and in breastfeeding

Ilevro Eye Drops should not be used in women of child bearing potential who are not using a contraceptive.

Ilevro Eye Drops is not recommended during breast feeding.

Before you use ILEVRO

When you must not use it

Do not use Ilevro if:

- you have an allergy to nepafenac, or any of the ingredients in Ilevro listed at the end of this leaflet
- you have an allergy to other non-steroidal anti-inflammatory drugs (NSAIDs). Examples of NSAIDs are: aspirin, ibuprofen, ketoprofen, diclofenac
- you have experienced asthma, skin allergy, or intense inflammation in your nose when using other NSAIDs.

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 wear soft contact lenses when you are using Ilevro as the preservative, benzalkonium chloride, can discolour soft lenses and may cause eye irritation.

Additionally, wearing contact lenses is not recommended after cataract surgery

Do not use Ilevro if:

- the bottle/package shows signs of tampering

- the expiry date on the bottle/
carton has passed.

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 work.

If you are not sure whether you should start using Ilevro, talk to your doctor.

Before you start to use it

Tell your doctor if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

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

Tell your doctor if you have or have had any medical conditions, particularly the following:

- known bleeding tendency, or have bleeding problems or have had them in the past
- any other eye disorder (e.g. an eye infection or dry eye) or if you are using other medicines in the eye (especially topical steroids)
- complicated eye surgery or repeated eye surgery within a short period of time
- diabetes mellitus
- rheumatoid arthritis.
- ocular surface disease (eg. dry eye syndrome).

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

Using or taking other medicines

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

Some medicines and Ilevro may interfere with each other.

These include:

- prostaglandin analogue medicines. Examples include latanoprost, travoprost, bimatoprost and tafluprost that are used to treat glaucoma
- steroid medicines used to treat inflammation
- other NSAIDs
- any medicines which may prolong bleeding time.

These medicines may be affected by Ilevro, or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

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

How to use ILEVRO

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

They may differ from the information contained in this leaflet.

If you are being changed from one medicine to another, follow your doctor's instructions carefully as to when to stop the medicine and when to start the new eye drops.

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

How much to use

For pain and inflammation:

The usual dose of Ilevro is one drop in the affected eye(s) daily beginning 1 day before cataract surgery, continued on the day of surgery and for as long as your doctor tells you to.

An additional drop should be administered 30 to 120 minutes prior to surgery.

For the reduction in the risk of postoperative macular oedema:

The usual dose of Ilevro is one drop in the affected eye(s) daily, beginning 1 day before cataract surgery, continued on the day of surgery and up to 60 days after surgery or for as long as your doctor tells you to.

An additional drop should be administered 30 to 120 minutes prior to surgery.

How to use it

It is important to use Ilevro exactly as your doctor or pharmacist has told you.

If you use the drops less often than prescribed, they may not work as well and the eye problem may not improve.

Using the drops more often than prescribed may not improve the eye problem any faster and may cause increased side effects.

Follow these steps to use the Ilevro eye drops 4 mL round shaped dropper bottle (DROP-TAINER® bottle):

1. Wash your hands thoroughly with soap and water.
2. Shake the bottle.
3. Remove the cap from the bottle. If a safety seal around the neck of the bottle is present and is loose, remove before using product.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

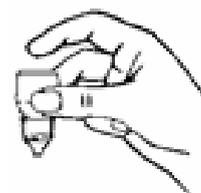


Diagram 1

5. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.

6. Place the tip of the bottle close to your eye. Do not let it touch your eye.
7. Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping (see Diagrams 2a and 3) or pressing the base of the bottle with your forefinger (see Diagrams 2b and 3).

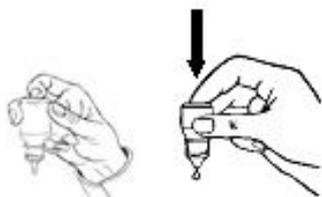


Diagram 2a Diagram 2b



Diagram 3

8. Close your eye. Do not blink or rub your eye.
9. 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. This will also reduce the unpleasant taste sensation that some people experience when using these drops.
10. If necessary, repeat the above steps for the other eye.
11. 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.
12. Replace the cap on the bottle, closing it tightly.
13. Wash your hands again with soap and water to remove any residue.

Follow these steps to use the Ilevro eye drops 4 mL oval shaped dropper bottle:

1. Wash your hands before you start.
2. Shake well before use.
3. Turn the closed bottle upside down and shake down once before each use.
4. Twist off the bottle cap.
5. After cap is removed, if a tamper evident snap collar is present and is loose, remove before using product.
6. Hold the bottle, pointing down, between your thumb and fingers.
7. Tilt your head back.
8. Pull down your lower eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (Diagram 1).

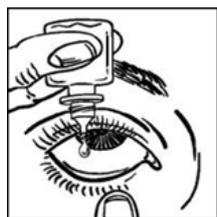


Diagram 1

9. Bring the bottle tip close to the eye, do not let it touch your eye. Do this in front of a mirror if it helps.
10. Gently squeeze the sides of the bottle until one drop is released into your eye (Diagram 2).

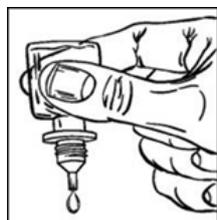


Diagram 2

11. Close your eye. Do not blink or rub your eye.
12. 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. This will also reduce the unpleasant taste sensation that some people experience when using these drops.

13. If you use drops in both eyes, repeat the steps for your other eye. It is not necessary to close and shake the bottle between administrations for both eyes. Close the bottle cap firmly immediately after use.

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 your eye, eyelid or anything else with the dropper tip.

This will help prevent the drops becoming dirty or contaminated.

After using Ilevro, wait at least 5 minutes before putting any other eye treatments in your eye. Eye ointments should be put in last.

When to use it

Use Ilevro every day, at about the same time each day, unless your doctor tells you otherwise.

Using your eye drops at the same times each day will help you remember when to use the eye drops.

How long to use it

Continue using Ilevro for as long as your doctor prescribes.

If you are unsure about when or how to stop using Ilevro, 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 them 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 whether to skip the dose, talk to your doctor or pharmacist.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

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

If you think that you or anyone else may have swallowed any, or all, of the contents of a bottle of Ilevro, immediately telephone your doctor or Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If Ilevro is accidentally swallowed, or if you use too many drops, you may feel light-headed, nauseous or dizzy.

While you are using ILEVRO

Things you must do

Avoid sunlight during treatment with Ilevro.

Your eyes may be more sensitive to light while you are using Ilevro.

Tell your doctor if you have any crusty discharge from your eyes while using Ilevro. This may mean your eyes are infected and you may need additional treatment.

Tell your doctor if you have any eye pain, tearing, blurry vision or any other changes to the surface of the eye.

Use of topical NSAIDs, including Ilevro may result in inflammation of the corneal surface of the eye and other corneal problems.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using Ilevro.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Ilevro.

Tell your doctor if, for any reason, you have not used Ilevro exactly as prescribed. Otherwise, your doctor may think that the eye drops were not effective and change the treatment unnecessarily.

Tell your doctor if your symptoms persist, worsen or recur.

Tell your doctor immediately if you become pregnant or decide to breastfeed.

Things you must not do

Do not use Ilevro to treat other complaints unless your doctor tells you to.

Do not give Ilevro to anyone else, even if they have the same condition as you.

Do not stop using Ilevro without first talking to your doctor.

The preservative in Ilevro (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used Ilevro.

Things to be careful of

Be careful driving, operating machinery or performing tasks requiring mental alertness and/or physical coordination until you know how Ilevro affects you and your vision.

As with any eye medicine, temporary blurred vision or other visual disturbances may affect the ability to drive or use machinery in some people. If blurred vision occurs when you use your drops, wait until your

vision is clear before driving or operating machinery.

Side effects

Tell your doctor as soon as possible if you notice any of the following effects in the eye(s) and the eye area, and they worry you.

This medicine helps most people but can have unwanted side effects in a few 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 doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following effects in the eye(s) and the eye area, and they worry you:

- red, watery eyes, sensitive to light
- changes in vision, blurred vision or temporary reduction of vision
- impaired eye healing
- damage to the surface of the eye, such as thinning or perforation
- clouding of the eye
- swelling of the eye

Additional side effects noticed more rarely in the eye(s) / area include:

- feeling of having something in the eye
- eye pain
- eyelid margin crusting
- deposits or scars on the eye surface
- eye discomfort
- eyelid swelling
- dry eye
- eye / eyelid inflammation
- eye irritation
- itchy eye

- eye discharge
- eye allergy (allergic conjunctivitis)

These are uncommon side effects of Ilevro.

Occasionally, some people notice unwanted effects in the rest of their body after using Ilevro.

These effects may include:

- headache
- dizziness
- nausea, vomiting
- increased blood pressure
- allergic dermatitis
- excess of skin in the upper or lower eyelid.

If any of the following happen, stop using Ilevro and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin rash
- swelling of the face, hands or feet
- wheezing, difficulty in breathing
- shortness of breath
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

After using ILEVRO

Storage

Store Ilevro in a cool dry place away from direct sunlight where the temperature stays below 25°C.

Do not store Ilevro or any other medicine in the car, in the

bathroom, on a window sill or in any other warm, damp place.

Heat and dampness can destroy some medicines.

Do not leave the top off the bottle for any length of time, to avoid contaminating the eye drops.

Keep it where children cannot reach it.

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

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative that 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 your doctor tells you to stop using Ilevro or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

Ilevro is a light yellow to yellow liquid suspension that comes in a 4 mL oval or round shaped dropper bottle (DROP-TAINER®) with a screw cap. Each bottle contains 3 mL of liquid. Each bottle may be presented in a pouch.

Ingredients

Ilevro Eye Drops contains the active ingredient nepafenac. Each 1 mL of Ilevro contains 3mg of nepafenac.

Ilevro Eye Drops also contains:

- boric acid
- propylene glycol
- carbomer 974P

- sodium chloride
- guar galactomannan
- carmellose sodium
- disodium edetate
- hydrochloric acid and/or sodium hydroxide are added to adjust pH
- benzalkonium chloride as a preservative
- water-purified.

Allergens:

May contain benzoates, sulfur dioxide/sulfites and hydroxybenzoates.

Supplier

Ilevro is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone No. 1800 671 203

www.novartis.com.au

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