NOVARTIS

ILEVRO®

(nepafenac)

3 mg/ml eye drops suspension

Patient Information Leaflet

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SCHEDULING STATUS: **S3**

ILEVRO 3 mg/ml eye drops, suspension

nepafenac

Read all of this leaflet carefully before you start using ILEVRO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ILEVRO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ILEVRO is and what it is used for

ILEVRO contains the active substance nepafenac, and belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs).

ILEVRO is to be used by adults:

- To prevent and relieve eye pain and inflammation following cataract surgery on the eye.
- To reduce the risk of macular oedema (swelling in the back of the eye) following cataract surgery on the eye in diabetic patients.

2. What you need to know before you use ILEVRO

Do not use NEVANAC

- if you are hypersensitive (allergic) to nepafenac or any of the other ingredients of ILEVRO (listed in section 6)
- if you are allergic to other nonsteroidal anti-inflammatory drugs (NSAID)
- if you have experienced asthma, skin allergy, or intense inflammation in your nose when using other NSAIDs. Examples of NSAIDs are: acetylsalicylic acid, ibuprofen, ketoprofen, piroxicam, diclofenac.

Warnings and precautions

Talk to your doctor or health care provider before using ILEVRO:

- if you bruise easily or have bleeding problems or have had them in the past
- if you have any other eye disorder (e.g. an eye infection) or if you are using other medicines in the eye (especially topical steroids)
- if you have diabetes
- if you have rheumatoid arthritis
- if you have had repeated eye surgery within a short period of time.

Avoid sunlight during treatment with ILEVRO.

Wearing contact lenses is not recommended after cataract surgery. Your doctor will advise you when you can use contact lenses again (see also “ILEVRO contains benzalkonium chloride”).

Children and adolescents

Do not give this medicine to children and adolescents below 18 years old because the safety and efficacy in this population has not been established.

Other medicines and ILEVRO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ILEVRO can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Also tell your doctor if you are taking medicines that reduce blood clotting (warfarin) or other NSAIDs. They may increase the risk of bleeding.

Pregnancy and breastfeeding

If you are pregnant, or might get pregnant, talk to your doctor before you use ILEVRO. Women who may become pregnant are advised to use effective contraception during ILEVRO treatment.
The use of ILEVRO is not recommended during pregnancy. Do not use ILEVRO unless clearly indicated by your doctor.

If you are breastfeeding, ILEVRO may pass into your milk. However, no effects on breastfed children are anticipated. ILEVRO can be used during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Do not drive or use machines until your vision is clear. You may find that your vision is blurred temporarily just after using ILEVRO.

ILEVRO contains benzalkonium chloride

This medicine contains 0,15 mg benzalkonium chloride in each 3 ml which is equivalent to 0,05 mg/ml.

The preservative in ILEVRO, benzalkonium chloride, may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. 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 ILEVRO

Do not share medicines prescribed for you with any other person.

Always use ILEVRO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Only use ILEVRO for your eyes. Do not swallow or inject.

The recommended dose is

One drop in the affected eye or eyes, once a day. Use at the same time each day.

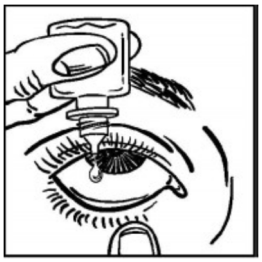
Your doctor will tell you how long your treatment with ILEVRO will last. Do not stop treatment early. If you have the impression that the effect of ILEVRO is too strong or too weak, tell your doctor or pharmacist.

When to take and for how long

Begin 1 day before cataract surgery. Continue on the day of surgery. Then use it for as long as your doctor tells you to. This may be up to 3 weeks (to prevent and relieve eye pain and inflammation) or 60 days (to prevent the development of macular oedema and to improve vision) after your operation.

How to use

Wash your hands before you start.



1



2

- Shake well before use.
- Turn the closed bottle upside down and shake down once before each use.
- Twist off the bottle cap.
- After cap is removed, if a tamper evident snap collar is present and is loose, remove before using product.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back.

- 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 (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 squeeze the sides of the bottle until one drop is released into your eye (picture 2).

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.

If a drop misses your eye, try again.

If you are using other eye drops, wait at least five minutes between using ILEVRO and the other drops.

If you use more ILEVRO than you should

Rinse your eye out with warm water. Do not put in any more drops until it is time for your next regular dose.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use ILEVRO

Use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose and continue with the next dose of your regular routine. Do not use a double dose to make up for a forgotten dose. Do not use more than one drop in the affected eye(s).

If you stop using ILEVRO

Do not stop using ILEVRO without speaking to your doctor first. You can usually carry on using the drops, unless you experience serious side effects.

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

4. Possible side effects

ILEVRO can have side effects.

Not all side effects reported for ILEVRO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ILEVRO, please consult your health care provider for advice.

There may be a higher risk of corneal side effects (eye surface problems) if you have:

- complicated eye surgery
- repeated eye surgery within a short period of time
- certain disorders of the surface of the eye, such as inflammation or dry eye
- certain general diseases, such as diabetes or rheumatoid arthritis.

Contact your doctor immediately if your eyes become more red or more painful whilst using the drops.

This may be a result of inflammation on the eye surface with or without loss or damage of cells or an inflammation of the coloured part of the eye (iritis). These side effects have been observed in up to 1 in 100 people.

The following side effects have been observed with nepafenac suspension.

Uncommon side effects *(may affect up to 1 in 100 people)*

- **Effects in the eye:** eye surface inflammation with or without loss or damage of cells, foreign body sensation in the eyes, eyelid crusting or drooping.

Rare side effects *(may affect up to 1 in 1,000 people)*

- **Effects in the eye:** iris inflammation, eye pain, eye discomfort, dry eye, eyelid swelling, eye irritation, itchy eye, eye discharge, allergic conjunctivitis (eye allergy), increased tear production, deposits on the eye surface, fluid or swelling at the back of the eye, eye redness.
- **General side effects:** dizziness, headache, allergic symptoms (eyelid allergic swelling), nausea, skin inflammation, redness and itching.

Side effects with frequency not known (frequency cannot be estimated from the available data)

- **Effects in the eye:** damage of the surface of the eye such as thinning or perforation, impaired healing of the eye, eye surface scar, clouding, reduced vision, eye swelling, blurred vision.
- **General side effects:** vomiting, increased blood pressure.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ILEVRO.

5. How to store ILEVRO

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

Store at or below 25 °C. Keep the bottle in the outer carton in order to protect from light.

Throw away the bottle 4 weeks after first opening, to prevent infections.

Do not throw away any medicines via waste water 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 ILEVRO contains

- The active substance is nepafenac. One ml of suspension contains 3 mg of nepafenac.
- The other ingredients are boric acid, propylene glycol, carbomer, sodium chloride, guar, carmellose sodium, disodium edetate, benzalkonium chloride (see section 2) and purified water. Tiny amounts of sodium hydroxide and/or hydrochloric acid are added to keep acidity levels (pH levels) normal.

What ILEVRO looks like and contents of the pack

ILEVRO eye drops, suspension (eye drops) is a liquid (light yellow to dark orange suspension) supplied in a plastic bottle with a screw cap. Each bottle may be placed in a pouch.

Each pack contains one bottle of 3 ml.

Holder of certificate of registration

Novartis South Africa (Pty) Ltd

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