

PART III: CONSUMER INFORMATION

Pr ILEVRO®

Nepafenac Ophthalmic Suspension, 0.3% w/v

This leaflet is part III of a three-part "Product Monograph" published when ILEVRO® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ILEVRO. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ILEVRO (nepafenac) ophthalmic–suspension, 0.3% is used to manage eye pain and inflammation following cataract surgery.

What it does:

ILEVRO is a nonsteroidal anti-inflammatory drug (NSAID); and can reduce formation of prostaglandins by your body, which cause pain and swelling in your eye.

When it should not be used:

Do not use ILEVRO if you:

- are allergic (*hypersensitive*) to nepafenac or any of the other ingredients of this medicine (see What the important nonmedicinal ingredients are).
- are allergic to other NSAIDs.
- have had reactions, such as asthma, itchy or runny nose, after taking acetylsalicylic acid or other NSAIDs.

What the medicinal ingredient is:

Nepafenac, 0.3% w/v

What the important nonmedicinal ingredients are:

Preservative: benzalkonium chloride.

Others: boric acid, propylene glycol, carbomer 974P, sodium chloride, guar, carmellose sodium, disodium edetate. Tiny amounts of hydrochloric acid or sodium hydroxide are sometimes added during the manufacture of the product to adjust to the proper pH.

What dosage forms it comes in:

ILEVRO contains tiny yellow particles suspended in a clear liquid. It is supplied as 3 mL of suspension in a 4 mL plastic bottle with a screw cap.

WARNINGS AND PRECAUTIONS

BEFORE you use ILEVRO ophthalmic suspension, talk to your doctor or pharmacist if you:

- have any allergies to ILEVRO or any of its ingredients (see What the important nonmedicinal ingredients are)
- bruise easily or have or have had bleeding problems.

- take any medicines that may make you bleed more like acetylsalicylic acid or warfarin.
- have an eye disorder called dry eye syndrome, a corneal ulcer, a corneal denervation or a corneal epithelial defect.
- have diabetes.
- have rheumatoid arthritis.
- have had many eye surgeries within a short period of time.
- have had complicated eye surgeries.
- wear contact lenses.
- apply other NSAID or steroid medications to your eye since these may slow the healing of your eye.
- are using other medications in the eye.
- have ever had an allergic reaction to NSAIDs, including acetylsalicylic acid, as you may be allergic to ILEVRO.

Pregnancy or breast-feeding

If you are pregnant, think you may be pregnant or are planning to become pregnant, talk to your doctor before you use ILEVRO. You should not use ILEVRO if you are pregnant. If you are breast-feeding, ILEVRO may get into your milk. Talk to your doctor about breastfeeding.

Other Medications

Please tell your doctor or pharmacist if you are taking (or recently took) any other medicines. Remember to mention also medicines that you bought without prescription, over the counter.

While taking ILEVRO

Tell your doctor if you are not getting any relief or if problems develop.

If you wear contact lenses

There is a preservative in ILEVRO (benzalkonium chloride) that can discolour soft lenses and may cause eye irritation. Additionally, wearing contact lenses is not recommended after cataract surgery. Do not wear contact lenses while using ILEVRO.

Driving and using machines

You may find that your vision is blurred or you may have other vision changes just after you use ILEVRO. Do not drive or use machines until your vision is clear.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all drugs that you are using or planning to use, including those without a prescription.

Do not use acetylsalicylic acid, phenylacetic acid or other nonsteroidal anti-inflammatories with ILEVRO if you have previously developed reactions to the use of these products (See When it should not be used).

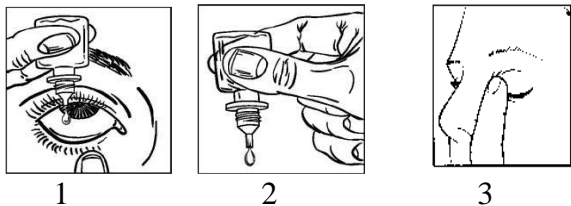
PROPER USE OF THIS MEDICATION

Always use ILEVRO exactly as your doctor has told you.

Usual adult dose:

One drop of ILEVRO should be applied to the affected eye(s) once daily. Begin 1 day before cataract surgery. Continue on the day of surgery. Then use it for as long as your doctor told you to. This may be up to 2 weeks after your operation.

How to Use:



- Get the ILEVRO suspension bottle and a mirror.
- Wash your hands.
- 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 tamper evident snap collar 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).
- After using ILEVRO suspension, press a finger into the corner of your eye, by the nose (picture 3). This helps to stop ILEVRO suspension getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Use up one bottle before opening the next bottle.
- If a drop misses your eye, try again.

If you are using other eye drops wait at least 5 minutes between putting in ILEVRO and the other drops.

Overdose:

If you use more ILEVRO than you should, rinse it all out with warm water. Don’t put in any more drops until it’s time for your

next regular dose. If accidentally ingested, contact your local poison control centre or doctor.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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 missed dose. Do not use more than one drop in the affected eye(s) once daily.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A small number of people who use ILEVRO may get side effects. They can be unpleasant, but most of them disappear rapidly.

Do not stop taking ILEVRO without speaking to your doctor. You can usually continue using ILEVRO, unless the effects are serious. If you’re worried, talk to a doctor or pharmacist.

The most common side effects include eye pain, abnormal sensation in the eye, crusty eyelids, and eye surface inflammation.

Less common side effects include eye surface damage with loss of cells, blurred vision, eye itching, dry eye, eye discharge, increased tear production, eyelid inflammation, sensitivity to light, eye allergy, increased allergic symptoms, nausea, skin allergy, headache and allergy.

Additional side effects may also affect people using ILEVRO including inflammation (pain, redness, swelling) of the eye or eyelid, reduced vision, eye irritation, eye redness, dizziness, vomiting and increased blood pressure.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Eyes get redder, eyes become more painful		✓	
Cornea (protective outer layer of the eye) disorder, including corneal disorder, surface changes, and damage including thinning or perforation and impaired healing, eye inflammation, clouding, eye surface scarring: blurred vision, eye pain and redness.		✓	

This is not a complete list of side effects. For any unexpected effects while taking ILEVRO, contact your doctor or pharmacist.

HOW TO STORE IT

Store at 2°C - 25°C. Protect from light. Discard 28 days after opening. Keep out of the reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.novartis.ca or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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ILEVRO is a registered trademark.

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