

NEVANAC Ophthalmic Suspension

Nepafenac 0.1% w/v

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What Nevanac is used for

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

Nevanac is indicated for the treatment of pain and inflammation associated with cataract surgery.

Reduction in the risk of after operation macular oedema (swelling in the macula, the central part of the retina at the back of the eye) associated with cataract surgery in diabetic patients.

How Nevanac works

Nevanac reduces pain and inflammation associated with cataract surgery.

Before you use Nevanac

- When you must not use it

Do not use Nevanac

- if you are allergic to nepafenac or any of the other ingredients of this medicine
- if you are allergic to non-steroidal anti-inflammatories (NSAIDs).
- 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.

- Before you start use it

Talk to your doctor, pharmacist or nurse before using Nevanac if you have the following condition:

1. bleeding tendency
2. eye disorder
3. eye infection
4. diabetes
5. rheumatoid arthritis
6. eye surgery

Avoid sunlight during treatment with Nevanac.

Wearing contact lenses is not recommended after cataract surgery. Your doctor will advise you when you can use contact lenses again.

Pregnancy and breast-feeding

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

If you are breast-feeding, Nevanac may pass into your milk. However, no effects on breast-fed children are anticipated. Nevanac can be used during breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nevanac 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.

How to use Nevanac

Wash your hands before you start.



1



2

- Shake well before use.
- Twist off the bottle cap.
- 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 press on the base of the bottle to release one drop of Nevanac at a time.
- Do not squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).

If you use drops in both eyes, repeat the steps for your other eye. 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 Nevanac and the other drops.

- How much to use

The recommended dose is one drop in each affected eye 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period.

For the reduction in the risk of postoperative macular oedema associated with cataract surgery

in diabetic patients, the dose is 1 drop of NEVANAC in the conjunctival sac of the affected eye(s) 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and up to 60 days of the postoperative period as directed by the clinician. An additional drop should be administered 30 to 120 minutes prior to surgery.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Nevanac for as long as your doctor recommends.

- If you forget to use it

Use a single dose as soon as you remember. If it is almost time for your 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) 3 times daily.

- If you use too much (overdose)

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

While you are using it

- Things you must do

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

Only use Nevanac for your eyes.

Do not swallow or inject.

Do not stop using Nevanac without speaking to your doctor first. You can usually carry on using the drops, unless you experience serious side effects. If you are worried talk to your doctor or pharmacist.

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

- Things you must not do

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.

Do not drive or use machines until your vision is clear. You may find that your vision is blurred for a time just after using Nevanac.

- Things to be careful of

This medicine contains 0.25 mg benzalkonium chloride in each 5 ml which is equivalent to 0.05 mg/ml.

The preservative in Nevanac, 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.

Side effects

Like all medicines, Nevanac can cause side effects, although not everybody gets them.

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 disease, 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 also been observed with nepafenac 1 mg/ml eye drops, suspension or nepafenac 3 mg/ml eye drops, suspension, or both.

Uncommon (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 (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.

Not known (frequency cannot be estimated from the available data)

- **Effects in the eye:** damage on 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or

Vaccines (AEFI)

Storage and Disposal of Nevanac

- Storage

Keep out of the reach and sight of children. Store below 30°C.
Discard 28 days after opening.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- What it looks like

Nevanac appears as a sterile light yellow to yellow eye drop suspension.

- Ingredients

- Active ingredient(s)
Nepafenac.

- Inactive ingredient(s)
Mannitol, carbomer 974P, sodium chloride, tyloxapol, edetate disodium, benzalkonium chloride 0.005%

MAL number:

MAL20081732ARZ

Manufacturer

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Product Registration Holder

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