# **NEVANAC** Ophthalmic Suspension

Nepafenac 0.1% w/v

#### What is in this leaflet

- 1. What Nevanac is used for
- 2. How Nevanac works
- 3. Before you use Nevanac
- 4. How to use Nevanac
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Nevanac
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

#### What Nevanac is used for

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

If you are allergic (hypersensitive) to the active ingredient of Nevanac or to any of the other ingredients of this medicine and have a history of allergy to non-steroidal antiinflammatories (NSAIDs).

## -Before you start use it

Please inform your doctor if you have the following condition:

- 1. eye disorder
- 2. diabetes
- 3. rheumatoid arthritis
- 4. eye surgery
- 5. dry eye

6. bleeding tendency7. eye infection

Please consult your doctor before start to use Nevanac if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Nevanac tablet against the benefits they expect it will have for you.

If you wear contact lenses, you should remove them before using Nevanac and avoid contact lens wear during treatment period.

## - Taking other medicines

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

Some medicines when taken with Nevanac may interfere with each other. These include: topical steroid

#### How to use Nevanac

- 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

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

#### - If you use too much (overdose)

Contact your doctor immediately if you think you may have used too much of this medicine. Do this even if there are no signs of discomfort. You may need urgent medical attention.

## While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Nevanac.

Tell your doctor immediately if you become pregnant while taking this medication

# - Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

# - Things to be careful of

Please take precaution if you have a history of bleeding tendencies or receiving other medications which may increase the risk of bleeding.

The use of both NSAID and steroid eye drops may increase the potential for healing problems. Avoid usage of both eye drops together.

Use of topical NSAIDs may result in corneal inflammation. Please consult your doctor if you experience signs and symptoms of corneal inflammation while using Nevanac. Be careful driving or operating machinery until you know how Nevanac affects you.

#### **Side effects**

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

Listed below are the know side effects from the use of Nevanac.

<u>Immune system disorders</u> Rare: hypersensitivity

Nervous system disorders Uncommon: headache

#### Eve disorders

Uncommon: cornea inflammation, eye redness, sensitive to light, eye discharge, conjunctivitis allergic, vision blurred, dry eye, eye pain, eye itchiness, lacrimation increased, eyelid margin crusting, foreign body sensation in eyes.

Rare: iris inflammation, conjunctivitis, corneal deposits, corneal disorder, photophobia, eyelids inflammation, buildup of fluid in the eye, conjunctiva redness, eye irritation, eyelid disorder, ocular discomfort.

Not known: corneal ulcer, scratch on the eye's cornea, clouding of the cornea, impaired healing (cornea), visual acuity reduced, eye swelling. **Gastrointestinal disorders** 

Rare: nausea, dry mouth

Skin and subcutaneous tissue

<u>disorders</u>

Rare: dermatitis allergic

Investigations

Not known: blood pressure

If one of the above-mentioned possible side effects occurs, you should discontinue the treatment and consult your physician. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting)

# **Storage and Disposal of Nevanac**

- Storage

Keep out of the reach and sight of children. Store at 2°C to 25°C.

## - 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% (preservative), sodium hydroxide and/or hydrochloric acid and purified water, USP.

MAL number: MAL20081732A

Manufacturer

ALCON LABORATORIES, INC. 6201 South Freeway, Fort Worth, Texas 76134 USA.

**Product Registration Holder** 

Alcon Laboratories (M) Sdn. Bhd. 9<sup>th</sup> Floor, Wisma Glomac 3, Kompleks Kelana Centre Point, Jalan SS7/19, 47301, Petaling Jaya, Selangor, Malaysia

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