NOVARTIS

NEVANAC® (nepafenac)

1 mg/ml eye drops suspension

Patient Information Leaflet

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SCHEDULING STATUS: S3

NEVANAC® Eye drops, 1 mg/ml suspension

Nepafenac

Contains sugar: mannitol

Read all of this leaflet carefully before you start using NEVANAC® EYE DROPS

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor, pharmacist, nurse or other health care providers.**
- **NEVANAC® EYE DROPS have 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 NEVANAC® EYE DROPS are and what it is used for

2. What you need to know before you take NEVANAC® EYE DROPS

3. How to use NEVANAC® EYE DROPS

4. Possible side effects

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6. Contents of the pack and other information

1. What NEVANAC® EYE DROPS are and what it is used for

The active substance of NEVANAC® EYE DROPS is nepafenac, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

NEVANAC® EYE DROPS are used to prevent and relieve pain and inflammation and to reduce the risk of swelling in the back of the eye (macular oedema) following cataract surgery on the eye.

2. What you need to know before you use NEVANAC® EYE DROPS

Do not use NEVANAC® Eye drops if you are allergic (hypersensitive) to nepafenac or any of the other ingredients in NEVANAC® Eye drops or to other non-steroidal anti-inflammatory drugs. Examples of NSAIDs are: aspirin, ibuprofen, ketoprofen, piroxicam, diclofenac.

- Do not use NEVANAC® Eye drops if you have a history of heart failure.
- Do not wear contact lenses whilst being treated with NEVANAC® Eye drops. (NEVANAC® Eye drops contains benzalkonium chloride which may discolour soft contact lenses.)
- Do not use in children less than 18 years old.

Tell your doctor and do not use NEVANAC® Eye drops if the above applies to you.

Warnings and precautions

Take special care with NEVANAC® EYE DROPS:

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

- If you have diabetes mellitus (sugar diabetes).
- If you have rheumatoid arthritis.
- If you have a history of high blood pressure.

Tell your doctor if any of the above applies to you.

Other medicines and NEVANAC® EYE DROPS:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription (this includes all complementary or traditional medicines).

This includes in particular:

- Medicine to prevent your blood from clotting, such as warfarin
- Other Non-Steriodal Anti-Inflammatory Drugs (NSAIDs) like aspirin, ibuprofen, ketoprofen, piroxicam or diclofenac
- Cortisones
- Certain antidepressants

Pregnancy, breastfeeding and fertility

If you are pregnant, or might get pregnant, do not use NEVANAC® Eye drops.

If you are breast-feeding, do not use NEVANAC® Eye drops, nepafenac may pass into your milk.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Do not drive or use machines after using NEVANAC® Eye drops until your vision is clear.

NEVANAC® Eye drops contains benzalkonium chloride

There is a preservative, benzalkonium chloride, in NEVANAC® Eye drops that can discolour soft lenses and may cause eye irritation. Additionally wearing contact lenses is not recommended after cataract surgery.

Therefore, do not wear lenses whilst using NEVANAC® Eye drops.

3. How to use NEVANAC® EYE DROPS

Always use NEVANAC® EYE DROPS exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose in adults is:

One drop in the affected eye or eyes, three times a day – morning, midday and evening. Use at the same time each day.

When to use NEVANAC® EYE DROPS 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 3 to 9 weeks after your operation.

Only use NEVANAC® Eye drops in both eyes if your doctor has told you to. Only use NEVANAC® Eye drops as an eye drop.

How to use NEVANAC® EYE DROPS

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 contaminate the dropper tip and solution.
- Gently squeeze on the base of the bottle to release one drop of NEVANAC® Eye drops at a time (picture 2).
- 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 use more NEVANAC® EYE DROPS than you should.

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 NEVANAC® EYE DROPS

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 missed dose. Do not use more than one drop in the affected eye(s) 3 times daily.

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

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

4. Possible side effects

NEVANAC® EYE DROPS can have side effects.

Not all side effects reported for NEVANAC® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Do not stop taking NEVANAC® Eye drops without speaking to your doctor. You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist.

If your eyes get more red or painful while using the drops, contact your doctor immediately.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following less frequent side effects:

- keratitis (swelling covering the center of the eye)
- allergic conjunctivitis (swelling of the white part of the eye)
- punctate keratitis (Degeneration of the cells covering the center of the eye)
- eye pain
- foreign body sensation in eyes
- eyelid margin crusting

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- hypersensitivity (allergic reaction, if your eyes get more red or painful while using the drops, contact your doctor immediately).
- headache
- dizziness
- blurred vision,
- eye pruritus (Itching)
- dry eye
- eye discharge
- photophobia (sensitivity of the eyes to light)
- eye irritation
- increased lacrimation (increased flow of tears)
- blepharitis (swelling of the eyelid)

- nausea
- allergic dermatitis (swelling of the skin around the eye)

Not all side effects reported for this medicine are included in this leaflet. If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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 NEVANAC® EYE DROPS.

5. How to store NEVANAC® EYE DROPS

Keep out of the reach and sight of children. Do not store above 30 ºC.

Keep the container well closed after first opening. Throw away bottle 4 weeks after first opening to prevent infections. Write the date of opening on the carton label in the space provided.

Do not use NEVANAC® Eye drops after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of the month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What NEVANAC® EYE DROPS contains

The active substance is nepafenac.

Preservatives are: disodium edetate and benzalkonium chloride.

Other ingredients are: carbomer 974P, tyloxapol, mannitol and sodium chloride. Tiny amounts of sodium hydroxide or hydrochloric acid are sometimes added to keep the acidity levels (pH levels) normal.

Contains sugar: mannitol

What NEVANAC® EYE DROPS looks like and contents of the pack

Light yellow to light orange uniform suspension.

NEVANAC® Eye drops is a liquid supplied in a pack containing one colourless plastic bottle with a white screw cap containing 5 ml suspension.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

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