PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Nevanac®
Eye Drops, Suspension

Active ingredient: nepafenac 1mg/ml 0.1%.

Inactive and allergenic ingredients in the preparation: Refer to section 6 "Further information" and to section 2 "Important information about some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of adults:

- For prevention and treatment of eye pain and inflammation following cataract surgery.
- To reduce the risk of development of macular edema (swelling in the posterior segment of the eye) following cataract surgery in diabetic patients.

Therapeutic group: non-steroidal anti-inflammatory drugs (NSAIDs)

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient nepafenac or to any of the additional ingredients contained in the medicine (appearing in section 6).
- You are sensitive (allergic) to other non-steroidal anti-inflammatory drugs (NSAIDs).
- You have suffered in the past from asthma, skin allergy or severe inflammation in the nose when using other preparations from the non-steroidal anti-inflammatory drug (NSAID) group such as: acetylsalicylic acid, ibuprofen, ketoprofen, piroxicam, diclofenac.

Special warnings regarding use of the medicine

Before beginning treatment with Nevanac, tell the doctor if:

- you bruise easily or suffer from bleeding problems, or have suffered from them in the past.
- you have other eye problems (such as eye infection) or if you are taking other medicines to treat the eyes (especially topical steroids).
- you are diabetic.
- you have rheumatoid arthritis.
- you have undergone recurrent eye surgery within a short period of time.

Avoid exposure to the sun during the course of treatment with Nevanac.

Wearing contact lenses after cataract surgery is not recommended. The doctor will advise you on when you can resume wearing your contact lenses (also see "Important information about some of the ingredients of the medicine").

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18, since the efficacy and safety of this medicine have not been determined for this population.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:

Blood thinners (warfarin) or other non-steroidal anti-inflammatory drugs (NSAIDs). They may increase the risk of bleeding.

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

Pregnancy and breast-feeding

If you are pregnant or may become pregnant, consult your doctor before you use Nevanac.

Women who may become pregnant are advised to use effective contraceptives during the use of Nevanac.

The use of Nevanac is not recommended during pregnancy.

Do not use Nevanac unless the medicine has been prescribed for you by the attending doctor, who is aware that you are pregnant.

If you are breast-feeding, Nevanac may pass into the breast milk; however, it is not expected to affect breast-feeding babies.

Nevanac can be used while breast-feeding.

If you are pregnant or are breast-feeding, think that you are pregnant or are planning to become pregnant, consult the attending doctor before taking this medicine.

Driving and operating machinery

Do not drive or operate machinery until your vision becomes clear again. You may notice that your vision is blurry immediately after using Nevanac.

Important information about some of the ingredients of the medicine

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

The preservative in Nevanac, benzalkonium chloride, may be absorbed by soft contact lenses and change the color of the contact lenses. Remove contact lenses before using this medicine and reinsert them after 15 minutes. Benzalkonium chloride may also cause eye irritation, especially if you suffer from dry eyes or from disorders of the cornea (the transparent layer at the front of the eye). If you feel an unusual feeling in the eye, stinging or pain in the eye after using the medicine, refer to a doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Nevanac is to be used in the eyes only. Do not swallow or inject the medicine.

Usual dosage

The dosage and treatment regimen will be determined by the doctor only. The usual adult dosage is generally:

One drop in the treated eye, 3 times a day - morning, afternoon and evening. The drops should be administered at the same time every day.

Do not exceed the recommended dosage.

When to take the treatment and for how long

The treatment should be started the day before cataract surgery. Treatment should be continued on the day of surgery. Then, proceed with the treatment for as long as the doctor instructs you to. This may take up to three weeks (for prevention and treatment of pain and inflammation in the eye) or 60 days (for reducing the risk of developing macular edema) after surgery.

Instructions for use

First, wash your hands.

- Shake the bottle well before use.
- Twist off the bottle cap.
- After removing the cap, if the tamper-evident snap collar is loose, remove it before use.
- Hold the bottle between your thumb and fingers, with the opening facing downward.
- Tilt your head back.
- With a clean finger, pull your lower eyelid downward to create a kind of "pocket" between the eyelid and the eye. The drop will go in here (Figure 1).
- Bring the tip of the bottle close to your eye. Do this in front of a mirror if it helps.
- Do not allow the dropper to come into contact with the eye, eyelid, adjacent areas or other surfaces. This may contaminate the drops.
- Gently press until a drop is released into the eye. Do not squeeze (firmly press) the bottle. The bottle was designed so that a gentle press on the bottom of the bottle is sufficient (Figure 2).

If you need to use the drops in both eyes, repeat the above steps for the other eye. Close the bottle tightly immediately after use.

If the drop did not enter the eye, try again.

If you use another type of eye drops, wait at least 5 minutes between administration of Nevanac and the other drops.

If you accidentally use a higher dosage than required, rinse the eye with warm water. Do not administer more drops until it is time for the next scheduled dose.

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to apply the Nevanac drops, administer one dose as soon as you remember. If it is almost time for the next dose, ignore the forgotten dose, and continue with the next dose as part of your routine treatment. Do not administer a double dose to compensate for the forgotten dose. Do not instill more than one drop three times per day in the treated eye.

Adhere to the treatment regimen recommended by the doctor.

If you stop using the medicine

Do not stop using Nevanac without first consulting the attending doctor. Usually, you may continue using the drops, unless you have experienced serious side effects. If you are concerned, consult your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of Nevanac, consult the attending doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Nevanac may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately:

If your eyes become more red or more painful while using the drops. This may be due to inflammation on the surface of the eye with/without loss or damage to the cells or inflammation of the iris (iritis). This side effect has been observed in up to one user in 100.

There may be a higher risk for corneal side effects (disturbances on the surface of the eye) if:

- You underwent complicated eye surgery.
- You underwent recurrent eye surgery within a short period of time.
- You have certain disorders on the surface of the eye, such as inflammation or a dry eye.
- You have a particular general disease such as: diabetes or rheumatoid arthritis.

Uncommon side effects - effects that occur in 1-10 users out of 1,000

Side effects in the eyes: Eye surface inflammation with or without loss or damage to cells, corneal epithelium defect, foreign body sensation in the eye, eyelid crusting or eyelid drooping.

Rare side effects - effects that occur in 1-10 users out of 10,000

Side effects in the eyes: Inflammation of the iris, eye pain, eye discomfort, dry eyes, eyelid swelling, eyelid inflammation, eye irritation, itchy eye, eye discharge, allergic conjunctivitis (eye allergy), increased tear production, deposits on the eye surface, fluid or swelling in the posterior segment of the eye, eye redness.

Generalized side effects: Dizziness, headaches, allergy symptoms (allergic swelling of the eyelid), nausea, inflammation of the skin, redness and itching.

Side effects of unknown frequency (the frequency cannot be determined from the available data)

Side effects in the eyes: Damage to the surface of the eye, such as thinning or perforation, abnormal healing of the eye, scarring on the surface of the eye, clouding, impaired vision, swelling of the eye, blurred vision, ulcerative keratitis.

Generalized side effects: Vomiting, increased blood pressure.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- The bottle should be discarded 4 weeks after opening it, to prevent contamination. Record the opening date on the bottle and the box.
- Do not discard medicines into the wastewater or household waste. Consult a pharmacist regarding where to discard medicines no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

What does the medicine Nevanac contain

In addition to the active ingredient, the medicine also contains

Mannitol, carbomer 974P, sodium chloride, disodium edetate, tyloxapol, benzalkonium chloride, purified water

In addition, there is a trace amount of sodium hydroxide and/or hydrochloric acid to maintain normal pH levels.

What does the medicine look like and what are the contents of the package?

Nevanac is a liquid (light yellow to light orange suspension) supplied in a pack containing a 5 ml plastic bottle and a cap.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in May 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health - 143 57 31467