

### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

**S3**

#### PANAMOR EYE DROPS 1 mg/ml ophthalmic solution

#### Diclofenac sodium

**Read all of this leaflet carefully before you start using PANAMOR EYE DROPS.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PANAMOR EYE DROPS has 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 PANAMOR EYE DROPS are and what it is used for
2. What you need to know before you use PANAMOR EYE DROPS
3. How to use PANAMOR EYE DROPS
4. Possible side effects
5. How to store PANAMOR EYE DROPS
6. Contents of the pack and other information

## **1. What PANAMOR EYE DROPS are and what it is used for**

PANAMOR EYE DROPS belong to a group of medicines called non-steroidal anti-inflammatory medicines (NSAIDs). These medicines are used to treat pain and reduce swelling.

PANAMOR EYE DROPS are used:

- After eye surgery to control pain and/or reduce the swelling.
- To treat surface pain on the eye.
- To treat swelling after laser surgery on the eye.

## **2. What you need to know before you use PANAMOR EYE DROPS**

**Do not use PANAMOR EYE DROPS:**

- if you are hypersensitive (allergic) to diclofenac or any of the other ingredients of PANAMOR EYE DROPS (listed in section 6).
- if you are wearing soft contact lenses.
- if you are hypersensitive to aspirin or other anti-inflammatory medicines (NSAIDs).
- if you get an asthma attack, skin rash or runny nose after taking medicines such as aspirin and other anti-inflammatory medicines(NSAIDs).
- if you are pregnant and you are already at 20 weeks or later in your pregnancy as PANAMOR EYE DROPS may cause problems in your unborn baby.
- if you are breastfeeding your baby.
- in young children.
- during any surgical procedures.
- if you have a history of gastrointestinal perforation, ulceration and bleeding in the stomach or small intestine (duodenum) (PUBs) related to previous use of

medicines for pain and inflammation (NSAIDs).

- if you have an active or a history of recurrent gastrointestinal ulcers or bleeding or perforations.
- if you have heart failure, established heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack, stroke, mini-stroke or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages.
- if you have or have had problems with your blood circulation (peripheral arterial disease).

### **Warnings and precautions**

Take special care with PANAMOR EYE DROPS:

- if you have certain medical conditions or if you are using PANAMOR EYE DROPS together with certain other medicines, you may require special monitoring.
- if you are using any other eye drops especially cortisone eye drops.
- if you have rheumatoid arthritis.
- if you have an eye infection.
- if you had cataract (eye) surgery.
- if you have a bleeding disorder or are taking medicines that could increase bleeding.
- if you have an eye infection since symptoms such as fever and inflammation may be masked. If you use this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- if you have heart problems such chest pain, blood clots, or if you had a stroke or think you might be at risk of these conditions (for example, if you have high blood pressure, high blood sugar levels, high amounts of fat in the blood or are a

smoker). There is a small increased risk of heart attack or stroke when you are using PANAMOR EYE DROPS. The risk is higher if you are using high doses for a long time.

- if you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease (inflammatory diseases), hiatus hernia, gastro-oesophageal reflux disease (reflux of gastric contents into the oesophagus), angiodysplasia (a small vascular malformation of the gut) as these conditions may be exacerbated.
- if you have or have had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen and report them at once to your doctor. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.
- if you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- if you are elderly.
- if you have serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS). PANAMOR EYE DROPS should be discontinued immediately at the first appearance of any type of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity. You should also contact your doctor as soon as possible.
- if you are pregnant, do not use PANAMOR EYE DROPS at 20 weeks or later in pregnancy. PANAMOR EYE DROPS may cause kidney problems in your unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Complications can occur with low levels of this fluid.

## **Children**

The use of PANAMOR EYE DROPS has not been studied in young children.

## **Other medicines and PANAMOR EYE DROPS**

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Anti-platelets and anticoagulants (medicines used to prevent your blood clotting).
- Eye drops or ointment containing steroids such as hydrocortisone or betamethasone.
- Eye drops or ointment containing acetylcholine and carbachol.
- Any other NSAID, for example aspirin or ibuprofen.
- Oral corticosteroids (an anti-inflammatory medicine).
- Selective serotonin reuptake inhibitors (SSRIs (used to treat depression)).

## **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before using this medicine.

### *Pregnancy*

PANAMOR EYE DROPS must not be used at 20 weeks or later in your pregnancy.

### *Breastfeeding*

You should not use PANAMOR EYE DROPS if you are breastfeeding your baby.

### **Driving and using machines**

PANAMOR EYE DROPS may cause blurred vision.

You should not drive, use machinery or perform any tasks that require concentration, until you are certain that PANAMOR EYE DROPS does not adversely affect your ability to do so.

It is not always possible to predict to what extent PANAMOR EYE DROPS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PANAMOR EYE DROPS affects you (see section 4).

### **PANAMOR EYE DROPS contains boric acid**

which may be harmful in children.

### **3. How to use PANAMOR EYE DROPS**

Do not share medicines prescribed for you with any other person.

Always use PANAMOR EYE DROPS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dosage and length of treatment will vary.

The usual dose of PANAMOR EYE DROPS before an operation: up to 5 drops, as indicated by your doctor, during three hours before surgery.

The usual dose of PANAMOR EYE DROPS after the operation: 3 drops after surgery. Thereafter instil one drop into the eye, 4 to 5 times daily.

The usual dose of PANAMOR EYE DROPS for other indications: One drop 4 to

5 times daily depending on the severity of the condition.

If you have the impression that the effect of PANAMOR EYE DROPS is too strong or too weak, tell your doctor or pharmacist.

How to instil the drops:

1. Wash your hands
2. Tilt your head back, pressing your finger on the skin just beneath the lower eye lid
3. Pull your eye lid away
4. Drop the medicine into this space
5. Let go of the eyelid and gently close the eyes - Do not blink
6. Apply pressure to the inner corner of the eye with your finger for 1 to 2 minutes
7. Wash your hands
8. An interval of at least five minutes between the application of different eye preparations must be allowed.

**If you use more PANAMOR EYE DROPS than you should**

There are no known symptoms of overdose.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to use PANAMOR EYE DROPS**

If you miss a dose, continue with the next dose as normal. Do not use a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

PANAMOR EYE DROPS can have side effects.

Not all side effects reported for PANAMOR EYE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using PANAMOR EYE DROPS, please consult your healthcare provider for advice.

If any of the following happens, stop using PANAMOR EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- red, itchy, and swollen eyes,
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PANAMOR EYE DROPS. You may need urgent medical attention or hospitalisation.

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

- shortness of breath, fatigue, rapid heartbeat, swelling of the feet or legs (signs of cardiac failure),

- breathlessness, coughing, a tightness across the chest, wheezing or other symptoms of asthma,
- lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or Crohn's disease),
- diarrhoea containing blood or rectal bleeding (haemorrhagic diarrhoea),
- any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit (haematemesis) or black, tarry faeces (melaena),
- corneal thinning, swelling or ulcers that might result in loss of sight.

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

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- eye disorders such as eye pain, irritation or mild transient burning sensation and stinging,
- stomach pain, heartburn, nausea, vomiting, diarrhoea, constipation, indigestion, wind, loss of appetite,
- inflammation, irritation or swelling of the stomach lining (gastritis),
- mouth ulcers with swelling and redness inside the mouth or individual painful sores.

*Less frequent side effects:*

- blurred vision immediately after using the eye drops,
- redness of the eyes,
- damage to cells on the surface of the cornea (the membrane covering the front of the eye),

- unusual sensitivity to light.

*Side effects with an unknown frequency:*

- high blood pressure (hypertension),
- fluid retention, symptoms of which include swollen ankles (oedema).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

**SAHPRA:** <https://www.sahpra.org.za/health-products-vigilance/>

**Aspen Pharmacare:**

**E-mail:** [Drugsafety@aspenpharma.com](mailto:Drugsafety@aspenpharma.com)

**Tel:** 0800 118 088

By reporting side effects, you can help provide more information on the safety of PANAMOR EYE DROPS.

### **5. How to store PANAMOR EYE DROPS**

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Do not freeze.

Discard 30 days after opening.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

## **6. Contents of the pack and other information**

### **What PANAMOR EYE DROPS contains**

The active substance is 1 mg of diclofenac sodium.

The other ingredients are boric acid, edetate disodium, polyoxyl 35 castor oil, sorbic acid.

Preservative: Sorbic acid 0,2 % *m/v*

### **What PANAMOR EYE DROPS looks like and contents of the pack**

PANAMOR EYE DROPS is a colourless to pale yellow solution. Free from visible particles.

2,5 ml or 5 ml is packed in a white opaque low density polyethylene bottle with a translucent low density polyethylene nozzle and a white high density polyethylene cap with tear off ring. The bottle is packed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.



**Holder of Certificate of Registration**

PHARMACARE LIMITED

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**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information**

**Leaflets:**

<https://www.sahpra.org.za/pi-pil-repository/>

**Aspen Pharmacare:**

**E-mail:** [Medinfo@aspenpharma.com](mailto:Medinfo@aspenpharma.com)

**Tel:** 0800 118 088

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