

## **Package leaflet: Information for the user**

### **Diclofenac Devatis 1 mg/ml, eye drops, solution, single dose container Diclofenac sodium**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Diclofenac Devatis is and what it is used for
2. What you need to know before you take Diclofenac Devatis
3. How to take Diclofenac Devatis
4. Possible side effects
5. How to store Diclofenac Devatis
6. Contents of the pack and other information

#### **1. What Diclofenac Devatis is and what it is used for**

This medicine belongs to a group of medicines called non steroidal anti-inflammatory drugs (NSAIDs), with analgesic properties. The medicine reduces inflammation and pain.

Diclofenac sodium is indicated for:

- Prevention of postoperative inflammation in cataract surgery.
- Maintenance of pupil dilation (mydriasis) during cataract surgery.
- Treatment of ocular pain in photorefractive surgery for up to the 24 first postoperative hours.

#### **2. What you need to know before you use Diclofenac Devatis**

##### **Do not use:**

- If you are allergic (hypersensitive) to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6).
- 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, nepafenac.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Diclofenac Devatis.

Take care with Diclofenac Devatis if you bruise easily or have bleeding problems or have had them in the past.

Take care with Diclofenac Devatis if you have any other eye disorder (e.g. an eye infection) or if you are using other medicines in the eye (especially topical steroids).

Take care with Diclofenac Devatis if you have diabetes, rheumatoid arthritis or you have had repeated eye surgery within a short period of time.

Avoid sunlight during treatment with Diclofenac Devatis.  
Do not wear contact lenses while you are using this medicine.

### **Children**

Diclofenac Devatis is not recommended for the use in children

**Contact your doctor or pharmacist if you have any questions about using Diclofenac Devatis.**

### **Other medicines and Diclofenac Devatis**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Be careful if you have a significant pre-existing corneal inflammation and you are treated with topical NSAIDs such as diclofenac and with other topical steroids at the same time. You may have an increased risk of developing corneal complication.

To prevent Diclofenac Devatis from being washed out when additional ophthalmic medication is used, an interval of at least 5 minutes between each application should be adhered to.

### **Pregnancy, breast-feeding and fertility**

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 using this medicine.

You should not use Diclofenac Devatis during the 3<sup>rd</sup> trimester of pregnancy due to possible complications for mother and child.

Diclofenac Regioemdica can pass into breast milk.

### **Driving and using machines**

It is possible, that your ability to drive or use machines may be impaired due to blurred-vision immediately after administration of Diclofenac Devatis.

## **3. How to use Diclofenac Devatis**

Always use Diclofenac Devatis exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

Maintenance of pupil dilation (mydriasis) during cataract surgery:

- Before surgery: the recommended dose is one drop in the affected eye 3 to 5 times during the 1-2 hours before surgery.

Prevention of inflammation in cataract and anterior eye segment surgeries:

- Before surgery: the recommended dose is one drop in the affected eye 3 to 5 times during the 1-2 hours before surgery;
- After surgery: the recommended dose is one drop in the affected eye three to five times daily. A treatment duration exceeding 4 weeks is not recommended.

Treatment of ocular pain in photorefractive surgery for up to the 24 first postoperative hours:

- Before surgery: the recommended dose is one drop two times in the affected eye within the hour prior to surgery;
- After surgery: the recommended dose is one drop two times within the hour following surgery and then four drops within the 24 post-operative hours.

### **Use in children**

Diclofenac Regioemdica is not recommended in children. There is only limited experience in children aged 2 years and older.

Do not allow the tip of the single-dose container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the single-dose container, keep the tip of the container away from contact with any surface.

The solution from one individual single-dose container of Diclofenac Devatis is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use and must be discarded immediately after administration.

If other eye drops also are used, wait for about 5 minutes between the eye drops are given.

### **How to use Diclofenac Devatis:**

1. Wash your hands before using the drops.
2. Remove the top from the single-dose container.
3. Make sure that the tip of the single-dose container does not touch anything.
4. Hold the single-dose container in one hand between the thumb and forefinger.
5. Tilt your head back, and use your other forefinger to pull down the lower eyelid.
6. Place the dropper tip close to your eye, but not touching the eye or lid, and gently squeeze the single-dose container to release one drop into your eye.
7. Close your eyelid and gently press the corner of your eye with your forefinger for one minute.
8. After instillation, discard the used single-dose container even if there is solution remaining.

Follow these instructions carefully. Consult your doctor or pharmacist if there is anything you do not understand.

### **If you use more Diclofenac Devatis than you should**

Rinse your eye out with warm water.

Do not put in any more drops until it is time for your next regular dose.

### **If you forget to use Diclofenac Devatis**

Do not take a double dose to make up for a forgotten dose.

If you forget a dose, take it as soon as you remember, except if it is near the time of the next dose; then, follow your usual dosing schedule. If you forget several doses, consult your doctor.

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

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

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

##### *Eye disorders*

Common (may affect up to 1 in 10 users): eye irritation, blurred vision, conjunctivitis.

Uncommon (may affect up to 1 in 100 users): eye pain, pruritus, hyperaemia, punctate keratitis

Rare (may affect up to 1 in 1000 users): corneal defects, pruritus, erythema, photosensitivity.

##### *Immune system disorders*

Rare (may affect up to 1 in 1000 users): hypersensitivity.

##### *Respiratory disorders*

Rare (may affect up to 1 in 1000 users): dyspnoea, exacerbation of asthma.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly **via the national reporting system listed in Appendix V\***. By reporting side effects, you can help provide more information on the safety of this medicine.

[\*For the printed material, please refer to the guidance of the annotated QRD template.]

#### **5. How to store Diclofenac Devatis**

Don't store Diclofenac Devatis above 25°C.

Store in the original package in order to protect from light and evaporation.

After first opening of the sachet: use the single dose containers within 28 days.

After first opening of the single-dose container: use immediately and discard the remaining content after use.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

##### **What Diclofenac Devatis contains**

- The active substance is diclofenac sodium, 1 mg/ml.
- The other ingredients are macroglycerol ricinoleate, boric acid (E284), trometamol and water for injections.

### **What Diclofenac Devatis looks like and contents of the pack**

Diclofenac Devatis is clear and colourless solution, free of particles.

It is supplied in 0.3 ml single-dose containers in sachets. Each sachet contains 5 single-dose containers.

Diclofenac Devatis is available in pack-sizes of 10 x 0.3 ml, 20 x 0.3 ml, 30 x 0.3 ml, 40 x 0.3 ml, 50 x 0.3 ml, 60 x 0.3 ml and 120 x 0.3 ml single dose containers.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

<[To be completed nationally]>

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Netherlands	Diclofenac Devatis 1 mg/ml, oogdruppels, oplossing, verpakking voor éénmalig gebruik
Germany	Diclofenac Devatis 1 mg/ml Augentropfen im Einzeldosisbehältnis

**This leaflet was approved in .**