



---

**Diclofenac Devatis 0.1% (1 mg/ml) Eye Drops, Single dose**

*Each ml contains 1 mg diclofenac sodium.*

---

**CONSUMER MEDICINE INFORMATION**

---

**WHAT IS IN THIS LEAFLET**

---

**Please read this leaflet carefully before you start taking Diclofenac.**

This leaflet answers some common questions about Diclofenac Devatis Eye Drops. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.**

**You can also download the most up to date leaflet from [www.medsafe.govt.nz](http://www.medsafe.govt.nz).**

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Diclofenac Devatis Eye Drops against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

---

**WHAT Diclofenac Devatis Eye Drops IS USED FOR**

---

Diclofenac Devatis Eye Drops contains diclofenac sodium.

It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

NSAIDs relieve pain and reduce inflammation (i.e. swelling, redness and throbbing).

This medicine is used to treat inflammation of the eye e.g. inflammation which occurs as a result of surgery.

Before prescribing Diclofenac Devatis Eye Drops your doctor will have examined your eye(s) and decided that this is the right medicine for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

**Ask your doctor if you have any questions about why Diclofenac Devatis Eye Drops has been prescribed for you.**

***Use in children***

There is not enough information to recommend the use of this medicine for children.

---

## BEFORE YOU USE Diclofenac Devatis Eye Drops

---

### *When you must not use it*

**Do not use Diclofenac Devatis Eye Drops if you have ever had an allergic reaction or attack of asthma after taking or using:**

- Any medicine containing diclofenac sodium, including tablets or suppositories.
- Aspirin or any other NSAID.
- Any of the ingredients listed under Product description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**If you are not sure if you are taking or using any of the medicines above ask your doctor or pharmacist for advice.**

**Do not give Diclofenac to children under 18 years of age.**

**Do not take this medicine if the packaging is torn or shows signs of tampering.**

If the packaging is damaged, return it to your pharmacist for disposal.

**Do not take this medicine after the expiry date printed on the pack and blister.**

The expiry date is printed on the carton and on each blister after “EXP” (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

**Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.**

**Do not use the individual single dose unit if the seal is broken.**

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### *Before you start to use it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- an eye infection
- stomach or bowel ulcers or other bowel trouble
- a tendency to bleed
- problems with your cornea
- asthma.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Diclofenac Devatis Eye Drops is not recommended for use during pregnancy or breast-feeding.

Do not use Diclofenac Devatis Eye Drops during the first 6 months of pregnancy, except on doctor's advice and it must not be used during the last 3 months.

Use of NSAIDs may increase the risk of miscarriage and congenital malformation particularly when taken in early pregnancy.

As with other NSAIDs, use of this medicine during the third trimester of pregnancy is contraindicated due to the possibility of delaying birth, fetal kidney complications and other fetal complications.

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are pregnant or intend to become pregnant.**

Diclofenac Devatis Eye Drops is not recommended in pregnant women. It should not be used in early pregnancy or the last trimester of pregnancy.

Your doctor will discuss the risks and benefits of using Diclofenac Devatis Eye Drops when pregnant.

**Tell your doctor if you are breast-feeding or intent to breast-feed.**

Diclofenac Devatis Eye Drops is not recommending while breast-feeding.

Your doctor will discuss the risks and benefits of using Diclofenac Devatis Eye Drops when breastfeeding.

**If you have not told your doctor about any of the above, tell him/her before you use Diclofenac.**

***Taking other medicines***

**Tell your doctor or pharmacist if you are using other eye drops, ointments or taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and Diclofenac Devatis Eye Drops may interfere with each other. These include:

- Medicines used to thin the blood or prevent blood clots such as warfarin, apixaban, dabigatran, or rivaroxaban
- Steroid eye drops or eye ointment used to treat inflammation.

These medicines may be affected by Diclofenac Devatis Eye Drops or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Diclofenac Eye Drop.

---

## **HOW TO USE Diclofenac Devatis Eye Drops**

---

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

The dosing instructions will be printed on the label that your pharmacist puts on the bottle or carton.

**If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.**

***How much to use***

The usual dose of Diclofenac Devatis Eye Drops is:

Before surgery:

Use up to 5 drops during the 3 hours before surgery.

After surgery:

Use 1 drop 3 times on the day of surgery followed by 1 drop 3 to 5 times daily.

Relief of pain, sensitivity to light, post-traumatic inflammation

1 drop 4 to 6 hourly.

When pain is due to surgery use 1-2 drops in the hour before surgery, then 1-2 drops within the first 15 minutes after surgery and 1 drop 4 to 6 hourly for 3 days after surgery.

### *How to use it*

**If you wear soft contact lenses, remove your contact lenses before using this medicine. Wait for 15 minutes after using it before reinserting your contact lenses into your eyes.**

Wearing your lenses is discouraged during treatment of inflammation.

### **Follow these steps to put the drops in your eyes**

1. Wash your hands before using the drops.
2. Open the blister pack of single dose units.
3. Remove the strip of single dose units and tear off one single dose unit from the strip. Hold it by the tab with the nozzle pointing downwards and tap gently until all the air bubbles are above the solution.
4. Twist the tab off the single dose unit.
5. Make sure the tip of the single dose unit does not touch anything as this may contaminate the solution.
6. Hold the bottle or single dose unit in one hand between the thumb and forefinger.
7. With your head tilted back, use the forefinger of your other hand to pull down the lower lid of the eye to be treated.
8. Place the single dose unit tip close to your eye, but without touching your eye or eyelid, and gently squeeze so that one drop falls into the pouch between your lower eyelid and your eye, and then release your lower eyelid.
9. Close your eye and gently press the inner corner of your eye with your forefinger for one minute.
10. Treat your other eye in the same way if your doctor has told you to do this.
11. Discard each single dose unit immediately after use.

**If you are using any other eye drops at the same time as Diclofenac Devatis Eye Drops, leave an interval of at least 5 minutes between each eye drop to stop the drops being washed out of the eye.**

### *How long to use it*

**Continue using your medicine for as long as your doctor tells you.**

### *If you forget to take it*

If you forget to use Diclofenac Devatis Eye Drops you should put the drops that you missed in the eye(s) as soon as you remember, and then go back to using them as recommended by your doctor.

If it is almost time for your next dose, skip the dose you missed and continue using them as recommended.

**Do not use a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

### *If you take too much (overdose)*

If you accidentally put too many drops in your eye(s) immediately rinse your eye(s) with warm water.

**Immediately telephone your doctor, or the Poisons Information Centre (New Zealand: 0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have swallowed the contents of the single dose unit of Diclofenac. Do this even if there are no signs of discomfort or poisoning.**

---

## **WHILE YOU ARE USING Diclofenac Devatis Eye Drops**

---

### *Things you must do*

**Tell your doctor if you have any crusty discharge from your eyes while using Diclofenac Devatis Eye Drops.**

This may mean your eyes are infected and you may need additional treatment.

**Tell your doctor if your symptoms persist, worsen or recur.**

**If you become pregnant while you are taking Diclofenac, tell your doctor immediately.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Diclofenac Devatis Eye Drops.**

**Tell all doctors, dentists and pharmacists who are treating you that you are using Diclofenac.**

**If you feel that Diclofenac Devatis Eye Drops is not helping your condition, tell your doctor (or pharmacist).**

**Keep all your doctor's appointments so that your progress can be checked.**

**Tell your doctor if, for any reason, you have not used Diclofenac Devatis Eye Drops exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

***Things you must not do***

**Do not stop using your medicine or lower the dosage without checking with your doctor.**

**Do not use Diclofenac Devatis Eye Drops to treat any other complaints unless your doctor tells you to.**

**Do not give this medicine to anyone else, even if they have the same complaint as you.**

***Things to be careful of***

**Be careful driving or operating machinery until you know how Diclofenac affects you.**

This medicine may cause blurred vision in some people. If you get blurred vision when you use it, do not drive, operate machinery or do anything else that could be dangerous until this effect has worn off.

---

## **SIDE EFFECTS**

---

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Diclofenac.**

This medicine helps most people with inflammation of the eye, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need medical attention if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- pain, itching, redness, discomfort or irritation of your eye
- blurred vision immediately after using the drops
- gritty foreign body sensation in your eye
- unusual sensitivity of your eyes to light

The above list includes the more common side effects of your medicine. They also occur with many other eye drops and are usually mild and short-lived.

Additional side effects that are noticed less often include:

- allergic conditions such as swollen, runny eyes, itching or rash elsewhere on your body, cough, sneezing, runny or blocked nose, facial pressure or pain.
- discharge from the eye

- crusty or irritated eyelids
- eye and eyelid swelling
- eyelid redness or itchiness
- watery eyes
- damage, scarring, thinning or cloudiness of eye surface
- increase in eye pressure
- impaired wound healing

**Tell your doctor as soon as possible if you notice any of the following:**

- Changes in your vision other than temporary blurring
- Wheezing or difficulty breathing.

The above list includes more serious side effects which may require medical attention. Serious side effects are rare.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor checks your eyes from time to time to check your progress.

**Do not be alarmed by the following lists of side effects.**

You may not experience any of them.

---

## **AFTER USING Diclofenac Devatis Eye Drops**

---

### *Storage*

**Keep your single use units in the blister pack until it is time to use them.**

**Keep them in a cool dry place where the temperature stays at or below 25°C.**

Once the inner blister is open, the contents may be kept at room temperature (below 25°C) for up to 28 days.

**Do not use the eye drops after more than 28 days storage at room temperature.**

**Discard each single dose unit and any remaining solution in it immediately after use. Do not save unused contents.**

**Do not store Diclofenac or any other medicine in the bathroom, near a sink, or on a window-sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep this medicine where children cannot reach them.**

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop using Diclofenac Devatis Eye Drops or it has passed its expiry date, ask your pharmacist what to do with any that is left over.**

---

## **PRODUCT DESCRIPTION**

---

### *What it looks like*

Diclofenac Devatis Eye Drops come in strips of 5 single dose units.

Each strip of 5 single dose units is sealed in a blister or pouch to protect it from light, air and water.



Each single dose unit contains 0.3 ml of a clear and colorless, particle free eye drop solution.  
A box of single dose units contains 10 x 0.3 ml, 20 x 0.3 ml, 30 x 0.3 ml or 60 x 0.3 ml single units and this leaflet.

Not all forms and pack sizes may be marketed.

### ***Ingredients***

Active ingredient:

Diclofenac Devatis Eye Drops contains diclofenac sodium 1 mg in 1 ml as the active ingredient.

Inactive ingredients:

Macrogolglycerol ricinoleate, Boric acid (E284), Trometamol, Water for injection.

---

### **Sponsor**

DEVATIS LIMITED  
45 Yarrow Street, Invercargill 9810, New Zealand  
Tel: +64 3 211 0080  
Fax: +64 3 211 0079  
[www.devatis.nz](http://www.devatis.nz)

---

### **Date of preparation**

This leaflet was revised in June 2022