

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

### **Prednisolon mibe 10 mg/ml eye drops, suspension**

prednisolone acetate

**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 Prednisolon mibe is and what it is used for
2. What you need to know before you use Prednisolon mibe
3. How to use Prednisolon mibe
4. Possible side effects
5. How to store Prednisolon mibe
6. Contents of the pack and other information

#### **1. What Prednisolon mibe is and what it is used for**

Prednisolon mibe is used in adults for the short-term treatment of

- severe, non-infectious inflammation of the anterior part of the eye, such as inflammation of the middle layer of the eye (uveitis anterior).
- inflammation after eye surgery, e.g. after cataract surgery.

Prednisolon mibe contains the active substance prednisolone acetate.

Prednisolone acetate is a glucocorticoid (a steroid) with a potent anti-inflammatory action. It prevents the release of inflammatory substances and thereby works against the signs of inflammation, e.g. oedema, blood vessel dilation and scarring.

#### **2. What you need to know before you use Prednisolon mibe**

##### **Do not use Prednisolon mibe**

- if you are allergic to prednisolone acetate, other glucocorticoids or any of the other ingredients of this medicine (listed in section 6).
- if you have an acute herpes simplex infection (dendritic keratitis) or any other viral eye infection.
- if you have an eye infection caused by bacteria or fungi, which is not being treated with appropriate antibiotic co-therapy.
- if you have narrow-angle or advanced glaucoma, which cannot be sufficiently controlled by medicinal products.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Prednisolon mibe.

Take special care with Prednisolon mibe if you have a history of herpes simplex.

In this case, Prednisolon mibe may only be used under strict medical supervision. Talk to your doctor before using this medicine if you have ever suffered from this condition in the past.

Talk to your doctor before using Prednisolon mibe if you currently have or have ever had any of the following conditions:

- eye ulcers or a history of tissue thinning as a result of disease or eye treatment.
- if you have glaucoma or if you are being treated for increased inner eye pressure.
- if you have had a cataract operation.
- eye infections caused by bacteria, viruses or fungi.

Before using Prednisolon mibe, tell your doctor if you are using or have been using any other eye drops containing steroids, as frequent or prolonged use of steroids can lead to additional side effects.

Contact your doctor if you experience blurred vision or other visual disturbances.

### **Children**

The safety and efficacy of Prednisolon mibe in children have not yet been established.

The lowest possible dose should be used. Long-term treatment should be avoided in children (see also section "Prednisolon mibe contains boric acid").

### **Other medicines and Prednisolon mibe**

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines including medicines obtained without a prescription.

No interactions with other medicines have occurred to date.

Apart from the use of Prednisolon mibe if you need to use other eye drops that can increase inner eye pressure, this side effect can be enhanced.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine as steroids may be harmful to your baby.

### **Driving and using machines**

Prednisolon mibe can lead to temporary blurred vision. Do not drive or use machines until this side effect has worn off.

### **Prednisolon mibe contains benzalkonium chloride**

This medicine contains 0.06 mg benzalkonium chloride per 1 ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

### **Prednisolon mibe contains boric acid**

This medicine should not be given to a child younger than 12 years without medical advice, as it contains boron and may impair fertility in the future.

## **3. How to use Prednisolon mibe**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, instil 1 drop into the affected eye(s), 4 times daily.

During the first two days of treatment, you may be instructed to use the eye drops every hour. Their use should then be reduced slowly in the following days and weeks.

**Directions for use**

You must not use the contents of the bottle if the tamper-proof closure on the bottleneck is broken before you first use it.

To open the bottle unscrew the cap by turning it until the tamper-proof closure breaks.

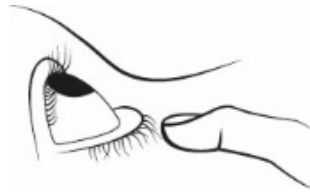
Wash your hands.

To prevent contamination, please ensure that the dispenser tip does not touch your eye nor the eyelid or the area around the eye or any other objects.

When opening the bottle for the first time please shake the bottle 10 times.

Please shake the bottle vigorously before use.

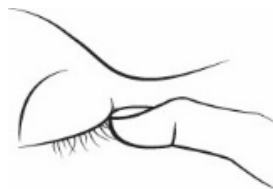
Open the bottle. Hold the bottle between thumb and fingers with the opening to the bottom.



Lean back your head. Pull the lower eyelid down with the index finger until there is a 'pocket' between eyelid and eye. Position the tip of the dropper very closely to your eye. Look upwards and drop one drop into the 'pocket' by slightly pressing the bottle.



Close your eye and press onto the corner of your eye beside the nose for a minute or gently close the eyelid. Please immediately clean excess overflow from the face. This prevents Prednisolon mibe from passing into the rest of the body via the tear duct and the skin.



If you use the eye drops in both eyes, repeat the procedure for the other eye.

Immediately after use, close the bottle by screwing the cap back on tightly in order to avoid contamination.

**If you use more Prednisolon mibe than you should**

Instillation of too many drops into the eye(s) is unlikely to lead to unwanted side effects. If you have inserted too many drops into your eye(s), rinse out your eye(s) with clear water. If this medicine has been drunk by mistake, tell your doctor immediately.

**If you forget to use Prednisolon mibe**

If you have forgotten a dose, make up for it as soon as you realise. However, if it is almost time for your next dose, skip the forgotten dose altogether, apply the next dose at the scheduled time and then continue your treatment as normal.

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

**If you stop using Prednisolon mibe**

Use Prednisolon mibe as instructed by your doctor. Do not stop using Prednisolon mibe until your doctor tells you to.

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.

As soon as you get any of the following side effects, please contact your doctor immediately:

- ulcers on the eye surface (corneal ulcers)
- severe eye pain.

Please contact your doctor if any of the following side effects gets serious or if they persist over a prolonged period:

- allergic reaction
- headache
- increased inner eye pressure
- clouding of the lens inside the eye (cataract)
- increased tearing or leakage as a result of eye injury (scleral or corneal perforation)
- feeling that something is in your eye
- eye infections (bacterial, fungal or viral)
- eye irritation
- red eye
- eye pain
- blurred or poor vision
- pupil dilation
- ptosis (drooping eyelid)
- impaired sense of taste
- rash or itching.

**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 (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.  
<to be completed nationally>

**5. How to store Prednisolon mibe**

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

Do not use this medicine if you notice that the protective seal on the bottle is damaged.

Do not store above 25 °C.

Keep the bottle in the outer carton in order to protect from light.

Store the bottle upright.

Do not use this medicine after the expiry date which is stated on the label and outer carton after {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

After opening the bottle, Prednisolon mibe has a shelf life of 4 weeks maximum.

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 Prednisolon mibe contains**

- The active substance is: prednisolone acetate.  
1 ml eye drops contains 10 mg prednisolone acetate.
- The other ingredients are:  
Boric acid, sodium citrate, sodium chloride, hypromellose, polysorbate 80, sodium edetate, benzalkonium chloride, sodium hydroxide solution or hydrochloric acid solution for pH adjustment, water for injections.

### **What Prednisolon mibe looks like and contents of the pack**

Prednisolon mibe is a white or almost white, sterile eye drops suspension and supplied in a plastic dropper container.

Each bottle contains 5 ml eye drops suspension.

Prednisolon mibe is available in packs with

1 x 5 ml,  
2 x 5 ml,  
3 x 5 ml and  
6 x 5 ml

eye drops, suspension.

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:**

|         |                                                   |
|---------|---------------------------------------------------|
| Austria | Prednifluid 10mg/ml Augentropfensuspension        |
| Germany | Prednifluid 10mg/ml Augentropfensuspension        |
| Sweden  | Prednisolon mibe 10 mg/ml ögondroppar, suspension |

**This leaflet was last revised in 2025-12-19.**