

**Scheduling Status:**

**S2**

## **Ketotifen iPharma (0,25 mg/ml, eye drops, solution) Ketotifen**

**Read all of this leaflet carefully because it contains important information for you**

Ketotifen iPharma is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Ketotifen iPharma carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Do not share Ketotifen iPharma with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 28 days.

**What is in this leaflet:**

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

**1. What Ketotifen iPharma is and what it is used for:**

Ketotifen iPharma contains the active substance ketotifen, which is an anti-allergic substance.

Ketotifen iPharma is used to treat eye symptoms of hay fever.

**2. What you need to know before you use Ketotifen iPharma:**

Do not use Ketotifen iPharma:

- if you are hypersensitive (allergic) to ketotifen or any of the other ingredients of Ketotifen iPharma (listed in section 6)
- if you are pregnant
- if you wear contact lenses.

### **Warnings and precautions:**

Ketotifen iPharma should only be used as eye drops.

Take special care with Ketotifen iPharma:

- if you wear contact lenses, because the preservative benzalkonium chloride may discolour your lenses and may also cause eye irritation (see “Ketotifen iPharma contains benzalkonium chloride” below)
- if you use Ketotifen iPharma for a long period of time, use it repeatedly or if you have an eye disease, because problems with your cornea (front transparent part of the eye) may develop and you should therefore go for regular eye examinations
- if you use other eye medicines, because you will need to wait at least 5 minutes between applying the different medicines (see “Other medicines and Ketotifen iPharma” below).

### **Children and adolescents**

Do not give Ketotifen iPharma to new-born babies and children below 3 years because it is unlikely to be safe.

### **Other medicines and Ketotifen iPharma**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are using any other eye medicines. If you need to apply any other medicine to your eyes together with Ketotifen iPharma, wait at least 5 minutes between applying each medicine.

Tell your doctor if you are taking any medicines used to treat depression or allergies. Ketotifen iPharma may increase the effect of these medicines.

### **Ketotifen iPharma with alcohol**

Ketotifen iPharma may increase the effect of alcohol.

### **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 health care provider for advice before taking this medicine.

The safe use of Ketotifen iPharma during breastfeeding has not been established.

### **Driving and using machines**

Ketotifen iPharma may make you drowsy or cause blurry vision. If this happens to you, wait until this has cleared before driving or operating machinery.

It is not always possible to predict to what extent Ketotifen iPharma may interfere with your daily activities. You should ensure not to drive or operate machinery until you are aware of the measure to which Ketotifen iPharma affects you.

### **Ketotifen iPharma contains benzalkonium chloride**

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.

### **3. How to use Ketotifen iPharma**

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

Always use Ketotifen iPharma exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children (age 3 years and older) is one drop into the affected eye(s) two to three times a day (in the morning, afternoon and evening, or in the morning and evening only).

#### **Instructions for use:**

1. Wash your hands.
2. Open the bottle. Do not touch the tip after opening the bottle.
3. Lean your head back (Figure 1).
4. Pull down your lower eyelid with your finger and hold the bottle in your other hand. Squeeze the bottle so that one drop falls into the eye (Figure 2).
5. Close your eyes and press the tip of one finger against the corner of the eye for around 1–2 minutes. This will prevent the drop running through the tear duct into your throat and most of the drop will remain in the eye (Figure 3). If necessary, repeat steps 3 to 5 with your other eye.
6. Close the bottle after use.



Figure 1



Figure 2

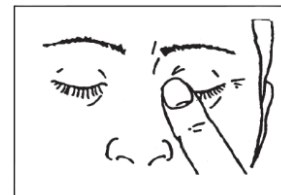


Figure 3

#### **If you use more Ketotifen iPharma than you should**

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

#### **If you forget to use Ketotifen iPharma**

If you forget to use Ketotifen iPharma you should treat your eyes as soon as you remember. Then continue with your normal routine.

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

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

Ketotifen iPharma can have side effects.

Not all side effects reported for Ketotifen iPharma are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Ketotifen iPharma, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- eye/eyelid rash or itching
- fainting.

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

#### **Tell your doctor if you notice any of the following:**

##### *Frequent side effects*

- eye irritation or pain
- inflammation of the eye, eye pain, blurred vision, abnormal intolerance to light (punctate keratitis and punctate corneal epithelial erosion)
- flu-like symptoms
- sore throat (pharyngitis)
- runny nose, sneezing, nasal congestion (rhinitis).

##### *Less frequent side effects*

- allergic reactions (hypersensitivity)
- headache
- drowsiness

- blurred vision when putting drops in the eye
- dry eyes
- eyelid disorder
- inflammation of the thin clear tissue that lies over the white part of the eye making it red and swollen (conjunctivitis)
- increased sensitivity of the eyes to light
- visible bleeding in the white of the eye
- watery eyes
- sticky eyes (discharge)
- enlarged pupil of the eye (mydriasis)
- burning or stinging of the eye
- itching of the eyes
- dry mouth
- skin rash (which may also itch)
- red, itchy, burning skin rash (eczema).

*Side effects with unknown frequency*

- allergic reactions presenting with dermatitis, eye swelling, itching and swelling of the eyelid
- allergic reactions presenting with swelling of the face, lips and tongue making it difficult to breathe
- worsening of existing asthma and eczema.

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 via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Ketotifen iPharma.

**5. How to store Ketotifen iPharma:**

Store all medicines out of reach of children.

Store at or below 25 °C.

There are no special storage instructions for Ketotifen iPharma.

After opening the bottle, the eye drops can only be stored for 28 days. Discard the remaining solution after 28 days.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

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

### **What Ketotifen iPharma contains:**

The active substance is ketotifen (as hydrogen fumarate). Each 1 ml contains 0,345 mg ketotifen hydrogen fumarate equivalent to 0,25 mg ketotifen.

The other ingredients are benzalkonium chloride, glycerol (E422), sodium hydroxide (E524) and water for injections.

Ketotifen iPharma contains 0,5 mg benzalkonium chloride in each 5 ml bottle which is equivalent to 0,1 mg/mL (0,01 % w/v).

### **What Ketotifen iPharma looks like and contents of the pack:**

Ketotifen iPharma is a clear, colourless solution.

5 ml solution is presented in a white low-density polyethylene (LDPE) bottle with a transparent LDPE dropper and white tamper-evident high-density polyethylene (HDPE) screw cap. Pack size: 1 bottle packed in an outer carton.

### **Holder of Certificate of Registration:**

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