

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

### KETAGEX™

#### Ketotifen fumarate 0,035 % eye drops, solution

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

KETAGEX is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use KETAGEX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share KETAGEX with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 3 days.

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

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

#### **1. What KETAGEX is and what it is used for**

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

KETAGEX is used for the temporary prevention of itching of the eye due to seasonal allergic conjunctivitis.

## 2. What you need to know before you use KETAGEX

### Do not use KETAGEX:

- If you are hypersensitive (allergic) to ketotifen fumarate or any of the other ingredients of KETAGEX (listed in section 6).
- If you are pregnant or breastfeeding since the safety has not yet been established.
- While wearing contact lenses.

### Warnings and precautions

KETAGEX should only be used in your eyes.

Do not use:

- if solution changes colour or becomes cloudy
- to treat contact lens related irritation.

Stop use and ask a doctor if you experience any of the following:

- eye pain
- changes in vision
- redness of the eyes
- itching that worsens or lasts more than 72 hours

### Children

Do not use KETAGEX in children younger than 3 years, as the safety and efficacy in this age group have not been established. Consult a doctor.

### Take special care with KETAGEX

- If you need to apply any other medicines to your eyes while using KETAGEX, wait at least 5 minutes between using each medicine.

- KETAGEX may make you feel drowsy.
- KETAGEX may increase the effect of alcohol and medicines including sedatives and antihistamines.
- If you use eye drops containing benzalkonium chloride, like KETAGEX, over a long period of time or repeatedly, you have a higher chance of experiencing side effects. Your doctor needs to examine your eyes regularly.
- If you wear soft contact lenses, you should consult your doctor before using KETAGEX.

### **Other medicines and KETAGEX**

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

The use of KETAGEX may increase the effects other medicines. Talk to your doctor or pharmacist before using KETAGEX if you take the following medicines:

- Central nervous system depressants, used to treat anxiety, stress or sleep disorders
- Other antihistamines, for the treatment of allergies

### **KETAGEX with alcohol**

The use of KETAGEX may increase the effects of alcohol.

### **Pregnancy and breastfeeding**

Do not use KETAGEX if you are pregnant or 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 using this medicine.

### **Driving and using machines**

You may experience blurred vision or somnolence (drowsiness) when you instil KETAGEX into your eye. If you experience blurred vision or somnolence (drowsiness) you should not drive or operate heavy machinery.

### **Important information about some of the ingredients of KETAGEX**

#### **KETAGEX contains benzalkonium chloride**

The preservative in KETAGEX, 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 KETAGEX 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, front layer of your eye). If you feel abnormal eye sensation, stinging or pain in the eye after using KETAGEX, talk to your doctor.

Your doctor may need to examine your eyes regularly if you use eye drops containing benzalkonium chloride for long periods.

### **3. How to use KETAGEX**

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

Always use KETAGEX exactly as described in this leaflet or as your doctor or pharmacist have 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 lower eyelid of the affected eye(s) twice daily, every 8-12 hours and no more than twice per day.

**Children under 3 years of age:** Consult a doctor

KETAGEX should not be used for longer than 4 weeks, as the safety and efficacy beyond 4 weeks have not been established.

### 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 (Fig. 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 (Fig. 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 (Fig. 3).  
If necessary, repeat steps 3 to 5 with your other eye.
6. Close the bottle after use.



Fig. 1



Fig. 2

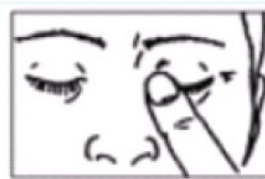


Fig. 3

### If you wear contact lenses

If you wear contact lenses, you should remove them before using KETAGEX. After using KETAGEX, you should wait 15 minutes before putting your contact lenses back in.

### If you use KETAGEX with other eye drops

Wait at least 5 minutes between using KETAGEX and other eye drops.

### How to handle the container

Do not let the tip of the bottle touch your eye, fingers or any other surfaces, as this may contaminate the eye drops.

Replace the cap after each use.

### **If you use more KETAGEX 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 KETAGEX**

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

## **4. Possible side effects**

KETAGEX can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

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

Tell your doctor if you experience any of the following while using KETAGEX:

Frequent side effects related to your eyes:

- allergic reactions,
- burning or stinging,
- discharge,
- dry eyes,
- eye pain,
- eyelid disorder,
- itching,
- tearing,
- sensitivity to light, or
- rash.

Other frequent side effects, unrelated to your eyes:

- headaches,
- a blocked nose, sore throat or other flu-symptoms, or
- drowsiness (sleepiness).

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>, or directly to the company, using the following e-mail address: [PV-SouthAfrica@bausch.com](mailto:PV-SouthAfrica@bausch.com)

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

## 5. How to store KETAGEX

Store all medicines out of reach of children.

- Store at 4 – 30 °C.
- After first opening, use within 60 days and discard any remaining solution.
- Keep the bottle tightly closed.
- Do not use after the expiry date stated on the carton or bottle.
- 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 KETAGEX contains

- The active substance is ketotifen fumarate. Each millilitre contains 0,345 mg ketotifen fumarate (0,035 % *m/v*), which is equivalent to 0,25 mg ketotifen (0,025 % *m/v*).
- The other ingredients are benzalkonium chloride, glycerine and water for injection.

### What KETAGEX looks like and contents of the pack

The solution is a clear, colourless to yellow liquid.

KETAGEX is supplied as a 10 ml solution in a 10 ml white, round low-density polyethylene bottle with a natural linear low-density polyethylene tip and white polypropylene cap. The bottle is labelled and supplied in a carton with a patient information leaflet.

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**Access to the corresponding Professional Information**

The Professional Information is available on the company website, [www.bausch.co.za](http://www.bausch.co.za), or may be requested telephonically: +27 10 025 2100.

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