

PACKAGE LEAFLET

Package leaflet: Information for the user

Ketofall 0.25 mg/ml eye drops, solution in single-dose container

Ketotifen

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ketofall is and what it is used for

Ketofall contains the active substance ketotifen hydrogen fumarate, which is an anti-allergic substance. Ketofall is used to treat eye symptoms of hay fever, which may include itchy, watery, inflamed or red eyes and puffy eyelids.

2. What you need to know before you use Ketofall

Do not use Ketofall:

- if you are allergic (hypersensitive) to ketotifen hydrogen fumarate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Ketofall.

Children

Ketofall has not been investigated in children below the age of 3 years.

Other medicines and Ketofall

If you need to use any other eye medicines at the same time as using Ketofall, wait at least 5 minutes between using each medicine.

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This is particularly important for medicines which are used to treat:

- depression, anxiety and sleep disorders
- allergy (e.g. antihistamines)

Ketofall with alcohol

Ketofall may increase the effect of alcohol.

Pregnancy and breast-feeding

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

Ketofall can be used during breast-feeding.

Driving and using machines

Ketofall may cause blurred vision or drowsiness. If this happens to you, wait until this has cleared before driving or operating machines.

3. How to use Ketofall

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

The usual dose for adults, the elderly and children (age 3 and older) is one drop into the affected eye(s) twice a day, once in the morning and once in the evening.

Use in children below the age of 3 years

Ketofall has not been investigated in children below the age of 3 years.

One single-dose container contains enough solution to treat both eyes in one use.

Instructions for use

1. Wash your hands.
2. Open the aluminium pouch and pull out the block of single-dose containers.
3. Remove one of the single-dose containers from the strip (Fig. 1).
4. Place the remaining single-dose containers back and close the pouch by folding the edge over. Place the pouch in the carton.
5. Open the single-dose container by twisting off the tip. Do not touch the tip after opening the container (Fig 2).
6. Lean your head back (Fig. 3).
7. Pull down your lower eyelid with your finger and hold the single-dose container in your other hand. Squeeze the container so that one drop falls into the eye (Fig 4).
8. Close your eyes and press the tip of one finger against the inner 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 5). If necessary repeat steps 6 to 8 with your other eye.
9. Throw away the single-dose container after use.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

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

If you use more Ketofall than you should

There is no danger if you have accidentally taken Ketofall by mouth or if you have used more than one drop in the eye. If you have any doubt, contact your doctor for advice.

If you forget to use Ketofall

If you forget to use Ketofall, treat your eyes as soon as you remember. Then continue with your normal routine. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

The following side effects have been reported.

Common side effects (may affect up to 1 in 10 patients)

- eye irritation or eye pain
- inflammation in the eye (pain, redness or swelling)
- corneal epithelial damage (damage to the layer that covers the front of the eye)

Uncommon side effects (may affect up to 1 in 100 patients)

- blurred vision when putting drops on the eye
- dry eye (dry, itchy, burning or feeling that there is something in your eye)
- eyelid disorder (a condition which affects the eyelid)
- conjunctivitis (red, sore, sticky eye)
- increased sensitivity of the eyes to light
- visible bleeding in white of eye
- headache
- drowsiness
- rash (which may also itch)
- eczema (itchy, red, burning rash)
- dry mouth
- allergic reaction (including swelling of the face and eyelids) and worsening of existing allergic conditions such as asthma and eczema

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:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ketofall

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 carton, the pouch and the single dose container after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze.

Keep the container in the aluminium pouch.

Ketofall contains no preservative. Once the single-dose container is open, use the contents immediately and do not store the open container. Throw away the solution left in the single-dose container after using.

After opening the aluminium pouch, do not use Ketofall for more than 4 weeks.

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 Ketofall contains

- The active substance is ketotifen (as hydrogen fumarate). One ml solution contains 0.25 mg ketotifen corresponding to 0.345 mg ketotifen hydrogen fumarate.
- The other ingredients (excipients) are glycerol (E422), sodium hydroxide (E524) (for pH-adjustment) and water for injections.

What Ketofall looks like and contents of the pack

Ketofall is a clear, colourless solution. One single-dose container contains 0.4 ml.

Ketofall is available in packs containing 5, 10, 20, 30, 50 and 60 single-dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pharma Stulln GmbH

Werksstrasse 3

92551 Stulln

Germany

Manufacturer

Pharma Stulln GmbH

Werksstrasse 3

92551 Stulln

Germany

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

Austria:	Ketotifen Stulln 250 Mikrogramm/ml Augentropfen im Einzeldosisbehältnis
Germany:	Allergo-Vision sine 0,25 mg/ml Augentropfen im Einzeldosisbehältnis
Netherlands:	Ketotifen Stulln Unit Dose 0,25 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik
Spain:	Ketotifeno Nicox Farma 0,25 mg/ml colirio en solución en envase unidos
Ireland and	
United Kingdom:	Ketofall 0.25 mg/ml eye drops, solution in single-dose container

This leaflet was last revised in month YYYY

If you would like any more information, or would like the leaflet in a different format, please contact Scope Ophthalmics Ltd, telephone number:

From Ireland FREEPHONE 1800 816 005