

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ketazed 0.25 mg/ml, eye drops, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains 0.345 mg ketotifen hydrogen fumarate corresponding to 0.25 mg ketotifen.

Each drop contains 9.5 microgram ketotifen fumarate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Clear, colourless to faintly yellow solution.

pH: 4.8 – 6.4

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of seasonal allergic conjunctivitis.

4.2 Posology and method of administration

Posology

Adults, elderly and children (from 3 years of age and older): one drop of Ketazed 0.25 mg/ml, eye drops solution into the conjunctival sac twice a day.

Paediatric population

The safety and efficacy of Ketazed 0.25 mg/ml, eye drops solution in children aged from birth to 3 years have not yet been established.

Method of administration

To avoid contamination do not touch any surface with the dropper tip.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

No special warnings or precautions for use.

4.5 Interaction with other medicinal products and other forms of interaction

If Ketazed 0.25 mg/ml, eye drops solution is used with other eye medications, an interval of at least 5 minutes must be observed between the administration of the two medications.

The use of oral dosage forms of ketotifen may potentiate the effect of CNS depressants, antihistamines and alcohol. Although this has not been observed with ketotifen fumarate eye drops, the possibility of such effects cannot be excluded.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are insufficient data on the use of ketotifen eye drops during pregnancy. Animal studies using maternally toxic oral doses showed increased pre- and postnatal mortality, but no teratogenicity. Systemic levels after ocular administration are much lower than after oral use. Caution is advised when prescribing to pregnant women.

Breast-feeding

Although animal data following oral administration show excretion into breast milk, it is unlikely that topical administration in humans leads to detectable

quantities in breast milk. Ketazed 0.25 mg/ml, eye drops solution can be used during lactation.

Fertility

There are no data available on the effect of ketotifen fumarate on fertility in humans.

4.7 Effects on ability to drive and use machines

Any patient who experiences blurred vision or somnolence should not drive or operate machines.

4.8 Undesirable effects

Adverse reactions are ranked under heading of frequency, using the following convention: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Immune system disorders

Uncommon: Hypersensitivity reactions

Nervous system disorders

Uncommon: Headache

Eye disorders

Common: Eye irritation, eye pain, punctate keratitis, punctate corneal epithelial erosion.

Uncommon: Blurred vision (during instillation), dry eyes, eyelid disorder, conjunctivitis, photophobia, conjunctival bleeding.

Gastrointestinal disorders

Uncommon: Dry mouth

Skin and subcutaneous tissue disorders

Uncommon: Rash, eczema, urticaria

General disorders and administration site conditions

Uncommon: Somnolence

Adverse drug reactions from post-marketing experience (Frequency not known):

The following post marketing events have also been observed during post-marketing: hypersensitivity reactions including local allergic reaction (mostly contact dermatitis, eye swelling, eyelid pruritis and oedema), systemic allergic reactions including facial swelling/oedema of the face (in some cases associated with contact dermatitis) and exacerbation of pre-existing allergic conditions such as asthma and eczema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme as www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No cases of overdose have been reported.

Oral ingestion of the contents 10 ml bottle would be equivalent to 2.5 mg of ketotifen which is 125% of a recommended oral daily dose for a 3 year old child. Clinical results have shown no serious signs or symptoms after oral ingestion of up to 20 mg of ketotifen.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, other antiallergics
ATC code: S01GX08

Ketotifen is a histamine H1-receptor antagonist. *In vivo* animal studies and *in vitro* studies suggest the additional activities of mast cell stabilization and inhibition of infiltration, activation and degranulation of eosinophils.

5.2 Pharmacokinetic properties

In a pharmacokinetic study conducted in 18 healthy volunteers who received Ketazed eye drops solution, the plasma levels of ketotifen after repeated ocular administration for 14 days were in most cases below the limit of quantitation (20 pg/ml).

After oral administration, ketotifen is eliminated biphasically with an initial half-life of 3 to 5 hours and a terminal half-life of 21 hours. About 1% of the substance is excreted unchanged in the urine within 48 hours and 60 to 70% are excreted in the form of metabolites. The main metabolite is the practically inactive ketotifen-N-glucuronide.

5.3 Preclinical safety data

Preclinical data from conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction do not indicate any special risks to humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hyaluronate
Glycerol (E 422)
Sodium hydroxide (E 524)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

In unopened bottle: 2 years
After opening: 3 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The container is a 10 ml white high density polyethylene bottle closed with a 28 µl dropper. One bottle contains 10 ml of solution.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

HORUS PHARMA
148 avenue Georges Guynemer
Cap Var D2
06700 Saint-Laurent-du-Var
France

8 MARKETING AUTHORISATION NUMBER(S)

PL 40934/0001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

05/01/2024

10 DATE OF REVISION OF THE TEXT

04/02/2026