Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zaditen 0.25 mg/ml, eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Each drop contains 8.5 microgram ketotifen fumarate.

Excipient(s) with known effect: Benzalkonium chloride (0.1mg/ml).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Clear, colourless to faintly yellow solution.

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 (age 3 and older): one drop of Zaditen into the conjunctival sac twice a day.

Paediatric population
The safety and efficacy of Zaditen in children aged from birth to 3 years have not yet been established.

Method of administration
The contents and dispenser remain sterile until the original closure is broken. 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

This medicine contains 2.6 micrograms benzalkonium chloride in each drop.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.
Benzalkonium chloride may also cause eye irritation, especially in dry eyes or disorders of the cornea.

4.5 Interaction with other medicinal products and other forms of interaction

If Zaditen is used concomitantly with other eye medications there must be an interval of at least 5 minutes between 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 Zaditen eye drops, the possibility of such effects cannot be excluded.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of ketotifen eye drops in pregnant women. 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 should be exercised when prescribing to pregnant women.

Breast-feeding
Although animal data following oral administration show excretion into breast milk, topical administration to human is unlikely to produce detectable quantities in breast milk. Zaditen eye drops can be used during lactation.

Fertility
There is 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, somnolence or dizziness should not drive or operate machines.

4.8 Undesirable effects

Adverse reactions are ranked under heading of frequency, using the following convention: Very common (≥1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 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

Nervous system disorders
Uncommon: Headache

Eye disorders
Common: Eye irritation, eye pain, punctate keratitis, punctate corneal epithelial erosion.
Uncommon: Vision blurred (during instillation), dry eye, eyelid disorder, conjunctivitis, photophobia, conjunctival haemorrhage.

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:

- hypersensitivity reactions including local allergic reaction (mostly contact dermatitis, eye swelling, eyelid pruritis and oedema), systemic allergic reactions including facial swelling/oedema (in some cases associated with contact dermatitis) and exacerbation of pre-existing allergic conditions such as asthma and eczema.
- dizziness.

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 HPRA Pharmacovigilance Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

Oral ingestion of the contents of a 5 ml bottle would be equivalent to 1.25 mg of ketotifen which is 60% 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 anti-allergics
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 stabilisation and inhibition of infiltration, activation and degranulation of eosinophils.

5.2 Pharmacokinetic properties

In a pharmacokinetic study conducted in 18 healthy volunteers with Zaditen eye drops, 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% as metabolites. The main metabolite is the practically inactive ketotifen-N-glucuronide.

5.3 Preclinical safety data

Preclinical data reveal no special hazard which is considered relevant in connection with use of Zaditen eye drops in humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Glycerol (E422)
Sodium hydroxide (E524)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened bottle: 2 years.
After opening: 4 weeks.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

The container is a white-coloured LDPE bottle with a transparent LDPE dropper and a white HDPE screw cap with an integrated safety ring. One bottle contains 5 ml of the solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratoires Thea
Zone Industrielle Du Brezet
12 Rue Louis Bleriot
Clermont Ferrand
63100
France

8 MARKETING AUTHORISATION NUMBER

PA1107/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 November 2000

Date of last renewal: 30 June 2010

10 DATE OF REVISION OF THE TEXT

October 2025