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SUMMARY OF PRODUCT CHARACTERISTIC

1. Name of the medicinal product

OPTAFEN

2. Qualitative and quantitative declaration

Each 1 mL contains:-

Ketotifen fumarate	0.345	mg
Equivalent to Ketotifen	0.25	mg

3. Pharmaceutical form

Clear colorless sterile solution

4. Clinical particulars

4.1 Therapeutic indications

Symptomatic treatment of seasonal allergic conjunctivitis.

4.2 Posology and method of administration

- Adults, elderly and children (age 3 and older): one drop of OPTAFEN into the conjunctival sac twice a day.
- The contents and dispenser remain sterile until the original closure is broken.
- To avoid contamination do not touch any surface with the dropper tip.
- The safety and efficacy of Ketotifen 0.25 mg/ml in children aged from birth to 3 years have not yet been established.

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

The formulation of OPTAFEN eye drops contains benzalkonium chloride as a preservative, which may be deposited in soft contact lenses; therefore OPTAFEN eye drops should not be instilled while the patient is wearing these lenses. The lenses should be removed before application of the drops and not reinserted earlier than 15 minutes after use.

All eye drops preserved with benzalkonium chloride may possibly discolour soft contact lenses. Benzalkonium chloride may cause eye irritation.

4.5 Interaction with other medicinal products and other forms of interaction

If OPTAFEN 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 Ketotifen 0.25 mg/ml eye drops, the possibility of such effects cannot be excluded.

4.6 Pregnancy and lactation

Pregnancy

There are no adequate data from the use of Ketotifen 0.25 mg/ml 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. Ketotifen 0.25 mg/ml eye drops can be used during lactation.

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 (≥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, urticarial

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.

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 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 stabilisation and inhibition of infiltration, activation and degranulation of eosinophils.

5.2 Pharmacokinetic properties

In a pharmacokinetic study conducted in 18 healthy volunteers with OPTAFEN 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-Nglucuronide.

5.3 Preclinical safety data

Preclinical data reveal no special hazard which is considered relevant in connection with use of Ketotifen 0.25 mg/ml 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

- Glycerin
- Benzalkonium chloride
- Sodium hydroxide
- Water for injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Shelf-life 2 years

After opening : 30 days

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Clear plastic bottle (LPDE) of 5 and 10 mL with a paper box of 1, 10, 20, 50 and 100 ampoules.

7. Marketing authorisation holder

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Tel. 0-2532-7181 Fax 0-2532-7019

8. Marketing authorisation number(s)

xx xxx/xx

9. Date of first authorization/ renewal of the authorization

DD/MM/YYYY

10. Date of revision of the text

4 April 2022