SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Azelastine OmniVision 0.5 mg/ml eye drops, solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One mL contains 0.5 mg azelastine hydrochloride.
Each drop contains 0.015 mg azelastine hydrochloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

Clear and colourless to nearly colourless, slightly viscous solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment and prevention of the symptoms of seasonal allergic conjunctivitis in adults and children 4 years and older.

Treatment of the symptoms of non-seasonal allergic conjunctivitis in adults and children 12 years and older.

4.2. Posology and method of administration

Posology

Seasonal allergic conjunctivitis
The usual dosage in adults and children 4 years and older is one drop in each eye twice daily that can be increased, if necessary to four times daily. If allergen exposure is anticipated, [nationally completed name] should be administered prophylactically, prior to the exposure.

Non-seasonal (perennial) allergic conjunctivitis:
The usual dosage in adults and children 12 years and older is one drop in each eye twice daily that can be increased, if necessary to four times daily.

As safety and efficacy have been demonstrated in clinical trials for a period of up to 6 weeks, the duration of any course should be limited to a maximum of 6 weeks.

Paediatric population
Safety and efficacy of [nationally completed name]in children aged less than 4 years has not been established.

Method of administration

Ocular use.

Advice for use without prescription: Patients should be advised to contact their doctor if symptoms worsen or do not improve after 48 hours.
It should be pointed out, that use for more than 6 weeks must take place under medical supervision even in seasonal allergic conjunctivitis.

For detailed information on how to use [nationally completed name], please refer to the Package Leaflet, section 3. “How to use [nationally completed name]”.

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

[nationally completed name]is not intended for treatment of eye infections.

Contact with soft contact lenses should be avoided.
Contact lenses should be removed prior to instillation and the patient should wait at least 15 minutes before reinsertion.

4.5. Interaction with other medicinal products and other forms of interaction

No specific interaction studies with [nationally completed name] have been performed.

Interaction studies at high oral doses have been performed however they bear no relevance to [nationally completed name]as systemic levels, after administration of the eye drops, are in the picogram range.

4.6. Fertility, pregnancy and lactation

Fertility
Effects on human fertility have not been investigated.
Pregnancy
There is insufficient information available to establish the safety of azelastine in human pregnancy. At high oral doses azelastine has shown to induce adverse effects (foetal death, growth retardation and skeletal malformation) in experimental animals. Local ocular application will result in minimal systemic exposure (picogram range). However, caution should be exercised when using [nationally completed name] during pregnancy.
Breast-feeding
Azelastine is excreted into the milk in low quantities. For that reason, [nationally completed name] is not recommended during breast feeding.

4.7. Effects on ability to drive and use machines

[nationally completed name] has moderate influence on the ability to drive and use machines.

The mild, transient irritation which can be experienced after application of [nationally completed name] is unlikely to affect vision to any greater extent. However, if there are any

transient effects on vision, the patient should be advised to wait until this clears before driving or operating machinery.

4.8. Undesirable effects

Assessment of undesirable effects is based on the following frequencies: 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).

The following adverse events have been reported during Azelastine hydrochloride therapy:

Eye disorders
Common: mild, transient irritation in the eye.

Nervous system disorders
Uncommon: bitter taste.

Immune system disorders
Very rare: allergic reactions (such as rash and pruritus).

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 national reporting system listed in Appendix V.

4.9. Overdose

No specific reactions after ocular overdose are known, and with the ocular route of administration, overdose reactions are not anticipated.

There is no experience with the administration of toxic doses of azelastine hydrochloride in humans. In the case of overdose or intoxication, disturbances of the central nervous system are to be expected based on the results of animal experiments. Treatment of these disorders must be symptomatic. There is no known antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic Group: Antiallergic, ATC code: S01G X07.

Azelastine, a phthalazinone derivative is classified as a potent long-acting anti-allergic compound with selective H1 antagonist properties. An additional anti-inflammatory effect could be detected after topical ocular administration.

Data from in vivo (pre-clinical) and in vitro studies show that azelastine inhibits the synthesis or release of the chemical mediators known to be involved in early and late stage allergic reactions e.g. leukotriene, histamine, PAF and serotonin.

To date, long term therapy ECG evaluations of patients treated with high oral doses of azelastine, have shown that in multiple dose studies, there is no clinically significant effect of azelastine on the corrected QT (QTc) interval.

No association of azelastine with ventricular arrhythmia or torsade de pointes was observed in over 3700 patients treated with oral azelastine.

5.2 Pharmacokinetic Properties

General characteristics (systemic pharmacokinetics)

Following oral administration azelastine is rapidly absorbed showing an absolute bioavailability of 81%. Food has no influence on absorption. The volume of distribution is high indicating distribution predominantly into the periphery. The level of protein binding is relatively low (80 - 90%, a level too low to give concern over drug displacement reactions).

Plasma elimination half-lives after a single dose of azelastine are approximately 20 hours for azelastine and about 45 hours for the therapeutically active metabolite N-Desmethyl azelastine. Excretion occurs mainly via the faeces. The sustained excretion of small amounts of the dose in the faeces suggests that some entero-hepatic circulation may take place.

Characteristics in patients (ocular pharmacokinetics)

After repeated ocular application of azelastine ophthalmic solution (up to one drop in each eye, four times daily), Cmax steady state plasma levels of azelastine hydrochloride were very low and were detected at or below the limit of quantification.

5.3 Preclinical safety data

Azelastine hydrochloride displayed no sensitising potential in the guinea pig. Azelastine demonstrated no genotoxic potential in a battery of in vitro and in vivo tests, nor any carcinogenic potential in rats or mice.

In male and female rats, azelastine at oral doses greater than 30 mg/kg/day caused a dose-related decrease in the fertility index; no substance-related alterations were found in the reproductive organs of males or females during chronic toxicity studies, however.

Embryotoxic and teratogenic effects in rats, mice and rabbits occurred only at maternal toxic doses (for example, skeletal malformations were observed in rats and rabbits at doses of 50 mg/kg/day).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sorbitol liquid
Hypromellose
Disodium edetate
Sodium hydroxide
Water for injections

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.
After first opening of the container: 12 weeks.

6.4. Special precautions for storage

Do not store above 30 °C.

6.5. Nature and contents of container

6 mL white HDPE bottle and white dropper with HDPE cap.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

2026-02-12