SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Otrivine-Antistin Eye Drops Xylometazoline 0.05% w/v Antazoline 0.5% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Xylometazoline hydrochloride 0.05%
Antazoline sulphate 0.5%

Excipients with known effect: Benzalkonium chloride (0.1 mg/ml), boric acid (30 mg/ml).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops solution

A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the temporary relief of redness and itching of the eye due to seasonal and perennial allergies such as hay fever or house dust allergy.

4.2 Posology and method of administration

Posology

Adults
1 or 2 drops instilled 2 - 3 times a day.

Paediatric population
Children aged 12 years and over: 1 drop instilled 2 to 3 times a day.
No specific studies are available in this patient group. Due to possible systemic effects, Otrivine-Antistin is not recommended for use in children younger than 12 years of age (see also section 4.4).

Elderly
1 drop instilled 2 to 3 times a day.

Otrivine-Antistin Eye Drops should not be used for more than seven consecutive days.

Method of administration

For local administration to the eye.

The dispenser remains sterile until the original closure is broken. Patients must be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures as this may contaminate the solution.

If more than one medication needs to be instilled in the eye, an interval of at least 5 minutes between application of the different medicinal products must be allowed.

4.3 Contraindications

- Hypersensitivity to the active substances to any of the excipients listed in section 6.1
- Presence of narrow angle glaucoma
- Use with contact lenses
- Use in patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment (see section 4.5)

4.4 Special warnings and precautions for use

Like other topically applied ophthalmic drugs, Otrivine-Antistin may be absorbed systemically and occasionally cause systemic sympathomimetic effects such as hypertension, nervousness, nausea, dizziness, headache, insomnia, palpitations, tachycardia, and arrhythmia.

Otrivine-Antistin should be used with caution in elderly patients with severe cardiovascular disease, including arrhythmia, poorly controlled hypertension or diabetes.

Use with caution in the presence of hypertension, cardiac irregularities, hyperthyroidism, diabetes mellitus or phaeochromocytomas.

Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.

Otrivine-Antistin should also be used with caution in patients with conditions causing urinary retention such as prostatic hypertrophy and should also be used in caution in patients who are currently receiving other sympathomimetic drugs.

Not suitable for patients suffering from dry eyes without first seeking medical advice. Rebound hyperaemia may follow prolonged frequent use. Otrivine-Antistin should not be used without supervision over a long period of time.

If the symptoms do not improve after 2 days, medical advice should be sought to rule out the possibility of a bacterial infection. Inflammation arising from infection should receive appropriate anti-bacterial therapy.

Eye drops are not for injection. They should never be injected subconjunctivally, nor should they be directly introduced into the anterior chamber of the eye.

This medicine contains 2.8 micrograms benzalkonium chloride in each drop, which is equivalent to 0.1 mg/ml.

Benzalkonium chloride may cause eye irritation, especially with dry eyes or disorders of the cornea. Patients should be instructed to talk to a doctor if they feel abnormal eye sensation, stinging or pain in the eye after using this medicine.

This medicine contains boric acid.

Otrivine-Antistin may impair fertility in the future as it contains boron. It should therefore not be administered to a child less than 2 years old.

4.5 Interaction with other medicinal products and other forms of interaction

This product should not be used in patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment (see section 4.3).

Sedating anti-histamines can enhance the sedating effects of CNS depressants including alcohol, hypnotics, opioid analgesics, anxiolytic sedatives and anti-psychotics. They also have an additive anti-muscarinic action with other anti-muscarinic drugs, such as atropine and some antidepressants. Otrivine-Antistin should be used with caution in patients receiving other medications such as digitalis, beta-adrenergic blockers, guanethidine, reserpine, methyldopa or anti-hypertensive agents. Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias.

4.6 Pregnancy and lactation

In line with common practice, the use of medication during pregnancy is not recommended unless considered essential.

It is not known whether the active ingredients are distributed in human milk. It should therefore not be administered to nursing mothers or breast feeding should be interrupted for 48 hours after administration.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Otrivine-Antistin is generally well tolerated. In a few cases, slight transient local stinging on instillation has been reported. Other side effects which have been reported very occasionally are blurred vision, mydriasis, headache, drowsiness and reactive hyperaemia.

Local allergic reactions (e.g. rash, oedema, pruritus) and eye irritation have also been reported post-marketing.

Systemic side effects, which may occur in sensitive patients, are tachycardia (especially in small children), palpitations, arrhythmia, hypertension, occipital headache, nausea, paleness and sweating.

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. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Excessive dosage and/or prolonged or too frequent use of xylometazoline hydrochloride, especially in children, may cause adverse systemic effects. Excessive dosage in children may cause profound CNS depression possibly necessitating intensive supportive care. CNS depression, shock-like hypotension and coma have occurred following overdose of naphazoline and tetrahydrozoline; the possibility that this may occur with xylometazoline should be kept in mind.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sensory organs, ophthalmologicals, decongestants and antiallergics, sympathomimetics used as decongestants, ATC code: S01GA53. Otrivine-Antistin is a combination of a long acting vasoconstrictor, xylometazoline and an antihistamine, antazoline.

Xylometazoline is a sympathomimetic agent with marked alpha-adrenergic activity. It acts as a vasoconstrictor which reduces eye redness.

Antazoline is an H1 receptor antagonist. It has antihistaminic, anticholinergic and local anaesthetic properties. The primary mediator of inflammation in allergic conjunctivitis appears to be histamine. Antazoline reduces histamine induced responses including itching. In clinical studies, Otrivine-Antistin was shown to cause a small mydriatic response but no change in intraocular pressure. The mydriatic response is too small to be of clinical significance or to impose any risk of pupil block or irido-corneal angle glaucoma, even in susceptible subjects.

5.2 Pharmacokinetic properties

No formal studies have been conducted.

5.3 Preclinical Safety Data

There are no other clinically relevant preclinical safety data in addition to those mentioned in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Boric acid
Disodium edetate
Sodium tetraborate
Water for injections

6.2 Incompatibilities

None anticipated

6.3 Shelf Life

Unopened: 24 months
Opened: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

10ml Polyethylene dropper bottle.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratoires THEA
12, rue Louis Blériot
63017 Clermont-Ferrand Cedex 2
France

8. MARKETING AUTHORISATION NUMBER(S)

PL 20162/0016

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28/10/2005

10. DATE OF REVISION OF THE TEXT

26/06/2019