SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME AND DOSAGE FORM

OXYLIN® Liquifilm Sterile Ophthalmic Solution

COMPOSITION

OXYLIN contains:

Oxymetazoline hydrochloride 0,25 mg/ml

Liquifilm (polyvinyl alcohol) 14 mg/ml

Preservative

Benzalkonium chloride 0,004 % m/v

PHARMACOLOGICAL CLASSIFICATION

A. 15.4 Ophthalmological preparations. Other.

PHARMACOLOGICAL ACTION

Oxymetazoline, an imidazoline derivative, is a sympathomimetic product that acts to constrict blood vessels. It is presumed that this effect is due to direct action of the product upon the alpha (postsynaptic) receptors of the vascular smooth muscle.

Oxymetazoline is characterised by an early onset of action. The effect lasts for several hours.

INDICATIONS

OXYLIN is indicated for short-term use in the treatment of conjunctivitis and irritation of the eye.

CONTRAINDICATIONS

OXYLIN is contraindicated in those individuals in whom pupillary dilation should be avoided (angle-closure glaucoma or those with critically narrow angles). This product should not be used by those individuals with known hypersensitivity to any of the components of this product.

Sympathomimetic medicines should be used with caution in patients using systemic MAO inhibitors as an increase in blood pressure may occur.

Use in children, especially infants, may result in CNS depression leading to coma and market reduction in body temperature.

Cardiovascular effects may occur following topical application of sympathomimetics to the eye. Excessive doses may cause peripheral vasoconstriction, decreased heart rate and increased blood pressure in children and susceptible adults, i.e. those rare adult patients with a predisposition to sympathetic sensitivity.

WARNINGS AND SPECIAL PRECAUTIONS

As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required.

Caution should be exercised in the use of benzalkonuim chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

Use with caution in patients with cardiovascular diseases, hypertension, hyperglycaemia (diabetes), hyperthyroidism, in individuals under treatment with antidepressants and when other medicines are being used.

Patients receiving MAO inhibitor therapy or within 14 days of stopping such treatment may experience hypertensive crisis.

OXYLIN should be given with care to patients with prostatic enlargement as it may increase difficulty in micturition.

Use with caution on the inflamed eye, as significant hyperaemia greatly increases the rate of systemic absorption through the conjunctiva, and prolonged or frequent use, especially in an inflamed eye, may result in increased absorption and possible systemic effects.

OXYLIN contains the preservative benzalkonium chloride, which may be absorbed by and cause discolouration of soft contact lenses. Patients wearing soft (hydrophilic) contact lenses should be instructed to remove contact lenses prior to administration of OXYLIN and wait at least 15 minutes following administration before reinserting soft contact lenses.

To prevent eye injury or contamination, care should be taken to avoid touching the dispensing bottle to the eye or to any other surface. The use of the bottle by more than one person may spread infection.

If symptoms persist or worsen after a short period of treatment (approximately 2-3 days), consult a doctor.

Paediatric Use

The safety and efficacy of OXYLIN in patients younger than 18 years of age have not been established.

Geriatric Use

The safety and efficacy of OXYLIN in the elderly population have not been established.

Effects on Ability to Drive and Use Machines

If transient blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

INTERACTIONS

No interaction studies have been performed.

Concurrent use of methyldopa, maprotiline, or tricyclic antidepressants with OXYLIN may alter the effects of OXYLIN.

PREGNANCY AND LACTATION

Safety and/or efficacy during pregnancy and lactation has not been established

DOSAGE AND DIRECTIONS FOR USE

One to two drops in the eye(s) two to four times a day.

SIDE EFFECTS

Eye irritation, pupillary dilation, rebound congestion, ocular pain and rebound miosis may occur and may be accompanied by an increase in intraocular pressure. Systemic effects due to absorption of topically applied oxymetazoline have not been reported (refer to CONTRAINDICATIONS).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In case of overdosage or accidental ingestion, OXYLIN can cause peripheral vasoconstriction and severe central nervous depression including hypertension followed by reflex bradycardia and hypotension, marked reduction in body temperature, sweating, drowsiness and coma, particularly in children and susceptible adults i.e. those rare adult patients with a predisposition to sympathetic sensitivity.

Should accidental overdosage in the eye(s) occur, flush the eye(s) with water or normal saline. If accidentally ingested, push fluids, induce emesis and institute gastric lavage.

IDENTIFICATION

OXYLIN is a clear, colourless to slightly yellow solution.

PRESENTATION

OXYLIN is supplied in sterile plastic dropper bottles containing 5 ml or 15 ml solution.

STORAGE INSTRUCTIONS

Store below 25 ºC. Do not use more than 30 days after first opening. KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

V/15.4/41

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION

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