

Allergan Pharmaceuticals (Pty) Ltd



OXYLIN[®] (oxymetazoline hydrochloride)

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME (AND DOSAGE FORM)

OXYLIN Liquifilm Sterile Ophthalmic Solution

COMPOSITION

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

CONTRA-INDICATIONS

OXYLIN Liquifilm Sterile Ophthalmic Solution is contra-indicated 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.

In children, sedation may occur. However, the amount absorbed from topical application has rarely caused more than sleep. Severe CNS depression may follow accidental ingestion of large quantities.

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

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 benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

DOSAGE AND DIRECTIONS FOR USE

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

SIDE EFFECTS AND SPECIAL PRECAUTIONS

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 "Contra-indications").

Precautions:

Use with caution in the presence of uncontrolled hypertension, cardiac irregularities, hyperglycemia (diabetes), hyperthyroidism, and when other medications are being used.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

For symptoms of overdosage, refer to "Side effects and special precautions" above. 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 Liquifilm Sterile Ophthalmic Solution is a clear, colourless to slightly yellow solution.

PRESENTATION

OXYLIN Liquifilm Sterile Ophthalmic Solution is supplied in sterile plastic dropper bottles containing 15 ml solution.

STORAGE INSTRUCTIONS

Store below 25°C. 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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