Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oxylin Liquifilm 0.025% w/v Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One millilitre contains 0.25mg Oxymetazoline Hydrochloride

Excipients: Benzalkonium Chloride 0.04mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution
A clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Oxylin is indicated in adults for symptomatic relief of redness due to non-infectious irritation of the conjunctiva.

4.2 Posology and method of administration

Posology
1-2 drops into the eye(s) every 8 hours.

Paediatric population

The safety and efficacy of Oxylin in children aged <18 years have not been established. No data are available.

As with any eye drops, to reduce possible systemic absorption, it is recommended that the lachrymal sac be compressed at the medial canthus (punctal occlusion) for one minute immediately following the instillation of each drop.

To avoid contamination, do not let the tip of the dropper touch your eye or anything else.

4.3 Contraindications

• Hypersensitivity to the active substance or to any of the excipients.

• Patients receiving monoamine oxidase inhibitors or within 14 days of stopping such treatment, since hypertensive crisis may occur.

• Patients with uncontrolled hypertension, cardiac irregularities, hyperglycaemia (diabetes mellitus) and hyperthyroidism.

• Patients in whom pupillary dilation should be avoided (angle-closure glaucoma or those with critically narrow angles).

4.4 Special warnings and precautions for use

Cardiovascular effects may very rarely occur following topical application of sympathomimetics to the eye. Excessive doses may cause peripheral vasoconstriction, decreased heart rate and increased blood pressure in susceptible adults i.e. those rare adults with a predisposition to sympathetic sensitivity. This product should be used with great care in patients suffering from angina and digitalized patients.

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.

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

The preservative in Oxylin, benzalkonium chloride, may cause eye irritation. Remove soft (hydrophilic) contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.
Avoid contact with soft contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

This product may alter the effects of methyldopa and tricyclic antidepressants.

Concurrent use of maprotiline or tricyclic antidepressants and oxymetazoline may potentiate the pressor effect of the oxymetazoline.

If Oxylin is used concomitantly with other topical eye medications there must be an interval of at least 5 minutes between the two medications.

4.6 Fertility, pregnancy and lactation

Pregnancy
According to current medical knowledge, oxymetazoline hydrochloride has not been associated with adverse pregnancy outcome. Oxymetazoline should not be used during pregnancy unless considered essential by the physician. Caution should be exercised in patients with hypertension or indications of reduced blood flow in the placenta. In the case of prolonged usage of high doses, reduced blood flow in the placenta cannot be excluded.

Breastfeeding
It is unknown whether oxymetazoline/metabolites are excreted in human milk. A risk to the newborn/ infant cannot be excluded.
Oxylin should not be used during breast-feeding.

Fertility
There are no adequate data from the use of oxymetazoline on fertility in humans.

4.7 Effects on ability to drive and use machines

Oxylin is unlikely to have an influence on the ability to drive and use machines.
Transient blurring of vision may occur, the patient should wait until their vision clears before driving or using machinery.

4.8 Undesirable effects

Within each frequency grouping, undesirable effects are presented to System in order of decreased seriousness. The following terminologies have been used in order to classify the occurrence of undesirable effects: 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 undesirable effects have been reported in published clinical studies or since the product was marketed:

Eye disorder:
Not known: eye irritation, eye pain

Mydriasis and increased intraocular pressure have been reported as class adverse reactions associated with topical imidazolines but not specifically with oxymetazoline. Similarly, systemic effects, including nausea, headaches, and dizziness have also been reported as a class effect associated with topical imidazolines but not specifically with oxymetazoline.

4.9 Overdose

Excessive dosing of ocular sympathomimetics may cause peripheral vasoconstriction, decreased heart rate and increased blood pressure as a class effect in susceptible adults. No case of overdose of Oxylin has been reported.

Should accidental overdosage occur in the eye(s), flush the eye(s) with water or normal saline.

Severe central nervous system depression with marked reduction of body temperature, bradycardia, sweating, drowsiness and coma may follow accidental ingestion of large quantities of Oxylin.

In accidentally ingested, induce emesis and institute gastric lavage. Blood pressure should be monitored and general supportive measures should be provided as needed.

Paediatric population
Children are particularly at risk of severe central nervous system depression following accidental ingestion of large quantities of Oxylin.
Management of overdosage is as for adults.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: sympathomimetics used as decongestants

ATC code: S01GA04

Oxymetazoline, an imidazoline derivative, is a directly acting sympathomimetic drug with α-agonist activity. The α-agonists are applied topically to the eye to induce local vasoconstriction in the scleroconjunctival blood vessels.It is presumed that vasoconstriction is due to direct action of the drug upon the α2a(post-synaptic) receptors of the vascular smooth muscle. Oxymetazoline is characterized by an early onset of action, a relatively long duration of action and a low tendency to rebound congestion.

Dose-response studies have been conducted to determine if responses (decongestant effect, mydriatic effect or IOP effect) are directly related with the increase/decrease of concentration. Results show that vasoconstrictor activity of oxymetazoline is the dominant effect in concentrations inferior to 0.05%. These dose-response studies support the use of the oxymetazoline 0.025% as a topical vasoconstrictor. Local vasoconstriction occurs within 5 minutes after topical application of Oxylin, and can persist for 6 hours or more.

5.2 Pharmacokinetic properties

Studies of ocular absorption, distribution and metabolism have been conducted to determine the local action of oxymetazoline and to verify whether ocular application can cause systemic effects. Results show that oxymetazoline is well absorbed by external ocular tissues and that the penetration through the cornea is very weak, rarely absorbed in a quantity that can cause systemic effects. Oxymetazoline administered by the ocular route is metabolised in the same way as nasally administered oxymetazoline.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Toxicity of Oxylin was evaluated by 3 different repeat dose studies: two subacute ocular toxicity studies with duration of 21 days and a systemic study via topical instillation over a period of 4 months.

In one study, rabbits were given 0.05% oxymetazoline 1x, 2x, or 4x/day in the left eye for 21 days. No drug related effects were observed in any animals on the study.
In a second study, rabbits were given 0.5% oxymetazoline 2x, 4x, or 8x/day in the left eye for 21 days. Mild hyperaemia, discharge and tearing were observed in all animals given 0.5% oxymetazoline 8x/day. No drug related effects were observed in the other dose groups.
In a study to assess systemic toxicity via topical instillation, 0.025%, 0.050% and 0.250% oxymetazoline was administered as 1 drop, 2x/day in the left eye of rabbits for four months. Mild congestion, hyperaemia, discharge, iritis and corneal staining were observed in treated groups, but the percent incidence was similar to controls. No effects were observed on body weight, organ weights, haematology or microscopic pathology. An increased glucose was observed in the 0.250% group. The high dose group received approximately 162 times the human dose for 124 consecutive days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl Alcohol
Povidone
Sodium Acetate Trihydrate
Sodium Chloride
Disodium Edetate
Benzalkonium Chloride
Glacial Acetic Acid (for pH adjustment)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Discard 28 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

5 ml, 10 ml and 15 ml LDPE bottles containing fill volumes of 2.5 ml, 5 ml and 7.5ml respectively, and an applicator tip of soft polyethylene (LDPE). A threaded cap of polystyrene. A safety seal is placed around the bottle cap to ensure integrity of the product.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
Co Mayo
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 148/39/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 August 1984

Date of last renewal: 14 August 2009

10 DATE OF REVISION OF THE TEXT

July 2011