פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר". ינואר 2012
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OPTRYL

EYE DROPS

Composition

Active Ingredients

Each ml contains:

Naphazoline hydrochloride	0.25 mg
Diphenhydramine hydrochloride	1 mg
Boric acid	22 mg

Other Ingredients
Benzalkonium chloride 50% solution, sodium carbonate 5% solution (for pH adjustment), hydrochloric acid 5% solution (for pH adjustment), water for injection.

Mechanism of Action
Optryl combines the action of naphazoline, a topical decongestant-vasoconstrictor with the action of diphenhydramine, an antihistamine.

Indications
Allergic conditions of the conjunctiva, conjunctivitis vernalis, conjunctivitis phylactaenulosa, kerato-conjunctivitis, episcleritis.

Contraindications
Hypersensitivity to any of the components.
- Persons suffering from glaucoma, serious eye disease, or who have had previous eye surgery.
- Use in patients taking monoamine oxidase inhibitors or within 14 days of stopping such medication.
- Use in patients with contact lenses except under medical supervision (see Warnings)

Warnings
Redness or inflammation may be due to more serious eye diseases such as acute iritis, acute glaucoma or corneal trauma. If redness, pain or blurring persists, use should be discontinued.

The benzalkonium chloride in this preparation may be deposited in soft contact lenses; therefore, this preparation should not be used while wearing such lenses. Before application of the drops, the lenses should be removed and not reinserted earlier than 15 minutes after application.

Because of the naphazoline component, this product should be used with caution on an inflamed eye, as hyperaemia greatly increases the rate of systematic absorption through the conjunctiva.

The physician should also be cautious if the patient is being treated for high blood pressure, depression, heart disease, diabetes or increased thyroid activity, if the patient experiences severe eye pain, changes of vision or discharge from the eye, or if the condition worsens or persists for more than one day .

Use in Pregnancy and Lactation

Safety has not been established.

There are no adequate and well-controlled studies in pregnant women. The product should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is unknown if there is sufficient systemic absorption of antihistamines to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, caution should be exercised when using ophthalmic antihistamines in a nursing mother.

Adverse Reactions

Due to the napahzoline component, transient irritation and stinging may occur. Following long term use a rebound secondary hyperaemia may occur.

With one antihistamine, namely azelastine ophthalmic solution, the following adverse reactions have been reported: transient eye burning/stinging, headaches and bitter taste. The occurrence of these events was generally mild. Other events that were reported: severe allergic reactions, blurred vision, conjunctivitis, eye pain, fatigue, rhinitis.

Precautions

Drug Interactions

Interactions due to the naphazoline component.

This product may interact with other topically applied autonomic drugs used in the treatment of glaucoma. It may interact with monamine oxidase inhibitors and therefore should not be used by patients receiving such treatment or within 14 days of ceasing therapy (see Contraindications). The antihypertensive action of drugs used in the treatment of hypertension may be reversed.

. There may be increased risk of arrhythmias in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

Directions for Use

1 drop, instilled several times daily into the affected eye.

Overdosage

If applied in excessive quantities to the eye, it may give rise to irritation and stinging. Accidental overdosage by mouth may cause nausea, headache, depression of the central nervous system with marked reduction of body temperature and symptoms of bradycardia, sweating, drowsiness and coma, particularly in children. In addition, may cause hypertension followed by rebound hypotension.

Treatment of adverse effects should be symptomatic and supportive.

Storage

Store in a cool place below 25°C.

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Manufacturer

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