

[DUOPHARMA (M) SDN BHD]

ALLERSINE EYE DROP (0.5 mg/ml)

DESCRIPTION: Allersine Eye Drop is a clear, colorless liquid.

COMPOSITION: Each ml contains Tetrahydrozoline HCl 0.5 mg
Preservative: Benzalkonium Chloride 0.01% w/v

PHARMACODYNAMICS:

The drug directly stimulates α -adrenergic receptors of the sympathetic nervous system and exerts little or no effect on β -adrenergic receptors. Following topical application of tetrahydrozoline to the conjunctiva, small arterioles are constricted and conjunctival congestion is temporarily relieved, but reactive hyperemia may occur. The drug also may produce mydriasis when applied to the conjunctiva, but this effect is usually minimal with the concentrations used as ocular decongestants.

PHARMACOKINETICS:

Following topical application of Tetrahydrozoline hydrochloride solutions to the conjunctiva local vasoconstriction usually occurs within a few minutes and may persist for 4-8 hours. Occasionally, enough tetrahydrozoline may be absorbed to produce systemic effects. Information on the distribution and elimination of the drug in humans is not available.

INDICATIONS:

Provides temporary relief from soreness, burning, itching, irritation and congestion of the eyes in a variety of allergy and eye irritation conditions caused by allergies, smog, smoke, dust, wind and other eye irritants.

RECOMMENDED DOSAGE:

Place one or two drops in the affected eye(s) up to four times daily or as directed by a physician. Not recommended for use in children under 6 years of age except on medical advice. To avoid contamination of this product, do not touch dropper tip to other surfaces and always replace cap after using. Patients should be cautioned to remove contact lenses before using this product, and that contact lenses should not be reinserted until after 15 minutes have elapsed after the instillation of the drops.

ROUTE OF ADMINISTRATION: For ophthalmic use.

CONTRAINDICATIONS:

Contraindicated in patients with a known hypersensitivity to any component of the product. Allersine should not be used in the presence of narrow-angle glaucoma and serious eye infections. If the solution changes colour or becomes cloudy, it should not be used.

WARNINGS AND PRECAUTIONS:

Patients should be warned that if they experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, that they should discontinue use and consult a doctor, as this may be the sign of a more serious condition. Overuse of this product may produce increased redness of the eye. This product should be used with caution in patients with glaucoma, other serious eye diseases, hyperthyroidism, heart disease, hypertension, or diabetes mellitus, or in those receiving monoamine oxidase inhibitors. This product should not be substituted for contact lens fluid.

INTERACTION WITH OTHER MEDICAMENTS: None available

USE IN PREGNANCY AND LACTATION:

Pregnancy: Safe use of Tetrahydrozoline HCl during pregnancy has not been established.
Lactation: None available

SIDE EFFECTS/ADVERSE EFFECTS:

The incidence of serious adverse effects is low in patients receiving therapeutic dosages of topical Tetrahydrozoline hydrochloride. Excessive dosage and/or prolonged or too frequent use may irritate conjunctiva, especially in children, and cause adverse systemic effects. Use of Tetrahydrozoline in the eye may cause blurred vision, irritation, and mydriasis. Conjunctival application of Tetrahydrozoline, especially when high concentrations are used in geriatric patients, may liberate pigment granules, presumably from the iris. Prolonged use may worsen symptoms and should be avoided. In children, excessive dosage of the drug may cause severe drowsiness accompanied by profuse sweating. Ophthalmic use of Tetrahydrozoline may occasionally cause systemic sympathomimetic effects such as headache, hypertension, weakness, sweating, palpitation, and tremors. Overdosage of the drug may produce CNS depression with drowsiness, decreased body temperature, bradycardia, shock like hypotension, apnea and coma.

SYMPTOMS AND TREATMENT OF OVERDOSE:

In case of accidental ingestion, seek professional advice. Symptoms of overdosage may include CNS depression with drowsiness, decreased body temperature, bradycardia, shock-like hypotension, apnea and coma.

STORAGE CONDITIONS:

Store below 30°C. Protect from light. Do not use 1 month after first opening. Keep out of children. *Jauhkan daripada kanak-kanak.*

PACK SIZES: Pack in 5 ml or 10 ml in a box of 50's

SHELF LIFE: Please refer to outer package.

PRODUCT REGISTRATION HOLDER AND MANUFACTURER:

DUOPHARMA (M) SDN BHD
Lot 2599 Jalan Seruling 59 Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

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