SHINALLERG EYE DROP

Ingredient(s):
Each ml contains:
Tetrahydrozoline HCl 0.4mg
Antazoline HCl 0.5mg
Benzalkonium Chloride (as preservative) 0.05mg

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetic):
Pharmacodynamic:
Antazoline is an anti-histamine of the ethylenediamine class, which are selective H1-antagonist. When used systemically, this group of anti-histamine can cause moderate sedation (despite having weak CNS effects), gastric disturbances, and skin sensitization. Antazoline competitively blocks H1 receptors. Effects mediated by H1 receptors include the contraction of smooth muscle and the dilatation and increased permeability of the capillaries.
Tetrahydrozoline is a sympathomimetic with alpha adrenergic activity. Its vasoconstrictive effect reduces redness and oedema in allergic conjunctivitis.
Antihistamines, which act by blocking the H1 histamine receptor, are highly effective in providing relief of itching but are not very active in relieving the associated redness. The use of products combining an anti-histamine and a vasoconstrictor is well established in the symptomatic relief of allergic eye disease. Tetrahydrozoline has a rapid onset of action and its effect can last for 4 to 8 hours.

Pharmacokinetic:
No specific human pharmacokinetic studies have been conducted with this product. However, systemic effects have been reported following topical administration of naphazoline (which is very similar to tetrahydrozoline).

Indication(s):
Non-infectious irritative conjunctivitis, allergic-inflammatory affections of the conjunctiva, hay fever and conjunctivitis vernalis.

Dosage and Administration(s):
Apply 1 drop every three hours during the acute phase, for maintenance therapy 1 drop 2-3 times per day is sufficient. 1-2 drops per day are sufficient for children.

Mode of Administration(s):
Ophthalmic.

Contraindication(s):
1) Known hypersensitivity to antazoline and /or tetrahydrozoline or to any of the excipient.
2) Concomitant use with Monoamine Oxidase Inhibitors (MAOI).

Warning and Precautions(s):
1) This product should be used with caution in elderly patients with severe cardiovascular disease, including arrhythmia, poorly controlled hypertension or diabetes.
2) Sympathomimetic drugs should be used with caution in patients with diabetes, hypertension, hyperthyroidism, and elevated thyroid hormone concentration, arrhythmias or tachycardia and phaeochromocytomas.
3) Care should be taken in patients at risk of or with angle closure glaucoma, unless iridectomy (or iridotomy) has been performed. Patients should be informed that overuse of vasoconstrictors may produce rebound hyperaemia.
4) This product is not suitable for patients suffering from dry eyes without first seeking medical advice. Patients experiencing symptoms of dry eyes should discontinue the use of this product and seek the advice of their medical practitioner. Eye infections may be masked by the use of this product.
5) Patients with rhinitis sicca should take special care to perform nasolacrimal occlusion correctly to prevent this product from reaching the nasal mucosa.
6) Patients should consult their doctor if symptoms persist for more than 3 to 4 days, if the symptoms become more severe, or if they experience ocular pain and blurred vision while using this product.
7) If the patient wears contact lenses, these should be removed before instillation and not reinserted for at least 15 minutes.
8) The preservative in this product, benzalkonium chloride may cause eye irritation and is known to discolour soft contact lenses.

Interaction with Other Medicaments:
MAOIs
Sympathomimetic agents may cause a hypertensive crisis if used during treatment with MAOIs. Concomitant use with MAOIs is therefore contraindicated.

Sedating anti-histamines
Sedating anti-histamines can enhance the sedating effects of CNS depressants including alcohol, hypnotics, opioid analgesics, anxiolytic sedatives and anti-psychotics. They also have an additive anti-muscarinic action with other anti-muscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOIs). As systemic absorption of antazoline is possible, caution should be exercised when using this product concomitantly with these medicinal products.

Bromocriptine
Possible systemic exposure of tetryzoline can lead to its interaction with bromocriptine and may result in hypertension, severe headache, seizures and psychosis.

Interactions resulting in hypertension
A theoretical possibility of severe hypertension cannot be excluded when Antazoline / Tetryzoline is used with drugs such as digitalis, beta-adrenergic blockers, guanetidine, reserpine, methyldopa or anti-hypertensive agents (particularly those whose action involves the sympathetic nervous system).

Interactions resulting in arrhythmia
The pharmacodynamic properties of Antazoline / Tetryzoline suggest its interaction with cyclopropane and halogenated anesthetic agents such as chloroform, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias.

Pregnancy and Lactation(s):
No clinical data on exposed pregnancies are available. This product should only be used if the potential benefits outweigh the risks to the foetus or infant.
It is not known whether either of the active substances of this product passes into breast milk. Caution should be exercised when using the product during breast-feeding.

Side Effects:
1) This product may cause drowsiness, dizziness, somnolence or blurred vision. Patients who experience any of these side effects should not drive or operate machines until they have resolved.
2) Patients may experience any of the adverse effects noted for each of the individual active substances. The most common adverse effect is burning / stinging upon instillation, which is mild and transient in nature.
3) Eye disorders: Burning sensation in eyes, stinging sensation in eyes, iris exfoliation, mydriasis, blurred vision, acute conjunctivitis, chronic conjunctivitis, acute follicular conjunctivitis, dry eye, conjunctival congestion, ocular hyperaemia, angle closure glaucoma
4) Nervous system disorders: These may include headache, somnolence, drowsiness, dizziness, tremor, and central excitation.
5) Cardiac disorder: These may include angina pectoris, hypertension and tachycardia
6) General disorders and administration site conditions: Burning sensation in the eye has been reported. Sweating may also occur.
7) Immune system disorder: Hypersensitivity reactions may occur very rarely.

Symptoms and Treatment of Overdose(s):
Inadvertent oral ingestion of one 10ml bottle of this product, corresponding to 5mg antazoline hydrochloride and 4mg tetrahydrozoline hydrochloride is not likely to have any serious consequences in an adult. In children, especially in those under 2 years of age, nausea, somnolence, arrhythmia/tachycardia and possibly shock may occur. CNS depression, shock like hypotension and coma have occurred following overdose of tetrahydrozoline.
In the event of accidental overdosage following oral ingestion, induce vomiting if the patient is still conscious. Otherwise, gastric lavage and/or activated charcoal should be considered. Give artificial respiration if necessary. General intensive supportive measures may be required in severe cases.

Storage Condition(s):
Store at temperature below 30ºC.

Shelf Life(s):
3 years from the date of manufacture
Discard 1 month after opening.

Product description & Packing(s):
A clear and colorless solution
Plastic bottle of 5ml x 1, 5ml x 10, 5ml x 12, 5ml x 20, 5ml x 24.

Y. S. P.®
Manufacturer and Product Registration Holder:
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