

Altadin[®]

Alcaftadine INN
Sterile Ophthalmic Solution

DESCRIPTION

Altadin[®] is a preparation of Alcaftadine. Alcaftadine is a topically administered H₁ receptor antagonist containing Alcaftadine for ophthalmic use. Alcaftadine is an H₁ histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation has also been demonstrated.

INDICATIONS

Altadin[®] is an H₁ histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

DOSAGE AND ADMINISTRATION

Instill one drop in each eye once daily.

SIDE EFFECTS

The most frequent ocular adverse reactions, occurring in treated eyes, were eye irritation, burning and/or stinging upon instillation, eye redness and eye pruritus.

PRECAUTION AND WARNING

Alcaftadine should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of Alcaftadine. The preservative in Alcaftadine, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of Alcaftadine. Patients should be advised not to wear a contact lens if their eye is red. Alcaftadine should not be used to treat contact lens-related irritation.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B. There are however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Alcaftadine is administered to a nursing woman.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Alcaftadine is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between elderly and younger subjects.

PHARMACEUTICAL PRECAUTION

Store below 30 °C temperature, keep away from light and wet place. Keep out of reach of children. To prevent contamination of the dropper tip and solution, care should be taken. Do not touch the eyelids, surrounding areas, finger or other surfaces with the dropper tip of the bottle. The bottle should be tightly closed when not in use. Do not use after 4 weeks of first opening.

PACKAGING

Altadin[®] Ophthalmic Solution: Plastic dropper bottle containing 5 mL Sterile Ophthalmic Solution. Each mL contains Alcaftadine INN 2.5 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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