

# MIATRIZINE

Sterile Ophthalmic Solution

## Composition:

Each 1ml of Miatrizine sterile ophthalmic solution contains Cetirizine 2.4 mg (equivalent to 2.85mg cetirizine hydrochloride), benzalkonium chloride 0.1 mg as a preservative.

## Excipients:

Eдетate disodium, Glycerin, Hypromellose, Polyethylene glycol 400, Polysorbate 80, sodium phosphate dibasic, Hydrochloric acid and/or Sodium Hydroxide, water for injection.

## Mechanism of action:

Miatrizine is a histamine-1 (H1) receptor antagonist (antihistamine) and an inhibitor of release of histamine from mast cells. Its effects are mediated via selective inhibition of H 1 histamine receptors.

## Pharmacokinetic:

In healthy subjects, bilateral topical ocular dosing of one drop of cetirizine ophthalmic solution 0.24% resulted in a mean cetirizine plasma Cmax of 1.7 ng/mL following a single dose and 3.1 ng/mL after twice-daily dosing for one week. The observed mean terminal half-life of cetirizine was 8.6 hours following a single dose and 8.2 hours after twice-daily dosing for one week.

## Indications:

Miatrizine ophthalmic solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

## Dosage and administration:

The recommended dosage of Miatrizine is to instill one drop in each affected eye twice daily (approximately 8 hours apart).

## Contraindications:

None.

## Warnings and precautions:

### Contamination of Tip and Solution

As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle to prevent contaminating the tip and solution. Keep the bottle closed when not in use.

### Contact Lens Wear

- Patients should be advised not to wear a contact lens if their eye is red.
- Miatrizine should not be instilled while wearing contact lenses:

Remove contact lenses prior to instillation of Miatrizine. The preservative in Miatrizine, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of Miatrizine.

## Pregnancy and lactation:

Pregnancy: There were no adequate or well-controlled studies with Cetirizine ophthalmic solution in pregnant women. Miatrizine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Cetirizine has been reported to be excreted in human breast milk following oral administration.

There is no adequate information regarding the effects of cetirizine on breastfed infants, or the effects on milk production to inform risk of Miatrizine to an infant during lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Miatrizine and any potential adverse effects on the breastfed child from Miatrizine.

## Side effects:

The most commonly reported side effect occurred in patients treated with Miatrizine: hyperemia, instillation site pain, and visual acuity reduced.

## Storage conditions:

Store at (15 – 25) °C.

## Packaging:

Miatrizine solution is supplied in polyethylene bottle 5mL with dropper, tightly sealed with a polyethylene closer, within a carton box.

Produced by MIAMED Pharmaceutical Industries –Damascus countryside –Syria

This is a medicament
- A medicament is a product but unlike any other products.
- A medicament is a product which affect your health, and its consumption contrary to instructions is dangerous for you.
- follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
Keep medicaments out of reach of children

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