

EMADINE (emedastine difumarate 0.05%)

0.5mg/mL ophthalmic solution

Basic Succinct Statement

CODE: BSS RD FEB 18; APPR 03 OCT 2018

This material is only meant for Healthcare Professionals

EMADINE®

Important note: Before prescribing, consult full prescribing information.

Presentation: DROP-TAINER® dispenser. Each ml of solution contains 0.5 mg emedastine and 0.1 mg Benzalkonium Chloride as a preservative.

Indications: Temporary relief of the signs and symptoms of allergic conjunctivitis.

Dosage and administration: One drop in the affected eye twice per day, and if needed, up to four times daily.

Contraindications: ♦Hypersensitivity to emedastine difumarate or any of its components.

Warnings and Precautions: ♦EMADINE contains benzalkonium chloride which may cause eye irritation and is known to discolor soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of EMADINE and wait at least 15 minutes before reinsertion. ♦**Ability to drive and use machines:** Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

Adverse drug reactions: The following adverse reactions have been observed during clinical trials with EMADINE and are classified according to the following convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. ♦**Common:** eye pain, eye pruritus ♦**Uncommon:** abnormal dreams, headache, dysgeusia, corneal infiltrates, vital dye staining cornea present, vision blurred, eye irritation, dry eye, foreign body sensation in eyes, lacrimation increased, asthenopia, ocular hyperaemia, rash

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