Lunette

Sterile Ophthalmic Solution

Composition:
Each 1 mL of **Lunette** ophthalmic solution contains 12.5 mg Pilocarpine Hydrochloride, and 0.0075% Benzalkonium Chloride as preservative.

Excipients:
Boric acid, sodium citrate dehydrates, sodium chloride, sodium hydroxide and/or hydrochloric acid QS to adjust pH, Water for injection USP QS to 1.5, 2.5, or 5mL.

Mechanism of action:
Pilocarpine hydrochloride is a cholinergic muscarinic agonist which activates muscarinic receptors located at smooth muscles such as the iris sphincter muscle and ciliary muscle. **Lunette** ophthalmic solution contracts the iris sphincter muscle, constricting the pupil to improve near and intermediate visual acuity while maintaining some pupillary response to light. It also contracts the ciliary muscle and may shift the eye to a more myopic state.

Pharmacokinetics:
Systemic exposure to pilocarpine was evaluated in 22 participants with presbyopia who were administered 1 drop in each eye once daily for 30 days. The mean C_{max} and $AUC_{0\text{-}t.ss}$ values on Day 30 were 1.95 ng/mL and 4.14 ng/hr/mL, respectively. The median T_{max} value on Day 30 was 0.3 hours post dose with a range from 0.2 to 0.5 hours post dose.

Indications:
Lunette Ophthalmic Solution is indicated for the treatment of presbyopia in adults.

Contraindications:
Lunette Ophthalmic Solution is contraindicated in patients with known hypersensitivity to the active ingredient or to any of the excipients.

Warnings and precautions:
Poor Illumination/blurred vision
Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination. In addition, miotics may cause accommodative spasm.
Patients should be advised not to drive or use machinery if vision is not clear.
Risk of Retinal Detachment
Rare cases of retinal detachment have been reported when Pilocarpine Hydrochloride 1.25% is used with other miotics when used in susceptible individuals and those with pre-existing retinal disease. Patients should be advised to seek immediate medical care with sudden onset of vision loss.
Iritis
Pilocarpine Hydrochloride 1.25% is not recommended to be used when iritis is present because adhesions (synechiae) may form between the iris and the lens.
Use with Contact Lenses
Contact lens wearers should be advised to remove their lenses prior to the instillation of Pilocarpine Hydrochloride 1.25% and to wait 10 minutes after dosing before reinserting their contact lenses.
Potential for Eye Injury or Contamination
To prevent eye injury or contamination, care should be taken to avoid touching the dispensing bottle to the eye or to any other surface.

Side effect:
Hypersensitivity.
The most common adverse reactions reported in >5% of patients: headache and conjunctival hyperemia.
Ocular adverse reactions reported in 1-5% of patients: blurred vision, eye pain, visual impairment, eye irritation, and increased lacrimation.

Dosage and Administration:
The recommended dosage of **Lunette** Ophthalmic Solution is one drop in each eye once daily.
If more than one topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.

Pregnancy and lactation:
Pregnancy: There are no adequate and well-controlled studies of administration in pregnant women to inform a drug-associated risk.
-In a retrospective case series of 15 women with glaucoma, 4 patients used ophthalmic pilocarpine either pre-pregnancy, during pregnancy or postpartum. There were no adverse effects observed in patients or in their infants.
Lactation: There is no information regarding the presence of pilocarpine in human milk, the effects on the breastfed infants, or milk production to inform risk of pilocarpine Hydrochloride to an infant during lactation.
-Pilocarpine and/or its metabolites are excreted in the milk of lactating rats. Systemic levels of pilocarpine following topical ocular administration are low, and it is not known whether measurable levels of pilocarpine would be present in maternal milk following topical ocular administration.
-The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for pilocarpine Hydrochloride and any potential adverse effects on the breastfed child.

Pediatric & Geriatric
Presbyopia does not occur in the pediatric population.
Clinical studies did not include people aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience with ophthalmic pilocarpine solutions have not identified overall differences in safety between elderly and younger patients.

Overdose:
Systemic toxicity following topical ocular administration of pilocarpine is rare, but occasionally patients who are sensitive may develop sweating and gastrointestinal overactivity. Accidental ingestion can produce sweating, salivation, nausea, tremors and slowing of the pulse and a decrease in blood pressure. In moderate overdosage, spontaneous recovery is to be expected and is aided by intravenous fluids to compensate for dehydration. For patients demonstrating severe poisoning, atropine, the pharmacologic antagonist to pilocarpine, should be used.

Storage conditions:
Store at (15 – 25) °C.

How supplied:
Lunette ophthalmic solution is supplied in polyethylene bottle 1.5, 2.5 or 5 mL 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

Council of Arab Health Ministers Arab pharmacist Association

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