



# ATAX-MEDIOTIC

(Coated Tablets - Syrup)



## Composition:

Each coated tablet contains: Hydroxyzine HCL 25 mg.

Each 5 ml syrup contains: Hydroxyzine HCL 10 mg

## Clinical Pharmacology:

- Hydroxyzine HCL is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system.
- Primary skeletal muscle relaxation, bronchodilator activity, antihistaminic, analgesic and antiemetic effects have been demonstrated experimentally and confirmed clinically.
- Clinical studies indicate that Hydroxyzine HCL in therapeutic dosage does not increase gastric secretion nor acidity, and in most cases has mild antisecretory activity.
- Hydroxyzine HCL is rapidly absorbed from the gastrointestinal tract and its clinical effects are usually noted within 15 – 30 minutes after oral administration.

## Indications:

- For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.
- Useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus.
- As a sedative when used as premedication and following general anesthesia.

## Contra-Indications:

- Hydroxyzine HCL is contraindicated for patients who have shown a previous hypersensitivity to it.

## Pregnancy & lactation:

- Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data is available, Hydroxyzine HCL is contraindicated in early pregnancy.
- Nursing Mothers: It is not known whether this drug is excreted in human milk. Since many drugs are so excreted, this medication should not be given to nursing mothers.

## Precautions:

- The potentiating action of Hydroxyzine HCL must be considered when the drug is used in conjunction with central nervous system depressants such as narcotics, non-narcotic analgesics and barbiturates. Therefore when central nervous system depressants are administered concomitantly with Hydroxyzine HCL their dosage should be reduced.
- Since drowsiness may occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking this medication.
- Patients should be advised against the simultaneous use of other CNS depressant drug, and cautioned that the effect of alcohol may be increased.

## Adverse reactions:

Side effects reported with the administration of this medication are usually mild and transitory in nature.

- The most common side effects: dry mouth and drowsiness.
- Respiratory depression, involuntary motor activity including tremor and convulsions have been reported, usually with doses considerably higher than those recommended.

## Overdosage:

- The most common manifestation of this medication overdose is hypersedation.
- If vomiting has not occurred spontaneously, it should be induced. Immediate gastric lavage is also recommended.
- General supportive care, including frequent monitoring of the vital signs and close observation of the patient, is indicated.

## Dosage & Administration:

- For symptomatic relief of anxiety and tension in:  
Children under 6 years: 50 mg daily in divided doses.  
Children over 6 years: 50 – 100 mg in divided doses.  
Adults: 50 - 100 mg (4 times daily).
- For use in the management of pruritus due to allergic conditions:  
Children under 6 years: 50 mg in divided doses.  
Children over 6 years: 50 – 100 mg daily in divided doses.  
Adults: 25 mg (3 or 4 times daily).
- As a sedative when used as a premedication and following general anesthesia: 50 – 100 mg in adults, and 0.6 mg / kg in children.
- As with all medications, the dosage should be adjusted according to the patient's response to therapy.

## Storage:

- Store below 25 °C.
- Do not dispense without a medical prescription.

## Presentation:

- **ATAX-Mediotic tablets** : 2 blisters each one contains 10 coated tablets / carton box.
- **ATAX-Mediotic syrup** : Glass bottle of 100ml / carton box.

## \* THIS IS A MEDICAMENT \*

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and 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.

( Council of Arab Ministers )

( Union of Arab Pharmacists )

**Mediotic Labs Pharmaceutical Industries**

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