

Acliz

Meclizine HCl USP

Composition:

Acliz: Each chewable tablet contains Meclizine Hydrochloride USP 50 mg.

Acliz Plus: Each film coated tablet contains Meclizine Hydrochloride USP 25 mg & Pyridoxine Hydrochloride BP 50 mg.

Pharmacology:

Meclizine has antiemetic, anticholinergic and antihistaminic properties. It reduces the sensitivity of the labyrinthine apparatus. The action may be mediated through nerve pathways to the vomiting center (VC) from the chemoreceptor trigger zone (CTZ), peripheral nerve pathways or other CNS centers. Pyridoxine Hydrochloride (Vitamin - B₆), either alone or combination has been used to prevent nausea & vomiting due to its antiemetic properties. Meclizine has an onset of action of 30 to 60 minutes and duration of action is 12 to 24 hours.

Indications:

For prophylaxis and symptomatic relief of nausea, vomiting, dizziness, motion sickness, radiation sickness, vertigo associated with diseases affecting the vestibular system, morning sickness during pregnancy, drug induced nausea and vomiting induced by oral contraceptives or estrogen preparations.

Dosage and Administration:

Nausea & vomiting (including morning sickness in pregnancy): **Acliz:** 25-50 mg daily or as directed by a physician. **Acliz Plus:** One tablet 1-2 times daily or as directed by physician. **Motion sickness:** **Acliz:** Take an initial dose of 25-50 mg, 1 hour prior to travel. The dose may be repeated every 24 hours for the duration of journey. **Acliz Plus:** One or two tablets one hour prior to journey. The dose may be repeated every 24 hours for the duration of journey. **Vertigo:** **Acliz:** 25-100 mg daily in divided doses. **Acliz Plus:** One tablet 2 times daily or as directed by physician.

Labyrinthine and vestibular disturbances: The optimal dose of Meclizine Hydrochloride is usually 25 to 100 mg daily in divided doses, depending on the clinical response.

Radiation sickness: 50 mg Meclizine Hydrochloride administered 2 to 12 hours prior to radiation treatment. Pyridoxine Hydrochloride (vitamin B₆) has been shown to be safe and effective in dosage of 50 to 200 mg per day.

Contraindications:

Meclizine or pyridoxine is contraindicated in individuals who have shown hypersensitivity to these ingredients.

Precautions:

Due to its potential anticholinergic action, patients with asthma, bronchitis, emphysema, enlarged prostate, glaucoma or urinary tract blockade should take Meclizine HCl (like other antiemetics) with caution.

Side Effects:

Drowsiness, dry mouth, urinary retention in rare occasions, blurred vision have been reported. Sensory neuropathy reported with high dosage of Pyridoxine Hydrochloride given for extended periods.

Use in Special Groups:

Use in Pregnancy: Meclizine Hydrochloride is pregnancy category B drug. Large-scale human studies have not demonstrated adverse fetal effects. It has been suggested that, based on available data, Meclizine Hydrochloride presents the lowest risk of teratogenicity and is the drug of first choice in treating nausea and vomiting during pregnancy. On the other hand, Pyridoxine Hydrochloride is pregnancy category A drug. Pyridoxine Hydrochloride itself is considered as safe during pregnancy and has been used in pregnant women without any evidence of fetal harm.

Use in Lactation: Meclizine Hydrochloride may be distributed into breast milk. However problem in human have not been documented. On the other hand, Pyridoxine Hydrochloride has no adverse effects during lactation.

Use in Children: Safety and efficacy have not been established below 12 years of children.

Drug Interactions:

There may be increased CNS depression when Meclizine Hydrochloride and Pyridoxine Hydrochloride is administered concurrently with other CNS depressants, including benzodiazepines, barbiturates, tricyclic antidepressants, opiate agonists, skeletal muscle relaxants, antihistamines, alcohol, tranquilizers. Meclizine Hydrochloride can increase the absorption of digoxin by decreasing gastrointestinal motility. MAO inhibitors may prolong and intensify the anticholinergic effects of Meclizine Hydrochloride.

Overdose:

Symptoms: Moderate overdose may cause hyperexcitability alternating with drowsiness. Massive overdose may cause convulsions, hallucinations and respiratory paralysis.

Storage:

Store below 30°C, keep in dry place & protect from light. Keep out of reach of the children.

Packing:

Acliz: Each box contains 100 tablets in blister pack.

Acliz Plus: Each box contains 100 tablets in blister pack.

Manufactured by:
 **ARISTOPHARMA LTD.**
Shampur-Kadamtai I/A, Dhaka-Bangladesh

20001890/03