

# Emezin Plus<sup>®</sup>

Meclizine HCl and Pyridoxine HCl film coated tablet

## DESCRIPTION

**Emezin Plus<sup>®</sup>** is a combination of meclizine HCl and pyridoxine HCl. Meclizine HCl is a piperazine-derivative antihistamine that is used as an antiemetic. It has antiemetic, anticholinergic and antihistaminic properties. It exhibits its action by an effect on CNS, possibly by its ability to block muscarinic receptors in the brain. It has marked effects in blocking the vasodepressor response to histamine, but only a slight blocking action against acetylcholine. It reduces the sensitivity of the labyrinthine apparatus. The site and mechanism of action of meclizine HCl in controlling vertigo from various conditions have not been clearly defined. Pyridoxine HCl (vit-B<sub>6</sub>), either alone or combination has been used to prevent nausea and vomiting due to its antiemetic properties.

## INDICATIONS

For prophylaxis and symptomatic relief of nausea, vomiting, dizziness, motion sickness, radiation sickness and vertigo associated with diseases of vestibular system (e.g. Meniere's syndrome, labyrinthitis and other vestibular disturbances) and morning sickness during pregnancy.

## DOSAGE AND ADMINISTRATION

The fixed-dose combination (FDC) is recommended for oral administration.

**Nausea & vomiting (including morning sickness in pregnancy):** One tablet 1-2 times daily or as directed by physician.

**Motion sickness:** The initial dose is one or two tablets daily, it should be taken one hour prior to journey for protection against motion sickness. Therefore, the dose may be repeated every 24 hours as indicated for the duration of journey.

**Vertigo:** One tablet two times daily or as directed by physician.

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

**Radiation sickness:** 50 mg (Meclizine HCl) administered 2 to 12 hours prior to radiation treatment.

Pyridoxine (vitamin B<sub>6</sub>) has been shown to be safe and effective in dosages of 50 to 200 mg per day.

## SIDE-EFFECTS

Drowsiness, dry mouth, urinary retention or rare occasions, blurred vision have been reported.

## PRECAUTIONS

Due to its potential anticholinergic action, patient with asthma, bronchitis, emphysema, enlarged prostate, glaucoma or urinary tract blockade should take meclizine HCl (like other antiemetics) with caution. Although meclizine HCl may excrete into the milk, it causes no harm in nursing babies.

**Meclizine HCl:** Pregnancy category B. Large-scale human studies have not demonstrated adverse fetal effects. It has been suggested that, based on available data, meclizine HCl presents the lowest risk of teratogenicity and is the drug of first choice in treating nausea and vomiting during pregnancy.

**Pyridoxine HCl:** Pregnancy category A. Pyridoxine HCl itself is considered safe during pregnancy and has been used in pregnant women without any evidence of fetal harm.

## CONTRAINDICATIONS

The fixed-dose combination is contra-indicated in individuals who have shown a previous hypersensitivity to these ingredients.

## DRUG INTERACTIONS

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

## OVERDOSAGE

**Symptoms:** Extreme excitability, seizure, drowsiness, temporary nerve damage, hallucination.

**Treatment:** Appropriate supportive and symptomatic treatment.

## PHARMACEUTICAL PRECAUTION

Store at or below 30 °C temperature. Keep away from light and wet place. Keep out of the reach of children.

## PACKAGING

**Emezin Plus<sup>®</sup>** tablet: Box containing 5 strips of 10 tablets each. Each film coated tablet contains meclizine HCl USP 25 mg and pyridoxine HCl USP 50 mg.

**SK+F**

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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