Emenil® Plus

Meclizine Hydrochloride &

Pyridoxine Hydrochloride film-coated tablet

Presentation

Emenil*Plus: Each film-coated tablet contains Meclizine Hydrochloride USP 25 mg and Pyridoxine Hydrochloride BP 50 mg.

Description

Meclizine is a piperazine-derivative antihistamine that is used as an antiemetic. It 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, the VC, or other CNS centers. Pyridoxine is vitamin B-6. It has been added to enhance the anti-emetic effects & as a dietary suppliment.

Indications and Uses

Prevention and treatment of nausea, vomiting, dizziness, motion sickness, radiation sickness and vertigo associated with diseases of the vestibular system (e.g. Ménière's syndrome, labyrinthitis and other vestibular disturbances).

Dosage & Administration

Emenil Plus is administered orally.

Adult and Children 12 years of age & over:

Nausea and vomiting: 25-50 mg daily or as directed by a physician.

Motion sickness: Take an initial dose of 25-50 mg, 1 hour prior to travel. May repeat the dose every 24 hours for the duration of the journey.

Radiation sickness: 50 mg administered 2-12 hours prior to radiation treatment.

Vertigo: 25-100 mg daily in divided doses.

Prevention of nausea and vomiting associated with emergency contraceptive pill (ECP): 25-50 mg, 1 hour before first ECP dose; repeat if needed in 24 hours.

The safety and efficacy for use in children less than 12 years of age have not been established.

Side Effects

Drowsiness, dry mouth and, on rare occasions, blurred vision have been reported.

Contraindications

Meclizine Hydrochloride and Pyridoxine Hydrochloride is contraindicated in patients who are hypersensitive to these ingredients.

Precautions

Patients should be warned that Meclizine Hydrochloride may impair their ability to perform hazardous activities requiring mental alertness or physical coordination (e.g., operating machinery, driving a motor vehicle). Patients should avoid alcoholic beverages while taking this drug. Due to its potential anticholinergic action, this drug should be used with caution in patients with asthma. glaucoma or enlargement of the prostate gland.

Use in Pregnancy and Lactation

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

Lactation: Safety for use in the nursing mother has not been established.

Drug Interactions

The CNS depressant effects of Meclizine can be potentiated by concurrent use of Ethanol or other CNS depressant agents such as Benzodiazepines, Barbiturates, Tricyclic antidepressants, opiate agonists, skeletal muscle relaxants and antihistamines. Concurrent use of other anticholinergics can potentiate the anticholinergic effects of Meclizine. Meclizine can increase the absorption of digoxin by decreasing qastrointestinal motility.

Overdosage

Symptoms: Extreme excitability, seizures, drowsiness and hallucinations.

Treatment: Appropriate supportive and symptomatic treatment. Consider dialysis.

Commercial Pack

Emenil®Plus: Each box contains 10 blister strips of 10 tablets.

