COMPOSITION
Xmec Tablet: Each tablet contains Meclizine Hydrochloride USP 25 mg & Pyridoxine Hydrochloride BP 50 mg.

PHARMACOLOGICAL INFORMATION
Pharmacological Action
Xmec is a combination preparation of Meclizine and Pyridoxine. Meclizine is a piperazine derivative antihistamine used as an antiemetic. Pyridoxine is a vitamin B component having some antiemetic property.

Mode of action
Meclizine: Meclizine has antiemetic, anticholinergic, antihistaminic properties. It exhibits its action by an effect on CNS, possibly by its ability to block muscarinic receptors in the brain. It has a marked effect in blocking the vasodepressor response to histamine, but only a slight blocking action against acetylcholine. It reduces the sensitivity of the labyrinthin apparatus. The site and mechanism of action of Meclizine in controlling vertigo from various conditions have not been clearly defined.

Pyridoxine: Pyridoxine (Vitamin B6), either alone or in combination has been used to prevent nausea and vomiting due to its antiemetic property.

CLINICAL INFORMATION
Therapeutic 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 disturbance) and morning sickness during pregnancy.

Dosage and Administration
The fixed dose combination (FDC) is recommended for oral administration. Nausea and vomiting (including morning sickness in pregnancy): One tablet 1-2 times daily or as directed by the 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 the journey. Vertigo: One tablet two times daily or as directed by the physician. Labyrinthin and vestibular disturbances: The optimal dosage of Meclizine is usually 25-100 mg daily in divided doses, depending on the clinical response. Radiation sickness: 50 mg (Meclizine) administered 2-12 hours prior to radiation treatment.

Use in Pregnancy & Lactation
Epidemiological studies with Meclizine and Pyridoxine in women experiencing nausea and vomiting of pregnancy have revealed no evidence of a teratogenic effect attributed to the drug.

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

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

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

Contraindications
Known hypersensitivity to Meclizine & Pyridoxine.

Precautions
Some drowsiness may, on occasion, occur with the use of this drug. Patients should be warned regarding operating machinery, driving a motor vehicle and other hazardous activities. 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.

Meclizine: Dosage varies from 25-50 mg/day in pregnancy or as directed by the physician. Not recommended in last 2 weeks of pregnancy due to retrolental fibroplasias risk.

Pyridoxine: 75 mg/day is FDA-approved for use in pregnancy. Pregnant and breast feeding women should not take more than 100 mg per day without a doctor’s supervision.

Drug Interaction
Meclizine: The CNS depressant effects of Meclizine can be potentiated by concurrent use of ethanol or other CNS depressant agents such as benzodiazepines, barbiturates, tricyclic antidepressant, opiate agonists, skeletal muscle relaxants, antihistamines and tranquilizer. Meclizine can increase the absorption of digoxin by decreasing gastrointestinal motility. MAO inhibitors may prolonged and intensify the anticholinergic effects of Meclizine.

Pyridoxine (Vitamin B6) reduces therapeutic effect of Levodopa.

PHARMACEUTICAL INFORMATION
Storage Conditions
Xmec tablet: Store in a cool and dry place away from light. Keep out of reach of children.

Presentation & Packaging
Xmec tablet: Each commercial pack contains 5 x 10’s tablets in blister strips.

Manufactured By
BECO Pharmaceuticals Limited
Mymensingh, Bangladesh