Pvridoxine Hvdrochloride EP 20 ma

Composition

Each extended release tablet contains Doxylamine Succinate BP 20 mg & Pyridoxine Hydrochloride EP 20 mg.

Pharmacology

Doxylamine is an antihistamine that blocks histamine (H1) receptor. It affects the vestibular system & decreases the stimulation of the vomiting centre. Its muscarinic receptor inhibition may also play a role in antihistamine & antiemetic activity. Pyridoxine (Vitamin B6) is a vitamin, which is used to prevent nausea and vomiting due to its antiemetic properties.

Indications & Uses

For the treatment of nausea and vomiting of pregnancy (NVP) in women.

Dosage & Administration

Take one tablet daily at night. If this dose adequately controls symptoms, the next day (Day 2) continue taking one tablet daily at night only.

If symptoms persist on Day 2, then take two tablets starting on day 3 (one tablet in the morning and one tablet at night).

The maximum recommended dose is two tablets per day, one in the morning and one at night.

Take on an empty stomach with a glass of water. Swallow tablets whole. Do not crush, chew, or split the tablet. Take daily and not on an as needed basis.

Contraindication

This combination is contraindicated in women with known hypersensitivity to Doxylamine Succinate, other ethanolamine derivative antihistamines, Pyridoxine Hydrochloride, monoamine oxidase inhibitors (MAO) or any inactive ingredient in the formulation.

Side Effects

Maximum observed side effect is somnolence.

Warning & Precaution

This combination may cause somnolence due to the anticholinergic properties of Doxylamine Succinate. Women should avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery. This combination is not recommended for women who are concurrently using Central Nervous System (CNS) depressants including alcohol. The combination may result in severe drowsiness leading to falls or accidents.

Drug Interactions

Concurrent use of alcohol and other CNS depressants (such as hypnotic sedatives and tranquilizers) with Doxylamine Succinate & Pyridoxine Hydrochloride is not recommended.

Over dosage

Signs and symptoms of overdose may include restlessness, dryness of mouth, dilated pupils, sleepiness, vertigo, mental confusion and tachycardia.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy category A. So, Doxylamine Succinate & Pyridoxine Hydrochloride can be given to pregnant women safely.

Lactation: Women should not breastfeed while using Doxylamine Succinate & Pyridoxine Hydrochloride. The molecular weight of Doxylamine Succinate is low enough that passage into breast milk can be expected.

Storage

Store below 30° C. Protect from light & moisture. Keep all the medicines out of the reach of children.

How supplied

Each box contains 30 ER tablets in blister pack.

Manufactured by

