

#### Composition

Each delayed release tablet contains Doxylamine Succinate BP 10 mg & Pyridoxine Hydrochloride BP 10 mg.

#### Pharmacology

Doxylamine is an antihistamine that blocks histamine ( $H_1$ ) receptor. It affects the vestibular system & decreases the stimulation of the vomiting center. Its muscarinic receptor inhibition may also play a role in antihistamine & antiemetic activity. Pyridoxine (Vitamin  $B_6$ ) is a vitamin which is used to prevent nausea and vomiting due to its antiemetic properties.

#### Indications

Vertina®-D is indicated for the treatment of nausea and vomiting during pregnancy.

#### **Dosage & Administration**

Take two tablets daily at bedtime. If symptom persists, then take three tablets starting on day 3 (one tablet in the morning and two tablets at bedtime). If these three tablets can't control symptoms adequately take maximun four tablets starting on day 4. (one tablet in the morning, one tablet mid-afternoon and two tablets at bedtime).

Take on an empty stomach with a glass of water.

#### Side Effects

Side effects may include somnolence.

#### **Pregnancy & Lactation**

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

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. Excitement, irritability and sedation have been reported in nursing infants presumably exposed to Doxylamine Succinate through breast milk. Infants with apnea or other respiratory syndromes may be particularly vulnerable to the sedative effects of Doxylamine Succinate & Pyridoxine Hydrochloride resulting in worsening of their apnea or respiratory conditions.

### Contraindications

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.

### Warning & Precaution

Doxylamine Succinate & Pyridoxine Hydrochloride 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.

Doxylamine Succinate & Pyridoxine Hydrochloride use is not recommended if a woman is concurrently using Central Nervous System (CNS) depressants including alcohol. The combination may result in severe drowsiness leading to falls or accidents.

## **Drug Interactions**

Use of Doxylamine Succinate & Pyridoxine Hydrochloride is contraindicated in women who are taking monoamine oxidase inhibitors (MAOIs), which prolong and intensify the anticholinergic (drying) effects of antihistamines.

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

# Overdosage

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

### Storage

Protect from light and moisture, store below 30° C. Keep out of the reach of children.

## How Supplied

Each box contains 50 DR tablets in alu-alu blister pack.

Manufactured by

