STOPY TABLET

Composition

Each enteric coated tablet contains :

Doxylamine Succinate	B.P.	10mg.
Pyridoxine HCL	I.P.	10mg.

DESCRIPTION:

DOXYLAMINE :

Doxylamine is a first-generation antihistamine , and is prescribed in combination with vitamin B6 (pyridoxine) to prevent morning sickness in pregnant women.
It is a histamine H1 antagonist with pronounced sedative properties. Doxylamine may work to suppress a vomiting center in the brain, thus it as antiemetic drug. Because of its sedative effect, it is used in the short-term management of insomnia.

MODE OF ACTION :

Like other antihistamines, Doxylamine acts by competitively inhibiting histamine at H1 receptors. It also has substantial sedative and anti cholinergic effects.

PHARMACOLOGY :

Absorption : Readily absorbed via the gastrointestinal tract.

Distribution : Doxylamine succinate is well distributed after orally administration. The apparent volume of distribution is 2.5 L/kg.

Bioavailability: Oral: 24.7%, Intranasal: 70.8%.

Metabolism : Most of the administered drug is metabolized in Liver. The major metabolic pathways are N-demethylation, N-oxidation, hydroxylation, N-acetylation, N-desalkylation and ether cleavage.

Half life : Variable; 6–12 hours.

Excretion : Most of the drug is excreted in the urine as unchanged doxylamine (60%) and rest as nordoxylamine and dinordoxylamine.

Pyridoxine : Pyridoxine is a one of several essential B vitamins and is sometimes called vitamin B6. It is used for preventing and treating low levels of pyridoxine (pyridoxine deficiency) and the “tired blood” (anemia) that may result. Women use pyridoxine for premenstrual syndrome (PMS) and other menstruation problems, "morning sickness" (nausea and vomiting) in early pregnancy. Pyridoxine may work by replenishing depleted Vitamin B6 levels in the pregnant woman.
The empirical formula is **C8H11NO3 • HCl** and the molecular mass is 205.64.

PHARMACOLOGY :

Vitamin B 6 functions as coenzyme in amino acid, carbohydrate, and lipid metabolism.
Absorption : Absorbed by passive diffusion in the jejunum and to a lesser extent in the ileum approximately 73% ±2.
Distribution : Primarily stored in the liver, lesser amount in the muscle and brain. Pyridoxine is highly protein bound, primarily to albumin. Its main active metabolite, pyridoxal 5’-phosphate (PLP) accounts for at least 60% of circulating vitamin B6 concentrations.
Metabolism : Pyridoxine is a prodrug primarily metabolized in the liver and converted to 4-pyridoxic acid metabolite.

Half life : The t ½ is 15 to 20 days.
Elimination : Excreted mostly as 4-pyridoxic acid in the urine.

STOPY TABLET :

Stopy belongs to the class of antinauseants drugs. Especially this drug is used to treat nausea and vomiting of pregnancy. It provide synergistic action of two medications, Doxylamine succinate and pyridoxine hydrochloride, that works on the vomiting center in the brain to control nausea and vomiting. Doxylamine competes with histamine for H1-receptor sites on effectors cells; blocks chemoreceptor trigger zone, diminishes vestibular stimulation, and depresses labyrinthine function through its central anticholinergic activity. Pyridoxine is a vitamin which may have modest antiemetic effects.

INDICATION :

Stopy is used to treat nausea and vomiting in pregnancy, Hyperemesis gravidarum, Motion sickness, Sea sickness.

USE OF STOPY IN DIFERENT AGE GROUP :

Use in pregnancy (Pregnancy Category A) - The combination of doxylamine succinate and pyridoxine hydrochloride has been the subject of many epidemiological studies designed to detect possible teratogenicity. A meta analysis carried out between 1963 and 1991 reported no increased risk for malformations from first trimester exposures to doxylamine succinate and pyridoxine hydrochloride, with or without dicyclomine hydrochloride.

Nursing Mothers – Breast feeding women should not be administered Stopy. The molecular weight of doxylamine succinate is low enough so, there are chances to pass doxylamine through breast milk. Excitement, irritability and sedation have been reported in nursing infants if the mother consumes doxylamine succinate. Infants with apnea or other respiratory syndromes may be particularly vulnerable to the sedative effects of Stopy resulting in worsening of their apnea or respiratory conditions.

Pyridoxine hydrochloride is excreted into breast milk. There have been no reports of adverse events in infants presumably exposed to pyridoxine hydrochloride through breast milk.

Pediatric Use - The safety and tolerability of Stopy in children under 18 years of age have not been established.

DOSAGE :

Pregnancy :
2 Tablets at bed time, one in the morning and one in the afternoon if required or as prescribed by the physician.
In morning sickness two tablet at bed time and if necessary one tablet in the morning.

OVERDOSE :

Adult : If overdose of Stopy is suspected then immediately consult to the health centre or to the doctor. Signs and symptoms of overdose may include vertigo, restlessness, dilated pupils, sleepiness, dryness of mouth, tachycardia and mental confusion.

At toxic doses, doxylamine exhibits anticholinergic effects, including seizures, rhabdomyolysis, acute renal failure and death.

If treatment is needed, it consists of gastric lavage or activated charcoal, whole bowel irrigation and symptomatic treatment.

Children : Fatalities have been reported from doxylamine overdose in children. The overdose cases have been characterized by coma, grand mal seizures and cardiorespiratory arrest. Children appear to be at a high risk for cardiorespiratory arrest. A toxic dose for children of more than 1.8 mg/kg has been reported.

CONTRA-INDICATION :

Stopy is contraindicated in women with any of the following conditions:
Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation.
Monoamine oxidase inhibitors intensify and prolong the adverse central nervous system effects of Stopy.

DRUG INTERECTION :

Use of Stopy is contraindicated in women who are taking monoamine oxidase inhibitors, 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 Stopy is not recommended.

DRUG- FOOD INTERECTION :

A food-effect study demonstrated that the delay in the onset of action of Stopy may be further delayed and a reduction in absorption may occur when tablets are taken with food. Therefore, Stopy should be taken on an empty stomach with a glass of water.

SIDE EFFECT :

It can cause rarely drowsiness, vertigo, headache, confusion, irritability, insomnia palpitation, diarrhea, disorientation, irritability, convulsions, urinary and gastric pain. In large doses, however, pyridoxine in Stopy can cause peripheral neuropathies.

Pyridoxine in Stopy can reduce the effects of levodopa, phenobarbital and phenytoin.

WARNINGS/PRECAUTIONS**:**

Stopy should be administered during pregnancy only if strictly required. It is not advisable during lactation since pyridoxine in Stopy can inhibit breast milk secretion. Stopy should be co-administered with caution along with other central nervous depressants, alcohol, in epileptic and levodopa-treated Parkinson patients.

Due to risk of drowsiness, Stopy must be advocated with caution in those engaged in driving, operating machinery or other hazardous tasks and activities necessitating alertness. It is not for use in children, and must be advocated with caution in non-pregnant cases.

STORAGE AND HANDLING :

Store at 20°C to 25°C at dry and dark place.

PRESENTATION :

Stopy tablet is available 1*10 in an Alu-Alu strip and 10 strips in a carton.