Novom 10mg /10mg

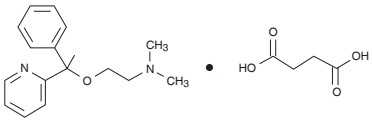
(Doxylamine Succinate + Pyridoxine Hydrochloride) delayed-release tablets

DESCRIPTION:
NOVOM is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B_6 analog, indicated for the treatment of morning sickness of pregnancy in women who do not respond to conservative management.

QUALITATIVE & QUANTITATIVE COMPOSITION:
Each delayed-release tablet contains:
Doxylamine Succinate BP 10mg
Pyridoxine Hydrochloride BP 10mg

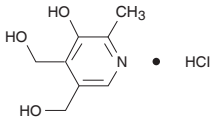
MECHANISM OF ACTION:
Doxylamine is an antihistamine derived from monoethanolamine possessing antimuscarinic and pronounced sedative effects. Pyridoxine is a precursor of pyridoxal, which functions in the metabolism of carbohydrates, proteins and fats. It is essential in Hb formation and GABA synthesis within the CNS. It also aids in the release of glycogen stored in the liver and muscles.

Doxylamine Succinate:



Doxylamine succinate is classified as an antihistamine. The chemical name for doxylamine succinate is ethanamine, N,N-dimethyl-2-[1-phenyl-1-(2-pyridinyl)ethoxy]-, butanedioate (1:1). The empirical formula is $C_{17}H_{22}N_2O \bullet C_4H_6O_4$ and the molecular mass is 388.46g/mol.

Pyridoxine Hydrochloride:



Pyridoxine hydrochloride is a Vitamin B_6 analog. The chemical name for pyridoxine hydrochloride is 3,4-pyridinedimethanol, 5-hydroxy-6-methyl-, hydrochloride. The empirical formula is $C_8H_{11}NO_3 \bullet HCl$ and the molecular mass is 205.64g/mol.

INDICATIONS AND USAGE:
Novom delayed-release tablets are used in the control of nausea and vomiting associated with pregnancy.

PHARMACOKINETICS:
Absorption:
Doxylamine and Pyridoxine are absorbed in the gastrointestinal tract, mainly in the jejunum.
The Cmax of doxylamine and pyridoxine are achieved within 7.5 and 5.5 hours, respectively.

Distribution
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
Doxylamine is biotransformed in the liver by N-dealkylation to its principle metabolites N-desmethyl-doxylamine and N, N-didesmethyldoxylamine.
Pyridoxine is a prodrug primarily metabolized in the liver.

Excretion
The principle metabolites of Doxylamine, N-desmethyl-doxylamine and N, N-didesmethyldoxylamine, are excreted by the kidney.
The terminal elimination half-life of Doxylamine and Pyridoxine are 12.5 hours and 0.5 hours, respectively.

DOSAGE & ADMINISTRATION :
Initially, take two NOVOM delayed-release tablets orally at bed time (Day 1). If this dose adequately controls symptoms the next day, continue taking two tablets daily at bedtime. However, if symptoms persist into the afternoon of Day 2, take the usual dose of two tablets at bedtime that night then take three tablets starting on Day 3 (one tablet in the morning and two tablets at bedtime). If these three tablets adequately control symptoms on Day 4, continue taking three tablets daily.

Otherwise take four tablets starting on Day 4 (one tablet in the morning, one tablet mid-afternoon and two tablets at bedtime). The maximum recommended dose is four tablets (one in the morning, one in the mid-afternoon and two at bedtime) daily.
Take on an empty stomach with a glass of water. Swallow tablets whole. Do not crush, chew, or split NOVOM delayed-release tablet.
Take as a daily prescription and not on an as needed basis. Reassess the woman for continued need for NOVOM as her pregnancy progresses.

USE IN SPECIFIC POPULATIONS :
Pregnancy
Pregnancy Category A
NOVOM is intended for use in pregnant women.

Nursing Mothers

Women should not breastfeed while using NOVOM.
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 NOVOM 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 effectiveness of NOVOM in children under 18 years of age have not been established.
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.

CONTRAINDICATIONS:
NOVOM 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 (MAO) inhibitors intensify and prolong the adverse central nervous system effects of NOVOM .

WARNINGS AND PRECAUTIONS:
NOVOM may cause somnolence due to the anticholinergic properties of doxylamine succinate, an antihistamine. Women should avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery, while using NOVOM until cleared to do so by their healthcare provider.
NOVOM 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 .
NOVOM has anticholinergic properties and, therefore, should be used with caution in women with: asthma, increased intraocular pressure, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction and urinary bladder-neck obstruction.

ADVERSE REACTIONS :
Somnolence:
Falls or other accidents resulting from the effect of the combined use of novom with CNS depressants including alcohol

Cardiovascular:
Palpitation , Tachycardia.
Central Nervous System: Dizziness , disorientation ,drowsiness , headache , paradoxical CNS Stimulation, Vertigo.
Gastrointestinal: Anorexia , dry mucous membrane , diarrhea , constipation , epigastric pain , xerostomia.
Genitourinary: Dysuria , urinary retention.
Ocular: Blurred vision , diplopia.

DRUG INTERACTIONS :
Use of NOVOM 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 NOVOM is not recommended.

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

SIGNS AND SYMPTOMS OF OVERDOSE:
NOVOM is a delayed-release formulation, therefore, signs and symptoms of intoxication may not be apparent immediately.
Signs and symptoms of overdose may include restlessness, dryness of mouth, dilated pupils, sleepiness, vertigo, mental confusion and tachycardia.At toxic doses, doxylamine exhibits anticholinergic effects, including seizures, rhabdomyolysis, acute renal failure and death.

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

STORAGE:
Store below 30°C.
Protect from heat, light & moisture.

PRESENTATION :
Novom (Doxylamine Succinate & Pyridoxine Hydrochloride) delayed-release tablets are available in ALU/PVC Blister pack of 3x10's.

For detailed information please contact:
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