Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets 10mg/10mg

INTRODUCING a fixed dose combination drug product of 10 mg doxylamine succinate, an antihistamine, and 10 mg pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management

Tablet shown not actual size.

Product Information	
Indication and Usage	Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets 10mg/10mg indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management
Product Description	100 ea. tablet/bottle, doxylamine succinate 10mg, pyridoxine hydrochloride 10mg delayed-release tablets
NDC Number	70505-100-10
UPC Number	3-70505-100-10-0
Packaging Information	
How supplied	Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are supplied in 100 count bottles
Packaging Dimensions/Unit Weight	Depth – 1.594” Height – 3.465” Width – 1.594” Weight – 0.093 lb.
Storage Guidelines	Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets 10mg/10mg should be stored at controlled room temperature of 20 to 25 degrees C (68 to 77 degrees F). For temperature excursion questions, contact Guylaine Pelchat at 1-877-833-7734
How to order	info@analogpharma.com Phone: (855) 752-9196 FAX: (855) 754-9418
Minimum Shipping Quantity (Case)	1 case (48 bottles) or multiples thereof
Shipping Case Outer Dimensions	Depth – 10.394” Height – 7.559” Width – 6.894”
Shipping Case Weight	4.784 lb.

INDICATION

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are a fixed-dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

LIMITATIONS OF USE

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets have not been studied in women with hyperemesis gravidarum.

SELECT SAFETY INFORMATION

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, or any inactive ingredient in the formulation. Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are also contraindicated in combination with monoamine oxidase inhibitors (MAOIs) as MAOIs intensify and prolong the adverse central nervous system (CNS) effects of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets 10mg/10mg . Use of MAOIs may also prolong and intensify the adverse CNS effects (the anticholinergic effects) of antihistamines.

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets 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 doxylamine succinate and pyridoxine hydrochloride delayed-release tablets until cleared to do so by their healthcare provider.

Use of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets is not recommended if a woman is concurrently using CNS depressants, such as alcohol or sedating medications, including other antihistamines (present in some cough and cold medications), opiates, and sleep aids. The combination of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets and CNS depressants could result in severe drowsiness leading to falls or other accidents.

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Please see Important Safety Information on reverse

ANALOG PHARMA

AGXD-2019-0003-01 May 2019

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IMPORTANT SAFETY INFORMATION

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

There have been reports of false positive urine screening tests for methadone, opiates, and PCP with doxylamine succinate/pyridoxine hydrochloride use. Women should be informed that use of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets may result in false positive urine drug screening for methadone, opiates and PCP.

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets have anticholinergic properties and should be used with caution in women who have: (1) asthma, (2) increased intraocular pressure, (3) narrow angle glaucoma, (4) a stenosing peptic ulcer, (5) pyloroduodenal obstruction, or (6) bladder-neck obstruction.

The most common adverse reaction with doxylamine succinate and pyridoxine hydrochloride delayed-release tablets (occurring at an incidence ≥5 percent and exceeding the incidence for placebo) is somnolence.

The safety and effectiveness of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets in children under 18 years of age have not been established. Fatalities have been reported from doxylamine overdose in children. Children appear to be at a high risk for cardiorespiratory arrest.

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are intended for use in pregnant women.

Women should not breastfeed while using doxylamine succinate and pyridoxine hydrochloride delayed-release tablets because the antihistamine component (doxylamine succinate) in doxylamine succinate and pyridoxine hydrochloride delayed-release tablets can pass into breast milk. 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 and pyridoxine hydrochloride delayed-release tablets resulting in worsening of their apnea or respiratory conditions.

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets 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. If treatment is needed, it consists of gastric lavage or activated charcoal, whole bowel irrigation and symptomatic treatment. If you suspect an overdose or seek additional information about overdose treatment, call a poison control center at 1-800-222-1222.

To report suspected adverse reactions, contact Analog Pharma Inc. at 1-844-884-5505 or medicalinfo@analogpharma.com or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

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