

Patient Information

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets

What are doxylamine succinate and pyridoxine hydrochloride delayed-release tablets?

- Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are a prescription medicine used to treat nausea and vomiting of pregnancy women who have not improved with change in diet or other non-medicine treatments.
- It is not known if doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are safe and effective in women with severe nausea and vomiting of pregnancy, a condition called hyperemesis gravidarum. Women with this condition may need to be hospitalized.
- It is not known if doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are safe and effective in children under 18 years of age.

Who should not take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets?

Do not take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets if you:

- are allergic to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any of the ingredients in doxylamine succinate and pyridoxine hydrochloride delayed-release tablets. See the end of this leaflet for a complete list of ingredients in doxylamine succinate and pyridoxine hydrochloride delayed-release tablets.
- take monoamine oxidase inhibitors (MAOIs). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including Marplan, Nardil, Emsam, Eldepryl, Zelapar, and Parnate.

Before taking doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have asthma.
- have eye problems called increased intraocular pressure or narrow angle glaucoma.
- have a stomach problem called stenosing peptic ulcer or pyloroduodenal obstruction.
- have a bladder problem called urinary bladder-neck obstruction.
- are breastfeeding or plan to breastfeed. Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets can pass into your breast milk and may harm your baby. You should not breastfeed while using doxylamine succinate and pyridoxine hydrochloride delayed-release tablets.

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements.

How should I take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets?

- Talk to your healthcare provider about how much doxylamine succinate and pyridoxine hydrochloride delayed-release tablets to take and when to take it.
- Take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets every day as prescribed by your healthcare provider. Do not stop taking doxylamine succinate and pyridoxine hydrochloride delayed-release tablets without talking to your healthcare provider first.
- **See the following schedule for the usual way you should start taking doxylamine succinate and pyridoxine hydrochloride delayed-release tablets:**
 - Day 1- Take 2 tablets, by mouth at bedtime.
 - Day 2- Take 2 tablets at bedtime. If your nausea and vomiting is better or controlled on Day 2, continue to take 2 tablets every night at bedtime. This will be your usual dose unless your healthcare provider tells you otherwise.
 - Day 3- If you still had nausea and vomiting on Day 2, take 3 tablets on Day 3 (1 tablet in the morning and 2 tablets at bedtime).
 - Day 4- If your nausea and vomiting was better or controlled on Day 3, continue to take 3 tablets each day (1 tablet in the morning and 2 tablets at bedtime). If you still had nausea and vomiting on Day 3, start taking 4 tablets each day (1 tablet in the morning, 1 tablet in the afternoon, and 2 tablets at bedtime).
- Do not take more than 4 tablets (1 in the morning, 1 in the mid-afternoon, and 2 at bedtime) in 1 day.

- Take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets on an empty stomach with a glass of water.
- Take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets whole. Do not crush, chew, or break doxylamine succinate and pyridoxine hydrochloride delayed-release tablets before swallowing. If you cannot swallow doxylamine succinate and pyridoxine hydrochloride delayed-release tablets whole, tell your healthcare provider.
- If you take too many doxylamine succinate and pyridoxine hydrochloride delayed-release tablets (overdose), you may have the following symptoms: restlessness, dry mouth, the pupils of your eyes become larger (dilated), sleepiness, dizziness, confusion, fast heart rate, seizures, muscle pain or weakness, and sudden and severe kidney problems. If you have these symptoms and they are severe, they may lead to death. Stop taking doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, call your healthcare provider or go to the nearest hospital emergency room right away. For more information about overdose treatment, call your poison control center at 1-800-222-1222.

What are the possible side effects of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets?

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets may cause serious side effects, including drowsiness.

Drowsiness is a common side effect when taking doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, but can also be severe:

- **Do not** drive, operate heavy machinery, or other activities that need your full attention unless your healthcare provider says that you may do so.
- **Do not** drink alcohol, or take other central nervous system depressants such as cough and cold medicines, certain pain medicines, and medicines that help you sleep while you take doxylamine succinate and pyridoxine hydrochloride delayed-release tablets. Severe drowsiness can happen or become worse causing falls or accidents.

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets may cause false positive urine drug screening test for methadone, opiates and PCP.

These are not all the possible side effects of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store doxylamine succinate and pyridoxine hydrochloride delayed-release tablets?

- Store doxylamine succinate and pyridoxine hydrochloride delayed-release tablets between 68°F to 77°F (20°C to 25°C).
- Keep doxylamine succinate and pyridoxine hydrochloride delayed-release tablets dry, in a tightly closed container, and out of the light.
- Safely throw away medicine that is out of date or no longer needed.

Keep doxylamine succinate and pyridoxine hydrochloride delayed-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of doxylamine succinate and pyridoxine hydrochloride delayed-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about doxylamine succinate and pyridoxine hydrochloride delayed-release tablets that is written for health professionals. Do not use doxylamine succinate and pyridoxine hydrochloride delayed-release tablets for a condition for which it was not prescribed. Do not give doxylamine succinate and pyridoxine hydrochloride delayed-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in doxylamine succinate and pyridoxine hydrochloride delayed-release tablets?

Active ingredient: doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B₆).

Inactive ingredients: ammonium hydroxide, n-butanol, carnauba wax powder, colloidal silicon dioxide, croscarmellose sodium, D&C Red#27, denatured alcohol, FD&C Blue #2, hypromellose, isopropyl alcohol, magnesium stearate, magnesium trisilicate, methacrylic acid copolymer, microcrystalline cellulose 102, PEG 400, PEG 8000, polysorbate 80, propylene glycol, shellac glaze, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate.

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This Patient Information has been approved by the U.S. Food and Drug Administration

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