

FDA Approved Diclegis for the Treatment of Nausea and Vomiting in Pregnant Women

During pregnancy, many women struggle with gastrointestinal issues. As many as 50-90% of women will experience nausea during the first 6-8 weeks of pregnancy. Patients who are young, obese, have a history of smoking cigarettes, or are having their first child are at an increased risk. These issues usually occur during the first trimester and are self-limiting. To manage mild nausea and vomiting, conservative treatment, such as dietary and lifestyle modifications, may be enough to reduce symptoms. For example, eating several small meals that are low in fat and high in carbohydrates throughout the day may relieve symptoms. For patients with severe symptoms, promethazine (Category C) or meclizine (Category B) may be utilized, but these medications are not recommended for routine use in pregnancy.

On April 8, 2013, the FDA approved Diclegis (doxylamine succinate, pyridoxine hydrochloride) for the treatment of nausea and vomiting due to pregnancy that is not responsive to conservative management. This delayed-release tablet is currently the only FDA-approved medication with this indication.

Doxylamine is a first generation H₁-antagonist combined with pyridoxine (vitamin B6). The mechanism of action of this combination for treating nausea and vomiting is unknown. Diclegis should be taken on an empty stomach with a glass of water and swallowed whole. It is intended for daily scheduled administration. The initial dose is two tablets at bedtime; however, if symptoms persist the patient may take up to a maximum of four tablets per day (one tablet in the morning, one tablet mid-afternoon, and two tablets at bedtime). The most common side effect associated with this medication is drowsiness. According to current literature, the possibility of fetal harm appears remote; therefore, the drug is listed as a Category A medication for all trimesters. It is unknown if the drug is able to cross the placenta and there is inconclusive evidence regarding the use of Diclegis during breastfeeding. Contraindications include: concomitant use of a monoamine oxidase inhibitor as well as hypersensitivity to either medication (doxylamine, pyridoxine) or the inactive ingredients. Diclegis should be used with caution in patients with preexisting asthma, peptic ulcer, urinary bladder neck obstruction, or patients with narrow-angle glaucoma.

Clinically, this medication will assist patients with nausea and vomiting associated with pregnancy, particularly during the first trimester. It is important to remember that each patient should be reassessed for continued treatment during pregnancy progression.

References:

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