

## New Drug Approvals

**Generic Name (Trade Name—Company)**

April 9, 2013

**Doxylamine succinate and pyridoxine hydrochloride**

**Uses/Notes**

**Treatment of pregnancy-related nausea and vomiting that cannot be managed by changes in diet and lifestyle**

[FDA has approved doxylamine succinate–pyridoxine hydrochloride](#) as the only category A drug for nausea and vomiting drug to pregnancy. Doxylamine succinate–pyridoxine hydrochloride is a delayed-release tablet intended for women who have not responded adequately to conservative management of nausea and vomiting during pregnancy, such as dietary and lifestyle modifications. These modifications include eating several small meals instead of three large meals, eating bland foods that are low in fat and easy to digest, and avoiding smells that can trigger nausea.

The drug was studied in 261 women experiencing nausea and vomiting due to pregnancy. Study participants in the clinical trial were at least 18 years old and had been pregnant for at least 7 weeks and up to 14 weeks. Women were randomly assigned to receive 2 weeks of treatment with doxylamine succinate–pyridoxine hydrochloride or a placebo. Women taking the drug experienced greater improvement in nausea and vomiting than those taking placebo. Additionally, observational (epidemiological) studies have shown that the combination of active ingredients does not pose an increased risk of harm to the fetus.

Doxylamine succinate–pyridoxine hydrochloride is taken daily. Tablets must be taken whole on an empty stomach. The recommended starting dose is two tablets taken at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one midafternoon, and two at bedtime).

Drowsiness or sleepiness, which can be severe, is the most common adverse effect reported. Women should avoid taking the medication when engaging in activities requiring mental alertness, such as driving or operating heavy machinery, until cleared to do so by their health

***(Diclegis—Duchesnay)***

care provider.

**New treatment for nausea and vomiting due to pregnancy**

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