DUCHESNAY USA
Caring for mother and child during pregnancy

MORNING SICKNESS FACT SHEET

What is morning sickness?

Morning sickness, clinically known as Nausea and Vomiting of Pregnancy (NVP), is a medical condition that affects 70-85% of pregnant women.[1,2,3,4] Therefore, of the approximately 4 million births that occur in the United States annually,[5] upwards of 3.4 million American women may suffer from morning sickness every year.[1,2,3,4] Although the condition is often referred to as "morning sickness,"[6] as many as 95% of pregnant women with this condition experience symptoms both before and after midday.[4]

What are the signs and symptoms of morning sickness?

Although morning sickness can present differently for each woman, the primary symptoms include: nausea, gagging, retching, dry heaving, vomiting, and odor and/or food aversion.[7] For most pregnant women, symptoms generally cease at approximately 16 to 20 weeks.[8] However, some women can experience symptoms throughout their pregnancy.[4,8]

Morning sickness symptoms can be evaluated using the Pregnancy-Unique Quantification of Emesis (PUQE) scale, a scoring system based on the number of daily vomiting episodes, the length of nausea per day in hours, and the number of retching episodes.[9]

What treatment options are currently available for managing NVP?

Pregnant women should speak with their healthcare professionals about morning sickness symptoms at their first appointment and subsequent appointments, so that the need for treatment can be evaluated as soon as possible. Symptoms should be monitored by both the healthcare professional and pregnant woman, and managed through conservative measures, such as diet and lifestyle changes.[5]

If conservative management is not effective, the Association of Professors of Gynecology and Obstetrics (APGO) recommends the use of Diclegis® (doxylamine succinate and pyridoxine hydrochloride) Delayed-Release Tablets.[10] Similarly, the American Congress of Obstetricians and Gynecologists (ACOG) recommends the combined use of pyridoxine (vitamin B_6) plus doxylamine (an antihistamine), the active ingredients in Diclegis, as a first-line pharmacotherapy to reduce nausea and vomiting.[5]

Diclegis is the only U.S. Food and Drug Administration (FDA)-approved prescription treatment indicated for nausea and vomiting of pregnancy in women who do not respond to conservative management.[11] Pregnant women struggling with morning sickness should speak with their healthcare professional to learn how to effectively manage and monitor symptoms.

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Important Safety Information for Diclegis

Indication
Diclegis® is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

Limitations of Use
Diclegis has not been studied in women with hyperemesis gravidarum.

Important Safety Information
Do not take Diclegis if you are allergic to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, or any of the ingredients in Diclegis. You should also not take Diclegis in combination with medicines called monoamine oxidase (MAO) inhibitors, as these medicines can intensify and prolong the adverse central nervous system (CNS) effects of Diclegis. Use of MAOs may also prolong and intensify the anticholinergic (drying) effects of antihistamines.

The most common side effect of Diclegis is drowsiness. You should avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery, while using Diclegis until cleared to do so by your healthcare provider.

Do not take Diclegis with alcohol or sedating medicines, including other antihistamines (present in some cough and cold medications), opiates, or sleep aids, because severe drowsiness can happen or become worse, causing falls or accidents.

Diclegis should be used with caution in women who have: (1) asthma, (2) increased pressure in the eye, (3) an eye problem called narrow angle glaucoma, (4) a stomach problem called stenosing peptic ulcer, (5) pyloroduodenal obstruction, or (6) a bladder problem called bladder-neck obstruction.

Fatalities have been reported from doxylamine overdose in children. Children appear to be at a high risk for cardiorespiratory arrest. However, the safety and effectiveness of Diclegis in children younger than 18 years have not been established.

Diclegis 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. If you suspect an overdose or seek additional overdose information, you can contact a poison control center at 1-800-222-1222.

The FDA granted Diclegis Pregnancy Category A status, which means that the results of controlled studies have not shown an increased risk to an unborn baby during pregnancy.

Women should not breast-feed while using Diclegis because the antihistamine component (doxylamine succinate) in Diclegis 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 Diclegis resulting in worsening of their apnea or respiratory conditions.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For full prescribing information, please visit www.diclegis.com.

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