WHAT IS NVP? NVP stands for Nausea and Vomiting of Pregnancy. NVP is a medical condition commonly called morning sickness that can affect up to 85% of pregnant women.¹,³ The exact cause of NVP is unknown, although it may be caused by hormonal changes early on in the pregnancy.¹

COMMON SYMPTOMS OF NVP, Morning sickness is a misnomer. Despite the name, about 95% of moms with morning sickness experience symptoms throughout the day.²,⁴ These symptoms include: nausea, dry heaving, and vomiting.⁴

DON’T SUFFER IN SILENCE!
TALK WITH YOUR HEALTHCARE PROVIDER AS SOON AS YOU EXPERIENCE NVP SYMPTOMS.

WHEN DOES NVP TYPICALLY START AND STOP?
NVP typically starts around the 5th week of pregnancy and resolves toward the end of the first trimester.⁴,⁶

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• Eating frequent small meals
• Snacking on crackers
• Avoiding strong odors
• Taking ginger products (ginger ale, ginger tea)
• Eating bland or dry foods, high-protein snacks
• Eliminating high-fat foods from the diet

DICLEGIS®, (doxylamine succinate and pyridoxine hydrochloride) is the ONLY FDA-approved and ONLY Pregnancy Category A prescription medicine to help relieve morning sickness symptoms when diet and lifestyle fail.

Talk to your healthcare provider to learn if DICLEGIS® may be right for you.

VISIT WWW.DICLEGIS.COM FOR MORE INFORMATION

INDICATION
DICLEGIS® is 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
DICLEGIS® has not been studied in women with hyperemesis gravidarum.

IMPORTANT SAFETY INFORMATION
DICLEGIS® is contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, or any inactive ingredient in the formulation. DICLEGIS® is also contraindicated in combination with monoamine oxidase inhibitors (MAOIs) as MAOIs intensify and prolong the adverse CNS effects of DICLEGIS®. Use of MAOIs may also prolong and intensify the anticholinergic (drying) effects of antihistamines.

DICLEGIS® 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 DICLEGIS® until cleared to do so by their healthcare provider.
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Use of Diclegis® 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 Diclegis® and CNS depressants could result in severe drowsiness leading to falls or other accidents.

Diclegis® has anticholinergic properties and should be used with caution in women who have: (1) asthma, (2) increased intraocular pressure, (3) an eye problem called narrow angle glaucoma, (4) a stomach problem called stenosing peptic ulcer, (5) pyloroduodenal obstruction, or (6) a urinary 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 under 16 years of age 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.

Diclegis® is intended for use in pregnant women. Women should not breast-feed while using Diclegis® because the antihistamine component (doxylamine succinate) in Diclegis® can pass into 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.

To report suspected adverse reactions, contact Duchesnay Inc. at 1-855-722-7734 or medicalinfo@duchesnayusa.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
**What is DICLEGIS?**
- DICLEGIS is a prescription medicine used to treat nausea and vomiting of pregnancy in women who have not improved with change in diet or other non-medicine treatments.
- It is not known if DICLEGIS is safe and effective in children under 18 years of age.

**Who should not take DICLEGIS?**
- Do not take DICLEGIS if you:
  - are allergic to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any of the ingredients in DICLEGIS. See the end of this leaflet for a complete list of ingredients in DICLEGIS.
  - take monoamine oxidase inhibitors (MAOIs) (Marplan, Nardil, Emsam, Eldepryl, Zelapar, Parnate)

**Before taking DICLEGIS, tell your healthcare provider about all of your medical conditions, including:**
- if you are breastfeeding or plan to breastfeed. DICLEGIS can pass into your breast milk and may harm your baby. You should not breastfeed while using DICLEGIS.

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 DICLEGIS?**
- Talk to your healthcare provider about how much DICLEGIS to take and when to take it.
- Take DICLEGIS everyday as prescribed by your healthcare provider. Do not stop taking DICLEGIS without talking to your healthcare provider first.
- See the following schedule for the usual way you should start taking DICLEGIS:
  - 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 DICLEGIS on an empty stomach with a glass of water.
  - Take DICLEGIS tablets whole. Do not crush, chew, or break DICLEGIS tablets before swallowing. If you cannot swallow DICLEGIS tablets whole, tell your healthcare provider.

  - If you take too much DICLEGIS (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 DICLEGIS, 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 DICLEGIS?**
- DICLEGIS may cause serious side effects, including drowsiness.
  - 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 DICLEGIS. Severe drowsiness can happen or become worse causing falls or accidents.
These are not all the possible side effects of DICLEGIS. 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 DICLEGIS?**
- Store DICLEGIS between 68°F to 77°F (20°C to 25°C).
- Keep DICLEGIS 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 DICLEGIS and all medicines out of the reach of children.**

**General information about the safe and effective use of DICLEGIS.**
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 DICLEGIS that is written for health professionals. Do not use DICLEGIS for a condition for which it was not prescribed. Do not give DICLEGIS to other people, even if they have the same symptoms that you have. It may harm them.

**What are the ingredients in DICLEGIS?**
**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, talc, titanium dioxide.

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

**Issued:** 04/2013