

# Diclegis® Product Fact Sheet

## What is Diclegis®?

Diclegis (pronounced dye-CLEE-gis) (doxylamine succinate 10mg, pyridoxine hydrochloride 10mg) is the only U.S. Food and Drug Administration (FDA)-approved prescription treatment indicated for Nausea and Vomiting of Pregnancy (NVP), commonly known as morning sickness,<sup>1</sup> in women who do not respond to conservative management.<sup>2</sup> Diclegis has not been studied in women with hyperemesis gravidarum.<sup>2</sup>

The FDA granted Diclegis with the best rating available, Pregnancy Category A, which means the results of controlled studies have not shown an increased risk to an unborn baby during pregnancy.<sup>2,3</sup> Duchesnay USA received FDA approval for Diclegis on April 8, 2013.

The two active ingredients in Diclegis that reduce symptoms of nausea and vomiting – doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B<sub>6</sub>)<sup>2</sup> – continue to be recommended as a first-line pharmacotherapy for morning sickness by the American Congress of Obstetricians and Gynecologists (ACOG) and the Association of Professional Gynecology and Obstetrics (APGO).<sup>1,4</sup>

## When and How Do I Take Diclegis?

Diclegis has a special delayed-release coating designed to allow you to feel the effect 5-7 hours after you take it. Initially, you take two Diclegis tablets orally at bedtime (Day 1). If this dose adequately controls symptoms the next day, continue taking two tablets daily at bedtime.<sup>2</sup>

However, if symptoms persist into the afternoon of Day 2, take the usual dose of two tablets at bedtime that night, then take three tablets starting on Day 3 (one tablet in the morning and two tablets at bedtime). If three tablets adequately control symptoms on Day 4, continue taking three tablets daily. Otherwise, take four tablets starting on Day 4 (one tablet in the morning, one tablet mid-afternoon and two tablets at bedtime). The maximum recommended dose is four tablets (one in the morning, one in the mid-afternoon and two at bedtime) daily.<sup>2</sup>

Diclegis is taken as a daily prescription and not on an as-needed basis to help control morning sickness symptoms throughout the day.<sup>2</sup>

## Who Should Take Diclegis?

Morning sickness is a medical condition that affects 70-85% of pregnant women,<sup>5,6,7,8</sup> with symptoms ranging from mild to severe nausea, gagging/retching, and vomiting.<sup>9</sup> These symptoms can



Tablet shown is not actual size

<sup>1</sup> American College of Obstetrics and Gynecology. ACOG (American College of Obstetrics and Gynecology) Practice Bulletin: nausea and vomiting of pregnancy. *Obstet Gynecol.* 2004 Apr;103(4):803-14.

<sup>2</sup> Diclegis® (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets. Full Prescribing Information. Bryn Mawr, PA: Duchesnay USA, Inc.; 2013.

<sup>3</sup> Department of Health and Human Services, Food and Drug Administration. Content and format of labeling for human prescription drug and biological products; requirements for pregnancy and lactation labeling. *Federal Register.* 2008;73(104):30831-68

<sup>4</sup> Association of Professors of Gynecology and Obstetrics. Nausea and vomiting of pregnancy. APGO continuing series on women's health education. March 1, 2011. Available at: [https://www.apgo.org/images/nvp/nvp\\_monograph\\_021015\\_final.pdf](https://www.apgo.org/images/nvp/nvp_monograph_021015_final.pdf). Accessed on February 23, 2015

<sup>5</sup> Jewell, D, Young, G. Interventions for Nausea and Vomiting in Early Pregnancy. *The Cochrane Library.* 2002; 1

<sup>6</sup> Medalie, J. Relationship between Nausea and Vomiting in Early Pregnancy and/or Abortion. *The Lancet.* 1957; 117-119.

<sup>7</sup> Whitehead, SA, Andrews, LR, Chamberlain, VP. Characterisation of Nausea and Vomiting in Early Pregnancy: A Survey of 1000 Women. *Journal of Obstetrics and Gynaecology.* 1992; 12: 384-369

<sup>8</sup> Gadsby, R, Barnie-Adshead, A, Jagger, C. A Prospective Study of Nausea and Vomiting During Pregnancy. *British Journal of General Practice.* 1993; 43: 245-248.

<sup>9</sup> Clark S, Costantine M, Hankins GDV. Review of NVP and HG and early pharmacotherapeutic Intervention. *Obstetrics and Gynecology International Volume.* 2012.

occur anytime during the day or night, and last throughout pregnancy, although 90% of women have symptoms resolve by 14 to 16 weeks of pregnancy.<sup>8</sup>

Diclegis has received Kosher, Kosher for Passover, and Halal certifications.

Those who are allergic to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, or any of the ingredients in Diclegis should not take Diclegis. Diclegis should not be taken in combination with medicines called monoamine oxidase inhibitors.<sup>2</sup>

Talk to your healthcare provider to determine if Diclegis is right for you. Be sure to inform your provider about your medical conditions and any medications you take.

### ***Is Diclegis Safe?***

Diclegis was specifically created for pregnant women, and has been studied in pregnant women to ensure it is safe and effective.<sup>10</sup> It is not known if Diclegis is safe and effective in children under 18 years of age.<sup>2</sup>

The New Drug Application submission with the FDA included results from a randomized, double-blind, multicenter placebo-controlled trial conducted in pregnant women suffering from morning sickness. Pregnant women between 7 to 14 weeks of gestation with morning sickness were randomized to receive Diclegis or placebo for 14 days. Morning sickness symptoms were evaluated daily using the Pregnancy-Unique Quantification of Emesis (PUQE) scale. A statistically significant reduction in morning sickness symptoms was observed among women treated with Diclegis® as compared to placebo ( $-4.8 \pm 2.7$  vs.  $-3.9 \pm 2.6$ ;  $P = .006$ ).<sup>10</sup>

Diclegis is the only FDA-approved medicine for morning sickness.<sup>2</sup>

### **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 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.

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<sup>10</sup> Koren G, Clark S, Hankins GDV, et al. Effectiveness of delayed-release doxylamine and pyridoxine for nausea and vomiting of pregnancy: a randomized placebo controlled trial. *Am J Obstet Gynecol.* 2010; 203.

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

***Please see full Prescribing Information [here](#) and Patient Information [here](#)***

***Learn more about Diclegis at [www.Diclegis.com](http://www.Diclegis.com)***