Diclegis® for Nausea and Vomiting of Pregnancy Now Eligible for Medicaid Coverage in all States

Only FDA-approved treatment for “morning sickness” is made available nationwide through Medicaid Drug Rebate Program

Rosemont, Pa. – DATE – Duchesnay USA today announced that Diclegis® (doxylamine succinate 10mg, pyridoxine hydrochloride 10mg) delayed-release tablets for the treatment of nausea and vomiting of pregnancy (NVP), more commonly known as morning sickness, is now available for coverage under the state and federal Medicaid program effective July 1st, 2013. July 1st represented the mandatory effective date for state coverage following the execution of a rebate agreement with the Center for Medicare and Medicaid Services (CMS) after the FDA approval of Diclegis on April 8th.

Coverage by Medicaid of Diclegis, the only FDA-approved NVP treatment, complements the numerous commercially insured lives that can currently access the treatment as well. Diclegis is also the only FDA Pregnancy Category A product available to pregnant women in the U.S.

“Having an FDA-approved treatment for nausea and vomiting of pregnancy, or morning sickness, that is safe and effective was just half of the battle,” said Gary Hankins, MD, Jennie Sealy Smith Distinguished Professor and Chairman, University of Texas Medical Branch, Department of Obstetrics and Gynecology. “Making it accessible to almost every woman who might need the treatment will finally help fulfill a significant unmet need to the millions of women suffering from NVP.”

The Medicaid Drug Rebate Program is a partnership between CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. All 50 states and the District of Columbia cover prescription drugs under the Medicaid Drug Rebate Program.1

“We believe that women ought to have the option to treat conditions that truly impact them, and Diclegis is the only FDA-approved Pregnancy Category A treatment for NVP,” said Gilbert Godin, Chief Executive Officer, Duchesnay USA. “It has been Duchesnay USA’s critical focus to make Diclegis, affordable, accessible and broadly available. With Medicaid eligibility, we can help ensure that women of all backgrounds can access this one-of-a-kind safe and effective therapy.”


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.

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.
About Nausea and Vomiting of Pregnancy (NVP)
Nausea and vomiting of pregnancy (NVP), or morning sickness, affects 70 to 85 percent of pregnant women.\(^2\)\(^3\)\(^4\)\(^5\) NVP can present differently for each woman, the symptoms include: nausea, gagging, retching, dry heaving, vomiting, and odor and/or food aversion.\(^6\) For most pregnant women, symptoms generally cease at approximately 16 to 20 weeks.\(^5\) However, some women can experience symptoms throughout their pregnancy.\(^7\)

About Diclegis
Diclegis (doxylamine succinate 10 mg, pyridoxine hydrochloride 10 mg) delayed-release tablets is the only FDA-approved prescription treatment for nausea and vomiting of pregnancy (NVP) in women who do not respond to conservative management.\(^8\) Diclegis has proven to be a safe and effective treatment option for NVP and received a Pregnancy Category A status, which means the results of controlled studies have not shown an increased risk to an unborn baby.\(^9\)

About Duchesnay USA
Duchesnay USA is a unique healthcare company devoted to safeguarding the health and well-being of expectant mothers and their unborn babies. Its affiliate company, Duchesnay Inc. was founded in 1970 in Canada, the family-owned company realigned its business in 1992 to focus specifically on pregnant women after a family member experienced a very difficult pregnancy. Duchesnay USA was established in Rosemont, Pennsylvania in 2011 to pursue that same mission. Realizing a lack of sufficient information on medications for use in pregnancy, Duchesnay USA strives to ensure that expectant women who require pharmacological treatments have access to proper medical advice and therapies that are safe for them and their unborn babies. Duchesnay USA’s mission is to develop pharmacological solutions to reduce the symptoms of nausea and vomiting during pregnancy (NVP). For more information on Duchesnay USA, please visit [www.DuchesnayUSA.com](http://www.DuchesnayUSA.com).

Contact
Laney Cohen
Makovsky
lcohen@makovsky.com
212-508-9643

---

\(^8\) Diclegis Prescribing Information. Duchesnay USA. 2013.