FDA Approves Duchesnay USA’s Diclegis® for Treatment of Nausea and Vomiting of Pregnancy (NVP)

_Diclegis becomes only FDA-approved treatment for “morning sickness” in decades_

Rosemont, PA April 8th, 2013 – Duchesnay USA today announced that the Food and Drug Administration (FDA) has granted approval for Diclegis® (doxylamine succinate 10mg, pyridoxine hydrochloride 10mg) delayed-release tablets for the treatment of nausea and vomiting of pregnancy (NVP) in women who do not respond to conservative management. It is the only FDA-approved treatment for NVP, more commonly known as morning sickness, in more than 30 years.

The FDA granted Diclegis Pregnancy Category A status which means the results of controlled studies have not shown an increased risk to an unborn baby during pregnancy. The two active ingredients in Diclegis that reduce nausea and vomiting in pregnancy – doxylamine succinate and pyridoxine hydrochloride, or vitamin B6, – have been recommended as a first-line pharmacotherapy by the American Congress of Obstetricians and Gynecologists (ACOG) guidelines for the last nine years.

“The FDA approval of Diclegis provides an important new treatment to the millions of women suffering from nausea and vomiting of pregnancy, and fills a 30 year void in the treatment of NVP,” said Gilbert Godin, Chief Executive Officer, Duchesnay USA. “Duchesnay USA is honored to bring the only FDA-approved treatment to help control symptoms of morning sickness to market. Duchesnay has been dedicated to the health of pregnant women and their unborn children for years and is taking every step to make Diclegis available for women suffering from NVP.”

NVP is a medical condition that affects 70 to 85 percent of pregnant women with symptoms ranging from nausea to severe vomiting and retching that can last throughout the day. Some pregnant women may experience symptoms throughout their pregnancy.

“Millions of pregnant women suffering every year from nausea and vomiting of pregnancy now have a safe and effective FDA-approved treatment. Until now, women have been without an FDA-approved prescription options to help treat NVP symptoms, also known as morning sickness,” said Dr. Shannon Clark, Associate Professor, Division of Maternal and Fetal Medicine, University of Texas Medical Branch – Galveston. “Diclegis provides a safe and effective option for pregnant women. Its active ingredients are the most studied for this purpose.”

Diclegis is expected to be widely available in the US by the end of May 2013.

**Efficacy and Safety Profile of Diclegis in Patients with Nausea and Vomiting of Pregnancy**

Diclegis has proven to be a safe and effective treatment option for nausea and vomiting of Pregnancy (NVP).
The New Drug Application submission with the FDA was based on a 15-day double-blind, randomized, multi-center placebo-controlled trial studying pregnant women 18 years of age or older, 7 to 14 weeks gestation, with NVP. Use of Diclegis resulted in significantly larger improvement in symptoms of NVP compared with placebo, based on the PUQE score. This study concluded that Diclegis delayed release formulation of doxylamine succinate and pyridoxine hydrochloride is effective and well tolerated in treating NVP.

**Diclegis Dosage and Administration**

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 in women who do not respond to conservative management.

Initially, a patient takes two Diclegis delayed-release tablets orally at bedtime (Day 1). If symptoms persist into the afternoon of Day 2, the patient takes the usual dose of two tablets at bedtime that night and then adds one tablet the following morning on Day 3. If symptoms still persist on Day 4, the patient takes 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. Diclegis is taken as a daily prescription and not on an as needed basis to help control symptoms throughout the day.

**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.

Please see accompanying full Prescribing Information.

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

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About Nausea and Vomiting of Pregnancy (NVP)
Nausea and vomiting of pregnancy (NVP), or morning sickness, affects 70 to 85 percent of pregnant women, with symptoms that range from nausea to severe vomiting and retching.iii, iv For most pregnant women, symptoms generally cease at approximately 16 to 20 weeks.iv However, some women can experience symptoms throughout their pregnancy.iv

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.
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