

## Duchesnay Summarizes Comprehensive Body of Evidence for Most Studied Morning Sickness Drug Worldwide

– Over 40 years of clinical experience, 16 cohort studies, two meta-analyses support regulatory approvals and guidelines –

BLAINVILLE, QC (Canada) – January 4, 2017 – Duchesnay was informed today of a newly published report regarding the “8-Way Bendectin Study”. This report, published in PLOS ONE, refers to a 1970s study conducted by Merrell Dow on a drug called Bendectin, originally approved by the FDA in 1956. This study was conducted as part of the DESI program (Drug Efficacy Study Implementation), an FDA initiative to determine if drug products approved prior to 1962 were in fact effective.

The FDA’s review of this 8-way Bendectin study concluded that the combination of two of Bendectin’s ingredients, doxylamine succinate and pyridoxine hydrochloride, confirmed and supported previous findings that Bendectin was effective in the treatment of nausea and vomiting of pregnancy. “The conclusions expressed in the report published in PLOS ONE are highly inconsistent with the large and comprehensive body of evidence regarding this combination drug,” states Michael Gallo, Vice-President, Regulatory and Medical Affairs at Duchesnay.

Duchesnay is committed to providing pregnant women suffering from nausea and vomiting of pregnancy (NVP) with a safe and effective treatment option when diet and lifestyle changes fail to adequately control their symptoms. Diclectin® is the only prescription medication indicated for the treatment of nausea and vomiting of pregnancy approved by Health Canada. It has been prescribed for over 40 years in Canada and has been proven safe and efficacious for use throughout pregnancy.

The two active ingredients in Diclectin® — doxylamine succinate 10 mg and pyridoxine hydrochloride 10 mg — are the most studied drug combination used in pregnancy. The safety and efficacy of Diclectin® have been proven in 16 cohort studies, two meta-analyses, an ecological study, a neurological development study and numerous others. It is estimated that 35 million women around the world have used the combination of doxylamine succinate and pyridoxine hydrochloride to treat nausea and vomiting of pregnancy.

In July 2016, Health Canada’s Scientific Advisory Panel on Diclectin issued a report in which it reiterated its full confidence in Diclectin® as a safe and effective treatment option for NVP. The report concluded that: “the evidence continues to support Diclectin's safe and effective use for the treatment of nausea and vomiting during pregnancy”. We invite you to read Health Canada’s Summary Safety Review [here](#).

Also, in December 2016, the Society of Obstetricians and Gynaecologists of Canada (SOGC) issued its latest Guidelines on NVP and once again maintained its recommendation to use Diclectin as a first line treatment for NVP when other measures, such as dietary and lifestyle changes, have not been effective.

Additionally, in April 2013, Diclectin® was approved under the name Diclegis by the U.S. Food and Drug Administration as a New Drug Application (NDA). The application was supported by studies conducted by Duchesnay Inc., by historical data and by published literature on this drug combination as well as by many decades of use in millions of women worldwide.

Shortly after Diclegis received FDA approval, the [New England Journal of Medicine](#) published an article written by several FDA representatives in which the evidence-based approval process was described in detail. The authors proudly highlighted the thoroughness and soundness of the data supporting the drug's safety and efficacy profile.

Diclegis is considered first-line treatment for the management of NVP by the American Congress of Obstetricians and Gynecologists (ACOG) and by the Association of Professors of Gynecology and Obstetrics (APGO) when conservative management fails. Additionally, in his reference book, *Drugs in Pregnancy and Lactation Reference Guide*, author Gerald G. Briggs, B. Pharm., FCCP, granted Diclectin® the highest safety ranking: "Compatible" or "Category A".

Thus, we have complete confidence in the safety and efficacy of Diclectin® and are very proud to provide it as a safe and effective treatment option for women suffering from nausea and vomiting of pregnancy.

### **About Duchesnay**

Duchesnay is a specialty pharmaceutical company with a long-standing commitment to women's health. In addition to filling the void in terms of scientific research, education and information and developing pharmacological solutions that are safe for use during pregnancy and breastfeeding, Duchesnay is equally committed to ensuring women's health and improving their quality of life at every stage.

Thus, Duchesnay has broadened its portfolio of products to offer safe and effective therapeutic options that meet the health and quality of life needs of women and their family members at different stages of their lives. To learn more about Duchesnay, visit [duchesnay.com](http://duchesnay.com)

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