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Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-release Tablets (Diclegis)

??? ??????: 30 ??????/?????? 2017

The following adverse reactions are discussed elsewhere in the labeling:

- **WARNINGS AND PRECAUTIONS** Somnolence [see]
- **WARNINGS AND PRECAUTIONS** Falls or other accidents resulting from the effect of the combined use of DICLEGIS with CNS depressants including alcohol [see]

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety and efficacy of DICLEGIS were compared to placebo in a double-blind, randomized, multi-center trial in 261 women with nausea and vomiting of pregnancy. The mean gestational age at enrollment was 9.3 weeks, range 7 to 14 weeks gestation [see **Clinical Studies**]. Adverse reactions for DICLEGIS that occurred at an incidence ? 5 percent and exceeded the incidence for placebo are summarized in Table 1.

Table 1: Number (Percent) of Subjects with ? 5 Percent Adverse Reactions in a 15-Day Placebo- Controlled Study of DICLEGIS (Only Those Adverse Reactions Occurring at an Incidence ? 5 Percent and at a Higher Incidence with DIGLEGIS than Placebo are Shown)

Placebo (n = 128)	Diclegis (N = 133)	
15 (11.7%)	19 (14.3%)	Somnolence

Postmarketing Experience

The following adverse events, listed alphabetically, have been identified during post-approval use of the combination of 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

dyspnea, palpitation, tachycardia **Cardiac disorders:**

vertigo **Ear and labyrinth disorders:**

vision blurred, visual disturbances **Eye disorders:**

abdominal distension, abdominal pain, constipation, diarrhea **Gastrointestinal disorders:**

chest discomfort, fatigue, irritability, malaise **General disorders and administration site conditions:**

hypersensitivity **Immune system disorders:**

dizziness, headache, migraines, paresthesia, psychomotor hyperactivity **Nervous system disorders:**

anxiety, disorientation, insomnia, nightmares **Psychiatric disorders:**

dysuria, urinary retention **Renal and urinary disorders:**

hyperhidrosis, pruritus, rash, rash maculo-papular **Skin and subcutaneous tissue disorders:**