

**BONJESTA, DICLEGIS
(doxylamine-pyridoxine)**

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Nausea and vomiting of pregnancy (NVP) is a common problem that afflicts approximately 44 – 89% of pregnant women during their pregnancies. NVP generally starts around 4-6 weeks of pregnancy, peaks around 8 – 12 weeks, and then tapers off after around 20 weeks (however recent evidence suggests many women may experience NVP throughout pregnancy, even into late pregnancy). Conservative measures are often recommended before medications. Conservative measures involve dietary and lifestyle changes, which include: eating smaller and more frequent meals, staying adequately hydrated, and resting appropriately. Once conservative measures have failed, medications are used. The pregnancy category A medication(s) of choice include pyridoxine hydrochloride (Vitamin B₆) and doxylamine succinate (Unisom®) which are available separately over the counter. Legend medications, Diclegis and Bonjesta, include both of these agents in one tablet and are available with a prescription (1-5).

Regulatory Status

FDA-approved indications: Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (4-5).

Diclegis contains 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride in a delayed release dosage form. Bonjesta consist of an enteric-coated core containing 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride, and an immediate release coating of 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride. These medications are intended to be taken on a daily basis and not as needed for nausea (physician must reassess patient throughout pregnancy to determine if continued use is needed) (4-5).

The safety and effectiveness of Bonjesta and Diclegis in pediatric patients have not been established (4-5).

Summary

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89% of pregnant women during their pregnancies. Conservative measures are often recommended before medications. The pregnancy category A medication(s) of choice include pyridoxine hydrochloride (Vitamin B₆) and doxylamine succinate (Unisom®) which are available separately over the counter. Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (1-5).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bonjesta and Diclegis while maintaining optimal therapeutic outcomes.

References

1. Briggs GG, Freeman RK, Towers CV, Forinash AB. Drugs in Pregnancy and Lactation. 11th ed. Philadelphia, PA: Wolters Kluwer, 2017
2. Niebyl, JR and Briggs GG. The Pharmacologic Management of Nausea and Vomiting of Pregnancy. Supplement to The Journal of Family Practice. Vol 63 (2), S31; February 2014.
3. Einarson TR, Piwko C, Koren G. Prevalence of nausea and vomiting of pregnancy in the USA: a meta analysis. J Popul Ther Clin Pharmacol. 2013;20(2):e163-e170.
4. Bonjesta [package insert]. Bryn Mawr, PA: Dushesnay USA, Inc.; October 2022.
5. Diclegis [package insert]. Bryn Mawr, PA: Dushesnay USA, Inc.; March 2022.