



Bonjesta™ (doxylamine/pyridoxine) – New Drug Approval

- On November 7, 2016, the [FDA approved](#) Duchesnay's [Bonjesta \(doxylamine/pyridoxine\)](#) for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.
 - Bonjesta has not been studied in women with hyperemesis gravidarum.
- Bonjesta is a fixed dose combination product containing an antihistamine (doxylamine) and a vitamin B6 analog (pyridoxine). The exact mechanism of Bonjesta is not known.
 - Doxylamine/pyridoxine is also available as [Diclegis®](#), which contains 10 mg of doxylamine and 10 mg of pyridoxine as delayed-release tablets for the same indication.
- There have been no efficacy and safety trials for Bonjesta. However, a placebo-controlled study was conducted to support the safety and efficacy of 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride tablets (a different formulation and dosage strength than Bonjesta) in the treatment of nausea and vomiting of pregnancy.
- Bonjesta is contraindicated in women with known hypersensitivity to doxylamine, other ethanolamine derivative antihistamines, or pyridoxine or any inactive ingredient in the formulation; monoamine oxidase (MAO) inhibitors intensify and prolong the adverse central nervous system effects of Bonjesta.
- Warnings and precautions of Bonjesta include somnolence and concomitant medical conditions.
- The most common adverse event ($\geq 5\%$ and exceeding placebo) with combination 10 mg doxylamine and 10 mg pyridoxine tablets was somnolence.
- The recommended dose of Bonjesta is one tablet orally at bedtime on day 1. If the dose adequately controls symptoms the next day, the patient may continue taking one tablet daily at bedtime only. However, if symptoms persist on day 2, the dose may be increased to one tablet in the morning and one tablet at bedtime.
 - The maximum recommended dose is two tablets per day, one in the morning and one at bedtime.
 - Bonjesta should be taken daily and not on an as needed basis.
- Duchesnay's launch plans for Bonjesta are pending. Bonjesta will be available as extended-release tablets containing 20 mg doxylamine and 20 mg pyridoxine.



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