Bonjesta®
(doxylamine succinate and pyridoxine hydrochloride)
Extended-release tablets 20 mg/20 mg

The combination of doxylamine succinate and pyridoxine hydrochloride in Bonjesta® is **recommended as first-line pharmacotherapy in ACOG's latest guidelines** for treating out Nausea and Vomiting of Pregnancy when conservative management fails.[1,5]

TRUSTED RELIEF FOR YOUR NVP PATIENTS WHEN CONSERVATIVE MANAGEMENT FAILS.

- Fast-acting, long-lasting formulation designed for both immediate and continuous relief[1]
- Simple dosing and reduced pill burden may improve patient compliance[1,4]
- Accessible and affordable — now covered without restrictions on many State Medicaid programs and **~50% of patients with commercial insurance***

*Subject to the specific terms of the patient's prescription drug benefit.

INDICATION

Bonjesta® is a fixed-dose combination drug product of 20 mg doxylamine succinate, an antihistamine, and 20 mg pyridoxine hydrochloride, a vitamin B_6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

LIMITATIONS OF USE

Bonjesta® has not been studied in women with hyperemesis gravidarum.

IMPORTANT SAFETY INFORMATION

Contraindications:

Bonjesta® is contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation. It is also contraindicated in combination with monoamine oxidase inhibitors (MAOIs) as MAOIs intensify and prolong the adverse central nervous system (CNS) effects of Bonjesta®. Use of MAOIs may also intensify and prolong the adverse CNS effects (the anticholinergic effects) of antihistamines.

Bonjesta® may cause somnolence due to the anticholinergic properties of doxylamine succinate, an antihistamine. Women should avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery, while using Bonjesta® until cleared to do so by their healthcare provider.

Use of Bonjesta® is not recommended if a woman is concurrently using CNS depressants, such as alcohol or sedating medications, including other antihistamines (present in some cough and cold medications), opiates and sleep aids. The combination of Bonjesta® and CNS depressants could result in severe drowsiness leading to falls or other accidents.

Please see full Important Safety Information throughout and on the last page

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EFFICACY[1]

Bonjesta® is a multilayer, extended-release tablet designed to provide both fast-acting and long-lasting symptom relief:

Immediate-release outer coating for fast absorption and rapid onset of action
10 mg doxylamine succinate and
10 mg pyridoxine hydrochloride

Enteric-coated core for long-lasting therapeutic effects
10 mg doxylamine succinate and
10 mg pyridoxine hydrochloride

The combination of ingredients in Bonjesta® has been trusted by over 35 million women worldwide.

SAFETY[1,6]

This drug combination is one of the most studied in pregnancy, including in the first trimester, and has been shown to present no increased risk to a fetus.

Two Meta-Analyses:

- 16 cohort and 11 case-controlled studies
- 12 cohort and 5 case-controlled studies

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BONJESTA® HAS YOUR PATIENTS COVERED

Medicaid and Commercial Insurance

Accessible and affordable — now covered without restrictions on many State Medicaid programs and ~50% of patients with commercial insurance*

*Subject to the specific terms of the patient's prescription drug benefit.

Bonjesta® CoPay Savings Card

With the Bonjesta® CoPay Savings Card, your patients may pay as little as **$40 for a one-month prescription**.
For more information, please call 1-800-250-5195

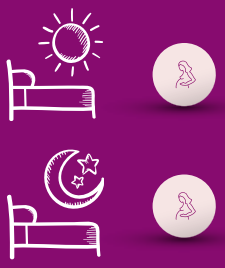
Bonjesta At Home®

When you prescribe through Bonjesta At Home®, patients pay **$60 for 30 tablets or $99 for 60 tablets** and receive free home delivery, on-staff pharmacists to answer their product questions, assistance with insurance benefit verification and monthly refill reminders.

DOSING AND ADMINISTRATION

Bonjesta® is taken as a daily prescription (not PRN) to achieve the steady-state concentration necessary for optimal anti-nauseant and anti-emetic effects:

Day 1:
Patient takes one Bonjesta® tablet orally at bedtime.



Day 2:
If symptoms persist the following day, patient should increase her daily dose to one tablet in the morning and one at bedtime.

Click Here to Order Samples

The maximum daily recommended dose for Bonjesta® is 2 tablets per day. Bonjesta® should be taken on an empty stomach with a glass of water. Tablets should be swallowed whole and should not be crushed, chewed or split.

IMPORTANCE OF EARLY TREATMENT

Timely treatment of NVP can prevent more serious complications, such as weight loss and dehydration, which could require hospitalization.[3,5]

IMPORTANT SAFETY INFORMATION (cont.)

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IMPORTANT SAFETY INFORMATION

Contraindications:

Bonjesta® is contraindicated in women with any of the following conditions:

- Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride 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:

- **Somnolence:** Bonjesta® may cause somnolence due to the anticholinergic properties of doxylamine succinate, an antihistamine. Women should avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery, while using Bonjesta® until cleared to do so by their healthcare provider.
- **Central nervous system (CNS) depressants**: Use of Bonjesta® is not recommended if a woman is concurrently using CNS depressants, such as alcohol or sedating medications, including other antihistamines (present in some cough and cold medications), opiates, and sleep aids. The combination of Bonjesta® and CNS depressants could result in severe drowsiness leading to falls or other accidents.
- **Concomitant Medical Conditions**: Use Bonjesta® with caution in women with (1) asthma, (2) increased intraocular pressure, (3) narrow angle glaucoma, (4) a stenosing peptic ulcer, (5) pyloroduodenal obstruction, or (6) bladder-neck obstruction.
- **Interference with Urine Screen for Methadone, Opiates and Phencyclidine Phosphate (PCP)**: There have been reports of false positive urine screening tests for methadone, opiates, and PCP with doxylamine succinate/pyridoxine hydrochloride use. Women should be informed that use of Bonjesta® may result in false positive urine drug screening for methadone, opiates and PCP.

Adverse Reactions: The most common adverse reaction (≥5 percent and exceeding the rate in placebo) with combination 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride tablets is somnolence.

Drug-Food Interactions: A food-effect trial demonstrated that the delay in the onset of action of Bonjesta® may be further delayed, and a reduction in absorption may occur when tablets are taken with food. Therefore, Bonjesta® should be taken on an empty stomach with a glass of water.

Use in Specific Populations:

- **Pregnancy**: Bonjesta® is intended for use in pregnant women.
- **Lactation**: Women should not breastfeed while using Bonjesta® because the antihistamine component (doxylamine succinate) in Bonjesta® 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 Bonjesta® resulting in worsening of their apnea or respiratory conditions.
- **Pediatric Use**: The safety and effectiveness of Bonjesta® in children under 18 years of age have not been established. Fatalities have been reported from doxylamine overdose in children. Children appear to be at a high risk for cardiorespiratory arrest.

Overdosage: Bonjesta® is an extended-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. At toxic doses, doxylamine exhibits anticholinergic effects, including seizures, rhabdomyolysis, acute renal failure and death. If treatment is needed, it consists of gastric lavage or activated charcoal, whole bowel irrigation and symptomatic treatment. If you suspect an overdose or seek additional information about overdose treatment, call a poison control center at 1-800-222-1222.

To report suspected adverse reactions, contact Duchesnay Inc. at **1-855-722-7734** or **medicalinfo@duchesnayusa.com** or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

References:

1. Bonjesta® Prescribing Information, Bryn Mawr, PA: Duchesnay USA Inc., 2018.
2. Diclegis® Prescribing Information, Bryn Mawr, PA: Duchesnay USA Inc. 2013
3. Bustos, M., et al. Nausea and vomiting of pregnancy - what's new? Auton Neurosci. 2017; 202:62-72.
4. Costantine, M. M., et al. Determinants of adherence to delayed-release doxylamine and pyridoxine in patients with nausea and vomiting of pregnancy. Ther Drug Monit. 2012; 34:569-573.
5. ACOG Practice Bulletin #189: Clinical Management Guidelines for Obstetrician-Gynecologists. Nausea and Vomiting of Pregnancy. Obstet Gynecol. 2018; 131(1):e15-e30.
6. Koren, G. Safety considerations surrounding use of treatment options for nausea and vomiting in pregnancy. Expert Opin Drug Saf. 2017; 16 (11):1227-1234.

For more information, see **hcp.Bonjesta.com**

DUCHESNAY USA

BON-2018-0015-05 April 2021