Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Bonjesta

Extended-release tablets

Active ingredients and quantities
Each extended-release tablet contains:
doxylamine succinate 20 mg
pyridoxine hydrochloride 20 mg

For the list of the inactive ingredients in this medicine, please see Section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours. It is not known if Bonjesta is safe and effective in women with severe nausea and vomiting of pregnancy, a condition called hyperemesis gravidarum. Women with this condition may need to be hospitalized.

1. What is this medicine intended for?

Bonjesta is intended 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 a condition called hyperemesis gravidarum.

Therapeutic group:
doxylamine succinate – an antihistamine.
pyridoxine hydrochloride – vitamin B_6.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredients (doxylamine succinate or pyridoxine hydrochloride), to other ethanolamine derivative antihistamines or to any of the other ingredients in this medicine (for a list of the inactive ingredients, see section 6 'Additional information').
- you take monoamine oxidase inhibitors (MAOIs). Ask your doctor or pharmacist if you are not sure if you take MAOIs, including isocarboxazid, phenelzine, selegiline and tranylcypromine.
- you are breastfeeding (see additional information under 'Pregnancy and breastfeeding').

Special warnings about using this medicine

Before using Bonjesta, tell your doctor if:
- you have increased intraocular pressure or narrow angle glaucoma
- you have a stomach problem called stenosing peptic ulcer or pyloroduodenal obstruction
- you have a bladder problem called urinary bladder-neck obstruction

Children and adolescents
It is not known if Bonjesta is safe and effective in children and adolescents under 18 years of age.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- central nervous system depressants such as cough and cold medicines, certain pain medicines and medicines for sleep. Concomitant use of Bonjesta may cause severe drowsiness or make drowsiness worse, causing falls or accidents.
- Do not use monoamine oxidase inhibitors (MAOIs) while taking Bonjesta (see under 'Do not use this medicine if').

Using this medicine and food
Take Bonjesta on an empty stomach with a glass of water.

Using this medicine and alcohol consumption
Do not drink alcoholic beverages while using the medicine.

Pregnancy and breastfeeding
Bonjesta is intended for use in pregnant women.
Do not breastfeed while using Bonjesta. If you are breastfeeding or plan to breastfeed, you should consult your doctor or pharmacist before using Bonjesta, as Bonjesta can pass into your breast milk and harm your baby.

Driving and using machines
Bonjesta may cause drowsiness. Do not drive, operate heavy machinery, or do other activities that need your full attention unless approved by your doctor.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually:
- On Day 1: Take one tablet by mouth at bedtime.
- On Day 2: If your nausea and vomiting is better on Day 2, continue to take 1 tablet each day at bedtime. If you still have nausea and vomiting on Day 2, start taking 1 tablet in the morning and 1 tablet at bedtime each day.

Do not take more than 2 tablets (1 tablet in the morning and 1 tablet at bedtime) each day.

Do not exceed the recommended dose.

Form of administration
Swallow the tablet whole on an empty stomach with a glass of water.
Do not crush, chew or split the tablets. If you cannot swallow the tablets whole, contact your doctor.

If you have accidentally taken a higher dose (overdose) or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
If you have taken an overdose, the following symptoms may appear: restlessness, dry mouth, the pupils of your eyes become larger (dilated pupils), sleepiness, dizziness, confusion, fast heart rate, seizures, muscle pain or weakness, urination changes and build-up of fluid in the body.
If you experience these symptoms and they are severe, they may lead to death.
Stop taking Bonjesta and go immediately to the closest hospital emergency room.

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>
As with any medicine, using Bonjesta may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

The following side effects have been reported:
- Drowsiness is a common side effect of Bonjesta, which can be severe (see section 2 'Driving and using machines' and under 'Interactions with other medicines').
- Falls or other accidents resulting from the combined use of Bonjesta with central nervous system depressants, including alcohol (see Section 2 under 'Interactions with other medicines' and 'Using this medicine and alcohol consumption').

Additional side effects
Side effects of unknown frequency (the frequency of these effects has not been established yet):

shortness of breath, heart palpitations, tachycardia (rapid heart rate), feeling dizzy (vertigo), blurred vision, visual disturbances, abdominal distension, abdominal pain, constipation, diarrhea, chest discomfort, fatigue, irritability, malaise, hypersensitivity (immune system response), dizziness, headache, migraines, paresthesia, psychomotor hyperactivity, anxiety, disorientation, insomnia, nightmares, painful urination, urinary retention, excessive sweating, itching, rash, maculopapular rash.

Bonjesta may cause false positive urine drug screening test for methadone, opiates and phencyclidine phosphate (PCP).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link:
https://sideeffects.health.gov.il
Additionally, side effects may also be reported by sending an e-mail to:
safety@tzamal-medical.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 30˚C. Keep the bottle tightly closed to protect from moisture. Do not remove the desiccant from the bottle.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:
Tablet core:
Microcrystalline cellulose PH 102, magnesium trisilicate, magnesium stearate, croscarmellose sodium, colloidal silicon dioxide.
Tablet coating:
Opadry clear 02O0190000, Acryl-Eze clear, Opadry II pink, triethyl citrate, carnauba wax powder, simethicone emulsion 30%, Opacode S-1-14022 pink.

What the medicine looks like and contents of the pack:
A round, pink, film-coated, extended-release tablet, imprinted on one side with the pink image of a pregnant woman and imprinted with the letter "D" on the other side.
The package contains a bottle with 50, 60 or 100 extended-release tablets or a blister of 50 tablets.
The bottle is child resistant and contains a desiccant.
Not all pack sizes may be marketed.

Registration holder's name and address: Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petah Tikva.

Manufacturer's name and address:

Duchesnay Inc. 950 boul. Michèle-Bohec, Blainville, Québec Canada J7C 5E2

Registration number of the medicine in the Ministry of Health's National Drug Registry:
167-52-36428-00

Revised in February 2024

BON_PIL_TZ_02.2024