PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Bonjesta, extended-release tablets

Active ingredients and their quantities:
Each extended-release tablet contains:
Doxylamine succinate 20 mg
Pyridoxine hydrochloride 20 mg

For the list of inactive ingredients, please see section 6.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

It is not known whether Bonjesta is safe and effective for women with severe nausea and vomiting during pregnancy, a condition called hyperemesis gravidarum. Women suffering from this condition may be hospitalized.

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

1. What is the medicine intended for?

Bonjesta is intended for the treatment of nausea and vomiting during pregnancy in women who do not respond to conservative management.

Therapeutic class:
Doxylamine succinate – antihistamine
Pyridoxine hydrochloride – vitamin B_6

2. Before using the 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 one of the other ingredients of the medicine, listed in section 6.
- You are taking monoamine oxidase inhibitors (MAOIs). Ask your doctor or pharmacist if you are not sure whether you are taking monoamine oxidase inhibitors, including isocarboxazid, phenelzine, selegiline, tranylcypromine.

Special warnings regarding the use of the medicine
Before treatment with Bonjesta, tell the doctor if:

- You have asthma
- You have increased intraocular pressure or narrow-angle glaucoma
- You have a peptic ulcer causing constriction, or an obstruction in the passage leading from the stomach to the duodenum
- You have an obstruction of the bladder neck
- You are breastfeeding or are planning to breastfeed

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines, vitamins, herbal remedies and dietary supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Medicines that depress the central nervous system, such as cough and cold medicines, certain analgesics or hypnotic medicines – concomitant use with Bonjesta may cause severe drowsiness or worsening of drowsiness, and thus cause falls or accidents.
- Do not use monoamine oxidase inhibitors (MAOIs) (see the section "Do not use this medicine if").

Use of the medicine and alcohol consumption:
Do not drink alcoholic beverages while using this medicine.

Pregnancy and breastfeeding:
Bonjesta is intended for use in pregnant women.

If you are breastfeeding or are planning to breastfeed, consult your doctor or pharmacist before using Bonjesta, as Bonjesta may pass into breast milk and harm your baby. Do not breastfeed while using Bonjesta.

Driving and operating machinery:
Bonjesta may cause drowsiness. Do not drive, operate heavy machinery, or engage in activities that require full attention, unless your doctor has approved it.

3. How should you use the medicine?
Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage is:
- On the first day: one tablet before bedtime.
- On the second day: if there is an improvement in the nausea and vomiting on the second day, continue taking one tablet each evening before bedtime. If on the second day you still suffer from nausea and vomiting, take one tablet in the morning and one tablet before bedtime.

Do not take more than 2 tablets per day (one tablet in the morning and one tablet before bedtime).

Do not exceed the recommended dose.

The tablet should be swallowed whole, on an empty stomach with a glass of water.

Do not crush, chew or halve the tablets. If you cannot swallow the tablets whole, refer to your doctor.

If you accidentally took a higher dosage or if a child accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

The following symptoms may occur: restlessness, dry mouth, dilated pupils, somnolence, dizziness, confusion, fast heartbeats, convulsions, muscle pain or weakness, changes in urination and accumulation of fluids 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 emergency room of the nearest hospital.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:
As with any medicine, using Bonjesta may cause side effects in some users. Do not be alarmed when reading the 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, but it can also be severe (see in section 2 "Driving and operating machinery" and in the section "Drug interactions").
- Falls or other accidents resulting from the concomitant use of Bonjesta with medicines that depress the central nervous system, including alcohol (see in section 2 "Drug interactions" and in the section "Use of the medicine and alcohol consumption").

Additional side effects:
Shortness of breath, palpitations (tachycardia), sensation of dizziness (vertigo), blurred vision, visual disturbances, a feeling of bloating in the abdomen, abdominal pain,

constipation, diarrhea, chest discomfort, fatigue, nervousness, feeling generally unwell, hypersensitivity of the immune system, dizziness, headache, migraines, sensation of numbness, psychomotor hyperactivity, anxiety, disorientation, insomnia, nightmares, pain when urinating, urinary retention, excessive sweating, itching, rash, maculopapular rash.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

Side effects may also be reported by sending an email to: safety@tzamal-medical.co.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 30°C.
- Do not discard medicines via waste water or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information:

In addition to the active ingredients the medicine also contains:

Tablet core:
Microcrystalline cellulose PH102, magnesium trisilicate, magnesium stearate, croscarmellose sodium, colloidal silicon dioxide

Tablet coating:
Opadry clear O2O0190000, acryl-eze clear, opadry II pink, triethyl citrate, carnauba wax powder, simethicone emulsion 30%, opacode S-1-14022 pink

What does the medicine look like and what are the contents of the package:

Available in packages of 100, 50 or 60 tablets.
A pink biconvex tablet, with one side imprinted with a pink image of a pregnant woman, and the other side imprinted with the letter "D".
Not all package sizes may be marketed.

Marketing authorization holder and address: Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petach Tikva.

Manufacturer and address: Duchesnay Inc., Blainville, Quebec, Canada.

Registration number of the medicine in the national drug registry of the Ministry of Health: 167-52-36428-00

This leaflet was approved by the Ministry of Health in June 2021.

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