

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

This medicine can be sold with a doctor's prescription only

Diclectin[®], delayed release tablets

Active ingredients and their quantities:

Each delayed release tablet contains:

Doxylamine succinate 10 mg

Pyridoxine hydrochloride 10 mg

For list of excipients, please see section 6.

Read this entire leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

It is not known if Diclectin[®] 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.

It is not known if Diclectin[®] is safe and effective in children under 18 years of age.

1. What is the medicine used for?

- To treat nausea and vomiting of pregnancy in women who have not improved with change in diet or other non-medicine treatments

Therapeutic group:

Doxylamine succinate – an antihistamine

Pyridoxine hydrochloride - vitamin B₆

2. Before you take the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients (doxylamine succinate or pyridoxine hydrochloride), other ethanolamine derivative antihistamines or to any of the other ingredients in this medicine.
- You are taking monoamine oxidase inhibitors (MAOIs). Ask your doctor or pharmacist if you are not sure if you take an MAOI, including Marplan, Nardil, Emsam, Eldepryl, Zelapar, and Parnate.

Special warnings regarding the use of this medicine:

- Consult the doctor if you suffer from any of the following conditions: risk of asthma attack, increased intraocular pressure, narrow angle glaucoma, peptic ulcer causing stenosis of the bowel, pyloroduodenal obstruction, bladder-neck obstruction.

If you are taking or have recently taken any other medicines, including non-prescription drugs, vitamins, herbal remedies and nutritional supplements, tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking:

- During treatment with Diclectin[®], do not consume alcohol or use other central nervous system depressants such as drugs for cough or colds, certain pain medicines or medicines that help you sleep - use in combination with Diclectin[®] may cause severe drowsiness or worsening of drowsiness causing falls or accidents.
- Do not use monoamine oxidase inhibitors (MAOIs) (see section "Do not use the medicine if").

Use of this medicine and food:

Take the medicine on an empty stomach.

Use of this medicine and alcohol consumption:

Do not drink alcoholic beverages while using the medicine.

Pregnancy and breastfeeding:

Diclectin[®] is for use in pregnant women.

If you are breastfeeding consult your doctor or pharmacist before using Diclectin[®].

Diclectin[®] can pass into your breast milk and may harm your baby. You should not breastfeed while using Diclectin[®].

Driving and use of machinery:

Diclectin[®] may cause drowsiness. Do not drive, operate heavy machinery, or engage in any other activities that need your full attention unless your doctor says that you may do so.

3. How to use this medicine

- Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and administration will be determined by the doctor only. Usual recommended dosage:

- On the first day: take 2 tablets at bedtime.
- On the second day: take 2 tablets at bedtime. If your nausea and vomiting are better on the second day, continue to take 2 tablets every night at bedtime. This will be your usual dose unless your doctor tells you otherwise.
- On the third day: if you still had nausea and vomiting on the second day, take 3 tablets on the third day (one tablet in the morning and 2 tablets at bedtime).
- On the fourth day: if your nausea and vomiting were better on the third day, continue to take 3 tablets each day (one tablet in the morning and 2 tablets at bedtime). If you still had nausea and vomiting on the third day, start taking 4 tablets each day (one tablet in the morning, one tablet in the afternoon, and 2 tablets at bedtime).

Do not take more than 4 tablets (one tablet in the morning, one tablet in the afternoon, and 2 tablets at bedtime) in 1 day.

Do not exceed the recommended dose.

- Swallow the medicine on an empty stomach with a glass of water.
- Swallow the tablets whole. Do not crush, chew, or divide the tablets. If you cannot swallow the

tablets whole, refer to your doctor.

If you have accidentally taken a higher dosage, the following symptoms may appear: restlessness, dryness of mouth, dilated pupils, sleepiness, dizziness, confusion, rapid heartbeat, seizures, muscle pain or weakness and sudden and severe kidney problems. If you have these symptoms and they are severe, they may lead to death. Stop taking Diclectin® and call your doctor or go to the nearest hospital emergency room right away.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the specified time, take the forgotten dose as soon as possible. However, if it is almost time for the next dose, skip the forgotten dose and continue with the regular dosing schedule. Do not take a double dose in order to make up for a forgotten dose.

Continue with the treatment as recommended by your doctor.

Even if there is an improvement in your health, do not stop taking this medicine on your own without consulting your doctor.

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

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

4. Side effects:

Like all medicines, Diclectin® can cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop use of this medicine and refer to your doctor immediately if:

- You suffer from disorientation, tachycardia (rapid pulse) or palpitation, seizures.

Refer to your doctor immediately if:

- You suffer from an allergic reaction (including skin rash, hives, swelling, trouble breathing).
- You suffer from difficulty urinating.

Additional side effects:

Diclectin® may cause drowsiness (a common side effect, but it can also be severe), shortness of breath, dizziness, vertigo, blurred vision, visual disturbances, abdominal distension, stomach pain, constipation, diarrhea, chest discomfort, fatigue, irritability, malaise, headache, migraines, tingling sensation, psychomotor hyperactivity, anxiety, insomnia, nightmares, urinary retention, excessive sweating, itching. Diclectin® may cause false positive urine drug screening test for methadone, opiates and PCP. (See additionally sections "If you are taking or have recently taken any other medicines" and "Driving and use of machinery").

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Ministry of Health’s website (www.health.gov.il) which links to an online form for reporting side effects, or via the following link:

<https://sideeffects.health.gov.il>

5. How to store the medicine

- **Avoid poisoning!** This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store below 30°C. Keep bottle tightly closed to protect from moisture. Do not remove the desiccant canister from bottle. Protect from light.
- Once the bottle has been first opened, it should be used until expiration date.
- Medicines should not be disposed of via household waste or wastewater. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Tablet core:

microcrystalline cellulose 102, magnesium trisilicate, magnesium stearate, croscarmellose sodium, colloidal silicon dioxide

Tablet coat:

acryl-eze clear, opadry white YS-1-7003, opadry clear YS-1-7472, triethyl citrate, carnauba wax powder, simethicone emulsion 30%, opacode S-1-14022 pink DC

What does the medicine look like and what does the package contain:

Each pack contains 100 delayed release tablets.

Each delayed release tablet is imprinted with a pink image of a pregnant woman.

Registration holder: Tzamal Bio-Pharma, 20 Hamagshimim St., Petah Tikva.

Manufacturer: Duchesnay Inc., Blainville, Quebec, Canada

Drug registration number at the national medicines registry of the Ministry of Health: 153 11 34066

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