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

This medicine is dispensed with a doctor's prescription only

DICLECTIN®

Delayed-release tablets

Active ingredients and quantities
Each delayed-release tablet contains:
doxylamine succinate 10 mg
pyridoxine hydrochloride 10 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 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.

1. What is this medicine intended for?

For the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

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 (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

Consult your doctor if you have any of the following conditions:

- increased intraocular pressure or narrow angle glaucoma
- stenosing peptic ulcer or pyloroduodenal obstruction
- a bladder problem called urinary bladder-neck obstruction

Children and adolescents

It is not known if Diclectin 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 Diclectin may cause severe drowsiness or make drowsiness worse, causing falls or accidents.
- Do not use monoamine oxidase inhibitors (MAOIs) (see section 'Do not use this medicine if').

Using this medicine and food
Take this medicine on an empty stomach.

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

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

Driving and using machines
Diclectin 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 two tablets at bedtime.
- On Day 2: Take 2 tablets at bedtime. If your nausea and vomiting are better on Day 2, continue to take 2 tablets each day at bedtime. This will be your usual dose, unless your doctor decides otherwise.
- On Day 3: If you still had nausea and vomiting on Day 2, take 3 tablets on Day 3 (1 tablet in the morning and 2 tablets at bedtime).
- On Day 4: If your nausea and vomiting improved on Day 3, continue to take 3 tablets each day (1 tablet in the morning and 2 tablets at bedtime). If you still had nausea and vomiting on Day 3, start taking 4 tablets each day (1 tablet in the morning, 1 tablet in the afternoon, and 2 tablets at bedtime).

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

Do not exceed the recommended dose.

Form of administration

- Swallow the medicine on an empty stomach with a glass of water.

- Swallow the tablets whole. 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 the following symptoms may appear: restlessness, dry mouth, the pupils of your eyes become larger (dilated), sleepiness, dizziness, confusion, heart palpitations, seizures, muscle pain or weakness, and severe and sudden kidney problems. If you have these symptoms and they are severe, they may lead to death. Stop taking Diclectin and inform your doctor or go immediately to the nearest hospital emergency room.
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 forget to take this medicine at the required time, take the forgotten dose as soon as possible. However, if it is almost time to take the next dose, skip the forgotten dose and continue with the regular medication schedule. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine on your own without consulting your doctor.
Your doctor will instruct you how to gradually reduce your dose in order to prevent the symptoms from returning.

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 Diclectin 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 Diclectin, which can be severe (see section 2 'Driving and using machines' and 'Interactions with other medicines').
- Falls or other accidents resulting from the combined use of Diclectin 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.

Diclectin may cause a 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. Close the bottle tightly to protect from moisture. Do not remove the desiccant from the bottle. Protect against light.
- 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 102, magnesium trisilicate, magnesium stearate, croscarmellose sodium, colloidal silicon dioxide.
Tablet coating:
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 the medicine looks like and contents of the pack:
A round, white, biconvex delayed-release tablet, imprinted on one side with a pink image of a pregnant woman.
The package contains a bottle with 100 delayed-release tablets.
The bottle is child resistant and contains a desiccant.

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

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Registration number of the medicine in the Ministry of Health's National Drug Registry:
153-11-34066

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