

PART III: CONSUMER INFORMATION

P^rDICLECTIN[®]

doxylamine succinate and pyridoxine hydrochloride delayed release tablets (10 mg/10mg)

This leaflet is part III of a three-part "Product Monograph" published when Diclectin[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Diclectin[®]. It does not take the place of talking to your doctor, pharmacist or healthcare professional. Contact your doctor, pharmacist or healthcare professional if you have any questions about the drug. Keep this leaflet with the medicine. You may need to read it again. As Diclectin[®] is a prescription medicine, it should only be used under medical supervision.

ABOUT THIS MEDICATION

What the medication is used for:

The management of nausea and vomiting of pregnancy. Diclectin[®] can be used during any trimester of pregnancy.

What it does:

Diclectin[®] provides the anti-nauseant and anti-vomiting action of two different ingredients: doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B₆).

When it should not be used:

You should not be given Diclectin[®] if you:

- are allergic to Diclectin[®] or to any of the nonmedicinal ingredients;
- have any of the following conditions: risk of asthmatic attack, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, bladder-neck obstruction;
- are receiving a monoamine oxidase inhibitor (MAOIs) [e.g., certain antidepressants, linezolid (an antibiotic), methylene blue (a diagnostic dye)].

What the medicinal ingredients are:

The medicinal ingredients of Diclectin[®] are doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B₆).

What the nonmedicinal ingredients are:

Nonmedicinal ingredients are as follows: ammonium hydroxide, n-butanol, carnauba wax powder, colloidal silicon dioxide, croscarmellose sodium, D&C Red#27, denatured alcohol, FD&C Blue#2, hypromellose, isopropyl alcohol, magnesium stearate, magnesium trisilicate, methacrylic acid copolymer, microcrystalline cellulose 102, PEG 400, PEG 8000, polysorbate 80, propylene

glycol, shellac glaze, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate.

What dosage forms it comes in:

Diclectin[®] is supplied in the form of a delayed release tablet, 10 mg doxylamine succinate + 10 mg pyridoxine hydrochloride. Each tablet is imprinted with a pink image



of a pregnant woman

WARNINGS AND PRECAUTIONS

Diclectin[®] may cause somnolence. Caution must be exercised in activities requiring mental alertness such as driving a car or operating heavy machinery. Until you know how you will react to this medication, do not drive or operate machinery.

Diclectin[®] may pass into breast milk and unusual excitement, irritability or sedation (sleepiness) may occur in the infant. Nursing mothers treated with Diclectin[®] should not breastfeed or the use of Diclectin[®] during lactation should be avoided.

INTERACTIONS WITH THIS MEDICATION

Deeper somnolence could be produced if Diclectin[®] is taken in combination with alcohol or other drugs such as drugs for cough or colds, pain killers or sleep aids.

You should tell your doctor if you are taking or have recently taken any medications (prescription or non-prescription) or natural/herbal products, especially:

- a monoamine oxidase inhibitor (MAOIs) [e.g., linezolid (an antibiotic), methylene blue (a diagnostic dye)]
- antimuscarinic drugs (used in treating a variety of conditions such as disorders of the bowel, bladder or respiratory systems, Parkinson's disease, certain heart conditions and insomnia).
- alcohol and other central nervous system depressants, such as drugs for anxiety, seizures, mental illness, and allergies, sleeping pills, anesthetics (used for surgery), certain pain medications.

PROPER USE OF THIS MEDICATION

Diclectin® is a delayed-release formulation that works best when taken 4 to 6 hours before needed and should be taken on a daily basis. If taken with food, it may take longer to feel a relief of symptoms.

Usual dose:

Diclectin® should be taken as prescribed by your doctor or healthcare professional.

1. Take two Diclectin® tablets at bedtime to control nausea and vomiting occurring in the morning.
2. Take 1 tablet in the morning and,
3. Take 1 tablet mid-afternoon to control your symptoms throughout the day.

Your doctor or healthcare professional may adjust the dosing schedule according to your condition.

Do not stop taking Diclectin® on your own. Always consult your doctor or healthcare professional. They will gradually reduce your dose when stopping Diclectin® treatment to prevent a sudden return of nausea and vomiting.

This drug is specifically prescribed for you and your actual state of health. Do not give it to others, even if they have the same symptoms, and you yourself must not use it for any other condition than the one for which it was prescribed.

Tablets should not be crushed or split.

Missed Dose:

If you forget to take a dose of Diclectin®, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosing schedule. Do not try to make up for a missed dose by taking a double dose.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you suspect an accidental overdose, seek medical attention immediately. Do not wait for any signs or symptoms to appear before seeking medical attention, as they may not occur immediately.

Signs and symptoms of overdosage are restlessness, dryness of mouth, dilated pupils, sleepiness, dizziness, mental confusion and rapid heartbeat.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, Diclectin® can cause some side effects. You may not experience any of them. For most patients, these side effects are likely to be minor and temporary. However, some may be serious. Some of these side effects may be dose-related. Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted.

If you experience an allergic reaction (including skin rash, hives, swelling, trouble breathing) or any severe or unusual side effects, seek immediate emergency medical assistance.

Side effects associated with Diclectin® are: somnolence, dizziness, nervousness, stomach pain, headache, diarrhea, irritability, or insomnia.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	None			
Very rare	Disorientation			✓
	Difficulty urinating		✓	
	Irregular heartbeat			✓
	Seizures			✓

This is not a complete list of side effects. For any unexpected effects while taking Diclectin® contact your doctor, pharmacist or healthcare professional.

HOW TO STORE IT

Store at room temperature (15-30°C).

Protect from light.

Keep out of sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

You may need to read this package insert again. Please do not throw it away until you have finished your medicine.

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Duchesnay Inc., at:
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