

PART III: CONSUMER INFORMATION

^{Pr}PINDOLOL – 5
^{Pr}PINDOLOL – 10
(pindolol)

This leaflet is part III of a three-part “Product Monograph” published when PINDOLOL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PINDOLOL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

PINDOLOL belongs to the group of medicines known as beta-adrenergic blocking agents (beta-blockers). It is used to treat high blood pressure, also called hypertension. It is also used to prevent a type of chest pain called Angina Pectoris.

What it does:

PINDOLOL works by reducing your hearts workload in order to prevent chest pain and heart attacks.

With its ability to dilate blood vessels it is used to treat high blood pressure.

When it should not be used:

Do not take PINDOLOL if you:

- **are allergic** to pindolol or any other beta blockers or any of the inactive ingredients of PINDOLOL listed under “What the nonmedicinal ingredients are”.
- **suffer from**, or have suffered in the past from, bronchial asthma, or other lung diseases or trouble in breathing,
- **suffer from** a severe heart disease,
- **have** had an alteration in the structure and function of the right ventricle of the heart caused by a primary disorder of respiratory system (called Cor pulmonale),
- **suffer from** chest pain, mainly occurring at rest,
- **suffer from** irregular or unusually slow heartbeat (less than 45 to 50 beats per minute),
- **have** had sudden loss of consciousness in the past,
- **suffer from** severe blood flow disturbances of your blood vessels causing paleness or poor circulation in the arms and legs (cold hands or feet)
- **suffer from** pheochromocytoma (a type of tumor of the adrenal glands).

What the medicinal ingredient is:

Pindolol

What the nonmedicinal ingredients are:

The nonmedicinal ingredients are cellulose microcrystalline, pregelatinized starch, magnesium stearate, silica colloidal anhydrous.

WARNING AND PRECAUTIONS

BEFORE you use PINDOLOL talk to your doctor or pharmacist if:

1. If you suffer from any of the following:
 - diabetes mellitus (sugar diabetes), and you are taking insulin or diabetes medicine by mouth,
 - severe kidney disease,
 - liver disease,
 - milder forms of circulatory disturbances of blood vessels (symptoms such as paleness, cold hands or feet),
 - overactive thyroid,
 - chronic bronchitis and emphysema,
 - psoriasis (a type of skin disease characterized by thickened patches of red/silver skin)
2. you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
3. you are pregnant, or plan to become pregnant.
4. you are breastfeeding (the active ingredient may pass into your milk and harm your baby).
1. you are having any kind of surgery or dental treatment.
2. you are experiencing eye problems (symptoms like dry, gritty or burning eyes).

If any of these apply to you, **tell your doctor before taking PINDOLOL**. The doctor will take these things into account before and during your treatment with PINDOLOL and your doctor may need to monitor you more closely while you are using this medicine.

Driving and using machines

In some people, PINDOLOL may cause dizziness or tiredness. If this happens to you, do not drive, use machinery, or perform other tasks that need full attention.

INTERACTIONS WITH THIS MEDICATION

Other medicines and PINDOLOL may interfere with each other.

These medicines include:

- medicines used to treat high blood pressure, chest pain (angina pectoris), disturbances of heart rhythm,
- digoxin and digitalis glycosides, a heart medicine,
- medicines containing adrenaline or similar substances, such as nose and eye drops, cough medicines, or remedies for the common cold (substances that raise blood pressure),
- insulin or Antidiabetic medications taken by mouth,

IMPORTANT: PLEASE READ

- medicines used to relieve pain or inflammation (especially non-steroidal anti-inflammatory drugs),
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches,
- monoamine oxidase inhibitors (antidepressant drugs),
- medicine used to relieve heartburns and gastrointestinal ulcer (called as cimetidine),
- medicines used to treat anxiety and/or panic disorder, schizophrenia or psychosis

PROPER USE OF THIS MEDICATION

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

How much PINDOLOL to take

The dose of this medicine will be different for different patients. Also, the number of doses you take each day and the time allowed between doses depend on the medical problem for which you are taking PINDOLOL.

Treatment is usually started with the lowest dose. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

In general the average daily dosage for the tablets is in the following ranges:

Usual adult dose:

- High blood pressure
5 to 15 mg once daily in the morning.
Doses of 20 mg should be taken in 2 divided doses in the morning and the evening.
- Angina pectoris (chest pain) and Increased heart rate (tachycardia)
10 to 30 mg daily in 3 or 4 divided doses.
- Hyperkinetic heart syndrome
10 to 20 mg daily

Take PINDOLOL at the same time each day. Swallow the table(s) with a little liquid with food. Do not stop taking this drug without your doctor's advice.

This drug is not recommended for children under 18 years of age.

Patients at the age of 65 or over may experience more side effects than young patients. Close monitoring by your doctor may be required.

If you have questions about how long to take PINDOLOL, talk to your doctor or your pharmacist.

Overdose:

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

If you accidentally take a lot more PINDOLOL tablets than your doctor has prescribed, contact or go to the nearest hospital emergency department or your doctor immediately, or make sure that someone else can contact them for you.

Signs and symptoms caused by taking more of PINDOLOL can be:

Abnormally low heartbeat, low blood pressure, low blood sugar; insufficient action of the heart to pump blood which may lead to loss of consciousness; irregular heart beat; heart failure; difficulty breathing with wheezing or coughing; shortness of breath; vomiting; convulsions (seizures); heart attack.

Missed Dose:

If you forget to take a dose of PINDOLOL, take the missed dose as you notice it. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosage schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients taking PINDOLOL may experience side effects. Keep track of your side effects and consult the table below for appropriate action.

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 seek immediate medical attention	
		Only if severe		In all cases
Unknown frequency:	Allergic Reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Slow heartbeat, heart rhythm disturbance, heart failure or sudden and oppressive chest pain			✓
	Coldness, burning, tingling or numbness in arms or legs		✓	
	Difficulty breathing with wheezing or coughing		✓	
	Hallucination (seeing or hearing things that are not there)		✓	
	Low blood pressure, shortness of breath, tiredness, dizziness, headache, trembling, nausea, vomiting, abdominal pain, diarrhea, muscle cramp, sleep disturbance, skin reaction, excessive sweating, aggravation of psoriasis (thick patches of red/silver skin)	✓		

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

HOW TO STORE IT

- Do not use after expiry date shown on the box.
- Store in the original package, protect from light.
- Keep out of the reach and sight 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, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator: 0701E
Ottawa, Ontario
K1A 0K9

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

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

INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by Pro Doc Ltée, Laval, Québec, H7L 3W9

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