

## PART III: CONSUMER INFORMATION

Pr**VISKEN®**  
(pindolol)

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

### ABOUT THIS MEDICATION

#### What the medication is used for:

VISKEN® 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:

VISKEN® 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 VISKEN® if you:**

- **are allergic** to pindolol or any other beta blockers or any of the inactive ingredients of VISKEN® 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.

#### What dosage forms it comes in:

Tablets; 5, 10 and 15 mg.

### WARNINGS AND PRECAUTIONS

#### **BEFORE you use VISKEN® 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).
5. you are having any kind of surgery or dental treatment.
6. you are experiencing eye problems (symptoms like dry, gritty or burning eyes).

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

#### **Driving and using machines**

In some people, VISKEN® 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 VISKEN® 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 medicines taken by mouth,

- 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,
- Fingolimod, a medicine used to treat multiple sclerosis.

## PROPER USE OF THIS MEDICATION

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

### How much VISKEN® 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 VISKEN®.

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 VISKEN® 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 VISKEN®, 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 VISKEN® 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 VISKEN® 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 VISKEN®, 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 VISKEN® 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:	<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	<b>Slow heart beat, heart rhythm disturbance, heart failure or sudden and oppressive chest pain</b>			√
	<b>Coldness, burning, tingling or numbness in arms or legs</b>		√	
	<b>Difficulty breathing with wheezing or coughing</b>		√	

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical attention
		Only if severe	In all cases	
	<b>Hallucination (seeing or hearing things that are not there)</b>		√	
	<b>Low blood pressure, shortness of breath, tiredness, dizziness, headache, trembling, nausea, vomiting, abdominal pain, diarrhea, muscle cramp, sleep disturbance, depression, skin reaction, excessive sweating, aggravation of psoriasis (thick patches of red/silver skin)</b>	√		

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

**HOW TO STORE IT**

- Do not use after the 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](http://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](http://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.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.tributepharma.ca>

or by contacting the sponsor, Tribute Pharmaceuticals Canada Inc., at: 1-866-391-4503 (toll-free)

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