

PART III: CONSUMER INFORMATION

Pr **VISKEN®** pindolol tablets

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® lowers high blood pressure (hypertension). VISKEN® can be used alone or with other medicines to treat this condition.

VISKEN® is also used to treat chest pains (angina) due to ischemic heart disease (disease caused by plaque building up along the inner walls of the arteries of the heart, which narrows the arteries and reduces blood flow to the heart).

What it does:

VISKEN® belongs to a class of drugs called "beta-blockers". These drugs block the action of certain chemicals on the heart that increase blood pressure and increase heart rate.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking VISKEN® regularly even if you feel fine.

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 non-medicinal ingredients of VISKEN® listed under "What the nonmedicinal ingredients are"
- have or have had asthma or other lung diseases (such as Chronic obstructive pulmonary disease known as COPD)
- have heart failure
- have high blood pressure that affects the arteries in your lungs and the right side of your heart
- have reduced blood flow to the heart causing heaviness, tightness or pain in your chest
- have a slow heartbeat (less than 45 to 50 beats per minute)
- have had a condition where your heart suddenly could not pump enough blood causing:
 - rapid heartbeat
 - shortness of breath
 - sweating
 - loss of consciousness
- will have surgery where you will need general anesthesia

- have certain types of abnormal heart beat caused when the heart's natural pacemaker doesn't work properly
- have narrowed arteries that reduce the blood flow to your limbs. This can cause paleness or poor circulation in the arms and legs (cold hands and feet)
- have a tumor of the adrenal gland known as pheochromocytoma.

What the medicinal ingredient is:

Pindolol

What the nonmedicinal ingredients are:

Cellulose microcrystalline, pregelatinized starch, magnesium stearate, silica colloidal anhydrous.

What dosage forms it comes in:

Tablets; 5 and 10 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use VISKEN® talk to your doctor or pharmacist if you:

- have history of heart failure
- have any of the following:
 - diabetes, and are taking insulin or oral diabetes medicine
 - severe kidney disease
 - liver disease
 - a condition causing overactivity of the thyroid gland
 - psoriasis (a type of skin disease characterized by thickened patches of red/silver skin)
- have had a severe allergic reaction in the past
- are taking medications to treat high blood pressure
- have asthma, chronic bronchitis, and emphysema, or an inflammation in the nose due to allergies
- are undergoing surgery or dental treatment
- are pregnant, or plan to become pregnant
- are breastfeeding (VISKEN® may pass into your milk and harm your baby)
- are less than 18 years old
- are currently taking or have recently taken any other prescription or over-the-counter medications.

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®. Your doctor may need to monitor you more closely while you are using this medicine.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to VISKEN®. Dizziness, and/or fatigue can especially occur after the first dose and when the dose is increased.

Slow heart beat

You may experience a slow heart beat while taking VISKEN®. If this happens, contact your doctor. Your dose may need to be reduced.

Laboratory Tests

Your doctor may perform tests at regular intervals if you are taking VISKEN® for a long time.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including prescription and over-the-counter medicines.

The following medicines may interact with VISKEN®:

- medicines used to treat the irregular rhythm of the heart such as digoxin and digitalis
- medicines found in some cold remedies and nose drops (e.g. noradrenaline, isoprenaline, ephedrine, phenylephrine, phenylpropanolamine, xanthine derivative)
- medicines used to treat high blood pressure, including clonidine and calcium channel blockers (e.g. oral verapamil, diltizem). Your doctor should carefully monitor you if you are taking these in combination with VISKEN®.
- insulin or oral antidiabetic medicines
- nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling (such as ibuprofen, naproxen, celecoxib)
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches
- cimetidine, used to relieve heartburn and gastrointestinal ulcers
- medicines used to treat depression, seizures, schizophrenia, or psychotic disorders (e.g., tricyclic antidepressants, barbiturates, phenothiazines, monoamine oxidase inhibitors)
- fingolimod, a medicine used to treat multiple sclerosis
- medicines used for anaesthesia such as cyclopropane, trichloroethylene.

PROPER USE OF THIS MEDICATION

Your doctor will determine your dose based on your individual medical needs and will tell you when and how to take VISKEN®. Take VISKEN® exactly as prescribed. It is recommended to take your dose at about the same time every day. VISKEN® should be taken with food.

Do not stop taking VISKEN® or change your dose without first talking to your doctor. Serious side effects, such as chest pain or heart attack can occur if you abruptly stop taking this medication.

Usual adult dose:

To treat high blood pressure:

The usual starting dose is 5 mg twice a day. In some cases, your doctor may prescribe a higher dose, up to a maximum of 45 mg each day.

To treat chest pain due to heart disease:

The usual starting dose is 5 mg, three times a day. In some cases, your doctor may prescribe a higher dose if needed, up to a maximum recommended dose of 40 mg each day.

Overdose:

If you think you have taken too much VISKEN®, contact your doctor, nurse pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, skip the missed dose and carry on with the next one at the usual time. Do not double the dose.

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 | |
| Common | Nausea | √ | | |
| Uncommon | Dry eyes | | √ | |
| Unknown frequency | Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing | | | √ |
| | Slow heart beat | | | √ |
| | Heart rhythm disturbance | | | √ |
| | Heart failure | | | √ |
| | Chest Pain: sudden and oppressive | | | √ |
| | Coldness, burning, tingling or numbness in arms or legs | | √ | |

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|---|-------------------------------------|--------------|---|
| | Only if severe | In all cases | |
| Difficulty breathing with wheezing or coughing | | √ | |
| Hallucination: see or hear things that are not there | | √ | |
| Low blood pressure | √ | | |
| Shortness of breath | √ | | |
| Tiredness | √ | | |
| Dizziness | √ | | |
| Headache | √ | | |
| Trembling | √ | | |
| Nausea | √ | | |
| Vomiting | √ | | |
| Abdominal pain | √ | | |
| Diarrhea | √ | | |
| Muscle cramp | √ | | |
| Sleep | √ | | |
| Depression | √ | | |
| Skin reaction | √ | | |
| Excessive sweating | √ | | |
| Aggravation of psoriasis (thick patches of red/silver skin) | √ | | |

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. 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.aralez.com> or by contacting the sponsor, Aralez Pharmaceuticals Canada Inc., at: 1-866-391-4503 (toll-free).

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This leaflet was prepared by:
 Aralez Pharmaceuticals Canada Inc.
 Mississauga, Ontario
 L5N 0E4

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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 bottle.
- Store at 15-30°C. Protect from light.
- Keep out of the reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by: