

PART III: CONSUMER INFORMATION

Pr SOLIFENACIN solifenacin succinate tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

SOLIFENACIN is used in the treatment of overactive bladder in adults with symptoms of frequent and urgent need to urinate (urinary frequency, urinary urgency) with urine leakage (urinary incontinence).

What it does:

SOLIFENACIN is a urinary antispasmodic medication that helps to relax the smooth muscle of the bladder which leads to reduction of the symptoms caused by overactive bladder.

When it should not be used:

You should not take SOLIFENACIN:

- If you are not able to empty your bladder (also called urinary retention).
- If you have End-Stage Kidney Disease and require dialysis.
- If you are not able to empty your stomach (also called gastroparesis).
- If you have narrow-angle glaucoma (high pressure and pain in the eyes).
- If you are allergic to solifenacin succinate or any of the other ingredients in SOLIFENACIN. See 'What the non-medicinal ingredients are'

What the medicinal ingredient is:

The medicinal ingredient in SOLIFENACIN tablet is 'solifenacin succinate'.

What the nonmedicinal ingredients are:

Each SOLIFENACIN tablet contains the following inert ingredients: corn starch, hypromellose, iron oxide yellow (5 mg solifenacin tablet) or iron oxide red (10 mg solifenacin tablet), lactose monohydrate, macrogol, magnesium stearate, talc, titanium dioxide.

What dosage forms it comes in:

SOLIFENACIN is available in 5 and 10 mg tablets.

WARNINGS AND PRECAUTIONS

Before you use SOLIFENACIN, talk to your doctor or pharmacist if you:

- Have stomach problems affecting passage and digestion of food, or severe constipation.
- Have glaucoma.

- Have difficulty urinating, or weak urine stream
- Have heart disease
- Have a rare heart problem called QT/QTc prolongation or family history of QT/QTc prolongation.
- Have kidney or liver problems.
- Have reduced ability to sweat.
- Are pregnant or planning to become pregnant. Women who might get pregnant should use an effective birth control method while taking SOLIFENACIN.
- Are breast feeding or plan to breast feed.

SOLIFENACIN should not be given to children or adolescents.

SOLIFENACIN may cause blurred vision and drowsiness. Do not drive a car or operate any machinery, or engage in any activities that require accurate vision and full attention.

In hot weather, SOLIFENACIN can cause heat prostration (fever and heat stroke due to decreased sweating). Do not stay long in a hot environment while taking the drug. If you have any symptoms of heat prostration, keep yourself cool and drink a lot of water.

Angioedema (the symptoms include swelling of the face or tongue, difficulty breathing) and anaphylactic reactions (the symptoms include hives, difficulty breathing, abdominal cramps, rapid heartbeat and feeling faint), which could be life-threatening, have been reported in some patients taking solifenacin succinate. If you experience any of these symptoms, stop taking SOLIFENACIN and see your doctor immediately.

INTERACTIONS WITH THIS MEDICATION

Before and while taking SOLIFENACIN you should tell your doctor about your other medications, even if the medicine you bought without prescription including vitamins and herbal supplements.

SOLIFENACIN is known to have drug interactions with the following drugs: drug known to prolong the QT/QTc interval and/or cause torsade de pointes, drugs that decrease electrolyte levels, anticholinergic drugs, drugs that stimulate the motility of the gut such as metoclopramide, ketoconazole, clarithromycin, erythromycin, diclofenac, nefazodone, verapamil.

Drinking grapefruit juice with SOLIFENACIN may increase your blood level of solifenacin.

PROPER USE OF THIS MEDICATION

Usual dose:

5 mg daily. The daily dose may be increased to 10 mg following consultation with your doctor. Swallow the tablet whole with water.

SOLIFENACIN tablets can be taken with or without food.

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.

Missed Dose:

If a dose is missed, the next tablet should be taken as planned. Doses should not be doubled to make up for a missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following side effects have been reported in clinical trials with SOLIFENACIN:

Most common side effects: dry mouth and constipation.

Common side effects: dry eyes, urinary retention, blurred vision, nausea, abdominal pain, indigestion, urinary tract infection.

The following side effects have been reported with the use of SOLIFENACIN in worldwide post-marketing experience, although the frequency of events or a causal relationship with SOLIFENACIN could not always be confirmed :acid reflux, change in sense of taste, decreased appetite, delirium, dizziness, dry skin, fast or irregular heartbeat, feeling sleepy, glaucoma, hallucination, headache, high potassium levels, hypersensitivity reactions, intestinal blockage, itchiness, kidney ailment, liver problems, muscle weakness, nasal dryness, voice disorder, severe skin scaling and redness, itching (exfoliative dermatitis), severe skin rash, itchiness and fever (erythema multiforme), swelling in the lower limbs and vomiting.

Tell your doctor or pharmacist if you have any side effects while taking SOLIFENACIN. This includes any side effects not listed above.

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 emergency medical attention
		Only if severe	In all cases	
Rare	Abdominal pain	✓		
	Constipation for more than 3 days		✓	
	Urinary retention		✓	
Very Rare	Swelling of the face or tongue, difficulty breathing			✓
	Fast or irregular heartbeat			✓

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
Anaphylactic reactions (severe allergic reactions)			✓

HOW TO STORE IT

Keep SOLIFENACIN and all other medications out of the reach of children.

Store SOLIFENACIN between 15° to 30°C.

Do not keep medicine that is out of date or that you no longer need.

Reporting Side Effects

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

- 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) (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 by contacting Pro Doc Ltée at 1-800-361-8559, www.prodqc.ca or info@prodqc.ca.

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

Last revised: September 3, 2019