CONSUMER INFORMATION
Product Monograph Part III

VESICARE®
solifenacin succinate
5 mg and 10 mg tablets

Astellas Pharma Canada Inc.

Submission Control No. 097340

The Consumer Information Section (Part III) of the Product Monograph for VESICARE® has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on February 20, 2006, and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III CONSUMER INFORMATION

VESICARE®
Solifenacin succinate

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

ABOUT THIS MEDICATION

What the medication is used for:
The treatment of a condition called overactive bladder. VESICARE® is an urinary antispasmodic medication.

What it does:
VESICARE® helps reduce the following symptoms caused by overactive bladder:
- Having to go to the bathroom too often, also called urinary frequency.
- Having a strong need to go to the bathroom right away, also called urinary urgency.
- Leaking or wetting accidents, also called urinary incontinence.

When it should not be used:
- If you are not able to empty your bladder (also called urinary retention).
- If you are a dialysis dependent patient.
- If you are not able to empty your stomach (also called gastroparesis).
- If you have a special type of glaucoma called narrow-angle glaucoma.
- If you are allergic to VESICARE® or any of its ingredients.
- Talk to your doctor or pharmacist: if you are pregnant or may become pregnant or if you are breastfeeding.
- VESICARE® should not be given to children and adolescents.

What the medicinal ingredient is:
The medicinal ingredient in VESICARE® Tablet is 'solifenacin succinate'.

What the non-medicinal ingredients are:
Each VESICARE® tablet contains the following inert ingredients: lactose monohydrate, corn starch, hypromellose, magnesium stearate, talc, polyethylene glycol and titanium dioxide with yellow ferric oxide (5 mg VESICARE® tablet) or red ferric oxide (10 mg VESICARE® tablet)

What dosage form it comes in:
VESICARE® is available in 5 and 10 mg tablets

WARNINGS AND PRECAUTIONS

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

- You have any intestinal blockages or long term difficulty with constipation.
- You have difficulty emptying your bladder or you have a weak urine stream.
- You have narrow angle glaucoma.
- You have liver disease.
- You have kidney disease.
- You have reduced ability to sweat.
- You should consider treatment only if you are using adequate contraception if you are a woman who might get pregnant.

You should be careful about driving vehicles, operating machinery, or doing any activities that require accurate vision because VESICARE® may cause blurred vision.

Heat prostration (due to decreased sweating) can occur when anticholinergic drugs, such as VESICARE® are used in a hot environment. You are advised not to stay long in a hot environment while taking the drug. If you develop any symptoms of heat prostration, keep yourself cool and drink a lot of water.

INTERACTIONS WITH THIS MEDICATION

VESICARE® may interfere with some drugs. Before you begin treatment with VESICARE® or while taking VESICARE®, it is important to tell your doctor what other medications you are taking, even if the medicine is over the counter (including vitamins and herbal supplements).

VESICARE® is known to have drug interactions with drugs such as ketoconazole, clarithromycin, erythromycin, diclofenac, nefazodone, and verapamil.

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

PROPER USE OF THIS MEDICATION

Usual Dose:

- You should take one VESICARE® tablet once a day.
- You should take VESICARE® with liquid and swallow the tablet whole.
- You should take VESICARE® with or without food.

Overdose:

If you take more tablets than your doctor prescribed, you should immediately contact either your doctor, your hospital emergency department, or the nearest Poison Control Centre.

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

In clinical studies, the most common side effects reported with VESICARE® were dry mouth and constipation. You may also experience dry eyes, urinary retention, and blurred vision. If you experience severe abdominal pain or become constipated for 3 or more days, contact your physician. Tell your doctor if you have any side effects while taking VESICARE®.

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	
Rare	Abdominal pain	✓		
	Constipation for more than 3 days		✓	
	Urinary retention		✓	

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

HOW TO STORE IT

- Keep VESICARE® and all other medications out of the reach of children.
- Store between 15°C - 30°C.
- Do not keep medicine that is out of date or that you no longer need.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll-free telephone: 866-234-2345
Toll-free fax: 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Health Canada
Address Locator: 0201C2
Ottawa, ON K1A 1B9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

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

Or by contacting Astellas Pharma Canada Inc., at 1-888-338-1824

This leaflet was prepared by Astellas Pharma Canada Inc.

Last Revised: