SCHEDULING STATUS:
South Africa: S3
Namibia: NS2
Botswana: Schedule 2
Kenya: POM

Proprietary name, strength and pharmaceutical form:
VESICARE 5 mg film-coated tablet (5 mg solifenacin succinate)
VESICARE 10 mg film-coated tablet (10 mg solifenacin succinate)

Please read this leaflet carefully before taking VESICARE tablets.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- VESICARE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT VESICARE CONTAINS:
- The active ingredient is solifenacin succinate.
- The other ingredients are: hypromellose, lactose monohydrate, macrogol 8000, magnesium stearate, maize starch , talc, titanium dioxide, red ferric oxide (VESICARE 10 mg), yellow ferric oxide (VESICARE 5 mg).
- Contains sugar: Lactose monohydrate (VESICARE 5 mg: 107,5 mg; VESICARE 10 mg: 102,5 mg)

2. WHAT VESICARE IS USED FOR:
VESICARE is used for the treatment of the symptoms of unstable bladder (or overactive bladder), e.g. needing to rush to the toilet without warning, needing to go to the toilet very frequently, wetting yourself because you did not get to the toilet in time.

3. BEFORE YOU TAKE VESICARE
Do not take VESICARE if you:
- are hypersensitive (allergic) to solifenacin succinate or any of the other ingredients of VESICARE.
- suffer from urinary retention (urine that remains in the bladder due to a reduced ability to empty the bladder).
- suffer from glaucoma (high pressure in the eyes, with gradual loss of eyesight), which is not adequately controlled.
- suffer from myasthenia gravis (a muscle disease).
- suffer from toxic megacolon (a complication associated with ulcerative colitis, a condition that affects the intestines).
- are undergoing blood dialysis.
- suffer from severe liver disease.
- suffer from severe kidney disease or moderate liver disease and are being treated with medicines that may decrease removal of VESICARE from the body (e.g. ketoconazole). Your doctor should tell you when this is the case.
- Are pregnant or are breastfeeding your baby.

Take special care with VESICARE if you:
- suffer from obstruction of the bladder or have difficulty passing urine (a poor stream of urine). You will have a build up of urine in the bladder (urinary retention).
- have an obstruction of the digestive tract.
- have decreased movement of the digestive tract affecting the passage and digestion of food (your doctor will have told you if you have this).
- have severe kidney disease.
- have a moderate liver disease.

- are being treated with medicines that may prevent the removal of VESICARE from the body. Your doctor or pharmacist should tell you when this is the case.
- if you have a stomach tear (hiatus hernia) or heartburn.
- if you have a nervous (autonomic neuropathy).
- have angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing). Stop VESICARE immediately and contact a doctor.

Ask your doctor or pharmacist before starting VESICARE if you think any of these might apply to you.

Pregnancy and breastfeeding
VESICARE is not to be used during pregnancy. VESICARE should not be used by women who are breastfeeding their babies.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines
VESICARE can cause blurred vision and sleepiness or tiredness. Do not drive or operate machinery if you suffer from this side effect.

Important information about some of the ingredients of VESICARE
VESICARE contains lactose. If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption you should not use this medicine.

Taking and/or using other medicines
Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)
If you take any of the following medicines, check with your doctor or pharmacist first before taking VESICARE:

- Other medicines belonging to the same class as VESICARE (anticholinergic medicines) as the effect and side effects of both medicines can be enhanced. An interval of approximately one week should be allowed after stopping treatment with VESICARE before starting other anticholinergic medicines.
- Medicines belonging to a different class which has the opposite effect of VESICARE (cholinergic receptor agonists) can reduce the effect of VESICARE.
- VESICARE can reduce the effect of medicines that stimulate the movement of the digestive tract e.g. metoclopramide and cisapride.
- If you are prescribed VESICARE and are also taking medicines which decrease the removal of VESICARE from the body (e.g. ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem) your dose should be limited to 5 mg per day. If you have severe kidney disease or moderate liver disease, VESICARE should not be used in combination with these medicines.
- Medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which VESICARE is broken down by the body.
- Medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

4. HOW TO TAKE VESICARE

Do not share medicines prescribed for you with others.

Always take VESICARE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is 5 mg once daily, unless your doctor has instructed you to take 10 mg once daily.

Try and take VESICARE at the same time each day.

VESICARE is taken by mouth and must be swallowed whole with water. It can be taken with or without food.

Talk to your doctor or pharmacist if you have the impression that the effect of VESICARE is too strong or too weak.

If you take more VESICARE than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.
In the case of children taking VESICARE by accident, seek medical help immediately.
Symptoms of overdose can be headache, dry mouth, dizziness, drowsiness and blurred vision.
Symptoms of serious overdose can be hallucinations, pronounced excitation, convulsions, breathing problems (respiratory insufficiency), increased heart rate (tachycardia), urinary retention, and dilation of the pupils (mydriasis).

If you forget to take VESICARE
If you forget to take a tablet at the usual time, take it as soon as you remember, unless it is time to take the next dose. Do not take more than one dose daily. In case of doubt consult your doctor or pharmacist.
If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

Effects when treatment with VESICARE is stopped
If you stop taking VESICARE, your symptoms of overactive bladder may return or worsen. Always consult your doctor if you consider stopping treatment.

5. POSSIBLE SIDE EFFECTS
VESICARE can have side effects. Not all side effects reported for VESICARE are included in this leaflet. Should your general health worsen while taking VESICARE, please consult your doctor, pharmacist or other health care professional for advice.

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or pharmacist immediately.

Angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing) has been reported in some patients on VESICARE. If angioedema occurs, VESICARE should be discontinued immediately and appropriate therapy and/or measures should be taken.

The most commonly reported side effect with VESICARE was dry mouth. It occurred in 11 % of patients treated with 5 mg once daily and in 22 % of patients treated with 10 mg once daily. The severity of dry mouth was generally mild.

VESICARE may cause the following:
Frequent side effects:
Dry mouth, blurred vision, constipation (difficulty passing stools), nausea, indigestion, stomach pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort

Less frequent side effects:
Urinary tract infection, bladder infection, excessive sleepiness, impaired sense of taste, dry eyes, nasal dryness, gastro-oesophageal reflux diseases (including heartburn), dry throat, dry skin, difficulty in passing urine, tiredness, swelling of feet, dizziness, headache, blockage in the intestines, hard stools that are difficult to pass, vomiting, dizziness, headache, itching, rash, difficulty passing urine, hallucinations,

feeling confused, red blotches on the skin or in the mouth, intensely itching skin rash (hives), swelling of the face/neck/limbs (hives), decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm, increased pressure in the eyes , changes in the electrical activity of the heart (ECG), irregular heartbeat , feeling your heartbeat, faster heart beat, voice disorder, liver disorder, muscle weakness, renal disorder.

If any of these side effects become troublesome, or if you suffer from any other unwanted side effects while taking VESICARE, please tell your doctor or pharmacist as soon as possible.

6. STORING AND DISPOSING OF VESICARE

Store at or below 25 °C.
Keep out of the reach of children.
Do not use after the expiry date stated on the carton and blister.
Return all unused medicines to your pharmacist.
Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF VESICARE

VESICARE tablets are supplied in transparent PVC/Aluminium blisters packs of 30 tablets. There are 10 tablets in each blister strip and 3 blister strips in each pack.

8. IDENTIFICATION OF VESICARE

VESICARE 5 mg tablets are round light yellow film-coated tablets marked with the Astellas logo and "150" (debossed on one side only).
VESICARE 10 mg tablets are round light pink film-coated tablets marked with the Astellas logo and "151" (debossed on one side only).

9. REGISTRATION NUMBER / REFERENCE NUMBER

South Africa:	VESICARE 5 mg: A39/5.4/0490
	VESICARE 10 mg: A39/5.4/0491
Namibia:	VESICARE 5 mg: Reg. No. 07/5.4/0084
	VESICARE 10 mg: Reg. No. 10/5.4/0466
Kenya:	VESICARE 5 mg: H2015/CTD 2283/003
	VESICARE 10 mg: H2015/CTD 2150/004
Botswana:	VESICARE 5 mg: BOT1702937
	VESICARE 10 mg: BOT1702938

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration: 7 April 2006
Date of the most recently revised patient information leaflet as approved by Council: 2 June 2020

Reporting of suspected adverse reactions in Botswana:
e-Reporting: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=BW
email: reportadr@bomra.co.bw