Applicant/PHRC: ***Hetero Drugs South Africa (Pty) Ltd***

*Product proprietary name****: UROTENA 5 & 10***

Dosage form and strength: ***Film coated tablet, contains solifenacin succinate 5 mg & 10 mg***

APPROVED PATIENT INFORMATION LEAFLET FOR UROTENA 5 & 10

SCHEDULING STATUS:

S3

UROTENA 5 (film coated tablet)

UROTENA 10 (film coated tablet)

Solifenacin succinate

Contains sugar (lactose monohydrate)

UROTENA 5: Contains 55,625 mg lactose monohydrate

UROTENA 10: Contains 111,25 mg lactose monohydrate

Read all of this leaflet carefully before you start taking UROTENA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **UROTENA** 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.

What is in this leaflet

1. What UROTENA is and what it is used for

UROTENA belongs to the group of anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

UROTENA is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

2. What you need to know before you take UROTENA

Do not take UROTENA:

- If you are hypersensitive (allergic) to solifenacin succinate or any of the other ingredients of **UROTENA** (listed in section 6).
- If you have an inability to pass water or to empty your bladder completely (urinary retention).
- If you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma).
- If you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles.
- If you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis).
- If you are undergoing kidney dialysis.
- If you have severe liver disease.
- If you suffer from severe kidney disease or moderate liver disease AND at the same time are being treated with medicines that may decrease the removal of **UROTENA** from the body (for example, ketoconazole).
- If you suffer from heart rhythm abnormalities.
- If you are breastfeeding (see **pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with UROTENA:

- If you have trouble emptying your bladder (= bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow). Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- If you have some obstruction of the digestive system (constipation).
- If you are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.
- If you suffer from severe kidney disease.
- If you have moderate liver disease.
- If you have a stomach tear (hiatus hernia) or heartburn.
- If you have a nervous disorder (autonomic neuropathy).

Before starting **UROTENA**, your doctor will assess whether there are other causes for your need to pass urine frequently (for example heart failure (insufficient pumping power of the heart) or kidney disease). If you have a urinary tract infection, your doctor will prescribe you an antibiotic (a treatment against particular bacterial infections).

Children and adolescents

UROTENA is not to be used in children or adolescents under 18 years.

Other medicines and UROTENA

Always tell your health care provider if you are taking any other medicine. (This included all complementary or traditional medicines).

Tell your doctor, pharmacist or health care provider if you are taking any of the following:

- Other anticholinergic medicines like scopolamine, orphenadrine and flavoxate, that prevents impulses responsible for muscle movement against someone's will. These medicines can increase the effects and side effects of the anticholinergic medicines and **UROTENA**.

- Cholinergics medicines such as botulinum toxin, nicotine and atropine that prevents or improve the contraction of smooth muscles, opens blood vessels and increase body secretions and slow the hearty rate. They can reduce the effects of **UROTENA**.
- Medicines, like metoclopramide and cisapride, which make the digestive system work faster. **UROTENA** can reduce their effect.
- Medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which **UROTENA** is broken down by the body.
- Medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which **UROTENA** is broken down by the body.
- Medicines such as bisphosphonates, that can cause inflammation of the gullet (oesophagitis).

UROTENA with food and drink

UROTENA can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not use **UROTENA** if you are pregnant unless clearly necessary.

Do not use **UROTENA** if you are breastfeeding as solifenacin may get into your breast milk.

Driving and using machines

UROTENA may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects, do not drive or operate machinery.

UROTENA contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this **UROTENA**.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **UROTENA**.

3. How to take UROTENA

Do not share medicines prescribed for you with any other person.

Always take **UROTENA** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 5 mg per day unless your doctor told you to take 10 mg per day.

If you take more UROTENA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose may include headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over-excitability, seizures (convulsions), difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

If you forget to take UROTENA

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **UROTENA** at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking UROTENA

If you stop taking **UROTENA**, your symptoms of overactive bladder may return or worsen. Do not stop taking **UROTENA** tablets unless your doctor tells you to.

4. Possible side effects

UROTENA can have side effects.

Not all side effects reported for **UROTENA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **UROTENA**, please consult your health care provider for advice.

If any of the following happens, stop taking UROTENA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to **UROTENA**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- Blurred vision
- Dry mouth

- Stomach pain

Less frequent:

- Infection that affects part of the urinary tract
- Inflammation of urinary tract
- Hallucinations
- Severe confusion
- Distortion of the sense of taste
- Dry (irritated) eyes
- Dry nasal passages
- Dry throat
- Blockage in the colon or rectum that prevents food or gas from passing through
- Lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- Severe condition of the skin that may affect the mouth and other parts of the body. Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body
- Hives or pinkish, itchy swelling on the skin or itchy rash
- Difficulty in passing urine
- Build up of urine in the bladder due to inability to empty the bladder (urinary retention)
- Accumulation of fluid under the skin causing swelling

Frequency unknown:

- High levels of blood potassium which can cause abnormal heart rhythm
- Pressure of fluid in the eye may be high (glaucoma)

- Changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat
- Voice disorder
- A painful obstruction of the ileum or other part of the intestine
- Liver disease
- Abnormal liver function tests
- Severe skin condition that causes extreme shedding of the top layers of your skin
- Muscle weakness
- Kidney disorder

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Constipation
- Feeling sick
- Indigestion

Less frequent:

- Sleepiness or drowsiness
- Headache
- Dizziness or spinning sensation
- Heartburn
- Dry skin
- Tiredness

Frequency unknown:

- Decreased appetite
- Stomach discomfort

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **Med Safety APP (Medsafety X SAHPRA)** and eReporting platform **(whoumc.org)** found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **UROTENA** or to the Holder of certificate of registration through the mail: **pvg.cdma@heterogroups.com.**

By reporting side effects, you can help provide more information on the safety of **UROTENA**. This includes any possible side effects not listed in this leaflet.

5. How to store UROTENA

- Store at or below 25 °C.
- Protect from light and moisture.
- Store the tablets in the original container until required for use.
- Store all medicines out of reach of children.
- There are no special storage instructions for **UROTENA**.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UROTENA contains

- The active substance is solifenacin succinate.
- The other ingredients are corn starch, Hypromellose 2910, lactose monohydrate, magnesium stearate, purified water and Opadry white 03F580030 (consists of HPMC 2910/hypromellose, titanium dioxide, macrogol/PEG, talc).

What UROTENA looks like and contents of the pack

UROTENA 5: White to off white color, round, biconvex tablets debossed with “V” on one side and “18” on the other side.

UROTENA 10: White to off white color, round, biconvex tablets debossed with “V” on one side and “19” on the other side.

Contents of the pack

HDPE bottle:

Tablets are pack in a white opaque high density polyethylene container (HDPE) container with white opaque polypropylene child resistant plastic cap with pulp liner.

Pack size: 30’s and 90’s

(Or)

Tablets are pack in a white opaque high density polyethylene container (HDPE) container with white opaque polypropylene, ribbed, child resistant plastic cap with pulp liner.

Pack size: 500’s

Blister strips:

Blister strips of clear, transparent, thermoformable, rigid PVC forming film and plain soft aluminium peel-push lidding foil, containing 10 tablets per blister.

Pack sizes: 10 tablets per blister. 10's x 10 blisters packed in a box.

Stimulated bulk pack:

Tablets are pack in a clear translucent low density polyethylene (poly bag), plain triple laminated bag containing 5 grams of silica gel sachet.

Pack size: 1000's

HDPE bottle and blister strips are enclosed in an outer carton box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration number(s)

UROTENA 5: 56/5.4/1027.025

UROTENA 10: 56/5.4/1028.026

Access to the corresponding Professional Information

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