PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SOLIFENACIN UNICORN 5 and 10 Film-coated tablet

Solifenacin succinate

Contains sugar (Lactose).

Read all of this leaflet carefully before you start taking SOLIFENACIN UNICORN:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **SOLIFENACIN UNICORN** 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 **SOLIFENACIN UNICORN** is and what it is used for.
2. What you need to know before you take **SOLIFENACIN UNICORN**.
3. How to take **SOLIFENACIN UNICORN**.
4. Possible side effects.
5. How to store **SOLIFENACIN UNICORN**.
6. Contents of the pack and other information.

1. What SOLIFENACIN UNICORN is and what it is used for

SOLIFENACIN UNICORN contains a medicine called Solifenacin succinate.

The active substance of **SOLIFENACIN UNICORN** belongs to the group of medicines called anticholinergics.

SOLIFENACIN UNICORN is 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.

2. What you need to know before you take SOLIFENACIN UNICORN:

Do not take SOLIFENACIN UNICORN:

- If you are hypersensitive (allergic) to solifenacin succinate or any of the ingredients of SOLIFENACIN UNICORN (listed in **section 6**).
- If you have the 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 (toxic megacolon).
- If you are undergoing kidney dialyses.
- If you have severe liver disease.
- If you suffer from severe kidney disease or moderate liver disease and at the same time being treated with medicines that may decrease the removal of **SOLIFENACIN UNICORN** from the body (for example, ketoconazole).
- If you have disorder of the heart known as prolonged QT interval,

  Whether is inherited or acquired
- If you are pregnant or breastfeeding

Warnings and precautions

Tell your doctor before taking **SOLIFENACIN UNICORN**:

Take special care with **SOLIFENACIN UNICORN**:

- If you have other underlying diseases (for example heart failure or kidney disease) which may also lead to the urge to frequently urinate. Your doctor should address these conditions first before treatment with **SOLIFENACIN UNICORN**.
- If you have trouble emptying your bladder (bladder obstruction) or have difficulty in passing urine. Risk of accumulation of urine in the bladder (urinary retention) is much higher.
- If you have obstruction in the digestive system (constipation).
- If you are at risk of your digestive system slowing down (stomach and bowel movements).
- If you suffer from severe kidney disease.
- If you have moderate liver disease.
- If you are taking medicines which decreases the rate of breakdown of **SOLIFENACIN UNICORN** by the body for example ketoconazole.
- If you have a stomach tear (hiatus hernia) or heartburn.
- If you have a nervous system disorder (autonomic neuropathy).
- If you have a condition called QT syndrome or Torsades de pointes, which are conditions associated with changes in the electrical activity of the heart (ECG), irregular heartbeat, feeling your heartbeat, faster heartbeat.

Skin allergy that results in swelling of the tissue just below the skin (angioedema) with obstruction of the airway has been reported. If this occurs, you should stop taking **SOLIFENACIN UNICORN** and inform your doctor immediately.

Potentially life-threatening allergic reactions (anaphylactic reactions) have been reported. If you experience any allergic reaction, you should stop taking **SOLIFENACIN UNICORN** and inform your doctor immediately.

SOLIFENACIN UNICORN will only reach its complete effect after 4 weeks at the earliest.

Children and adolescents

Safety in children has not been established, therefore **SOLIFENACIN UNICORN** is not recommended for children under 18 years.

Other medicines with SOLIFENACIN UNICORN:

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

- Amantadine (used as an anti-viral or Parkinson's disease), some anti-histamines, phenothiazine (for psychiatric disorders), and tricyclic antidepressants as they can reduce the effect of SOLIFENACIN UNICORN.
- Metoclopramide, domperidone and cisapride, which make the digestive system work faster, as SOLIFENACIN UNICORN can reduce their effect.
- Ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which SOLIFENACIN UNICORN is broken down by the body. If you have severe kidney disease you should not take these medicines with **SOLIFENACIN UNICORN** (see **"section 2"**).
- Rifampicin, phenytoin and carbamazepine, as they increase the rate at which **SOLIFENACIN UNICORN** is broken down by the body.

Taking SOLIFENACIN UNICORN with food, drink and alcohol:

SOLIFENACIN UNICORN 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.

SOLIFENACIN UNICORN is contraindicated in pregnancy and during breastfeeding.

Driving and using machines

SOLIFENACIN UNICORN may cause blurred vision, sleepiness and a general feeling of tiredness (somnolence and fatigue). If you suffer from these side effect, do not drive or operate machinery, as it may affect these activities.

Important information about some of the ingredients of SOLIFENACIN UNICORN:

SOLIFENACIN UNICORN contains a sugar called lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SOLIFENACIN UNICORN.

3. How to take SOLIFENACIN UNICORN:

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

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

The usual dose for SOLIFENACIN UNICORN is 5 mg per day. your doctor may increase your dose to 10 mg per day if needed.

You should swallow the whole tablet with some liquid. It can be taken with or without food.

If you take more SOLIFENACIN UNICORN than you should:

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

The most frequent side effects side effects associated with overdose of **SOLIFENACIN UNICORN** are headache, dry mouth, dizziness, drowsiness and blurred vision with overdose.

If you forget to take SOLIFENACIN UNICORN:

It is important that you do not miss any doses. If you miss a dose of **SOLIFENACIN UNICORN**, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule once daily.

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

If you stop taking SOLIFENACIN UNICORN

Do not stop taking SOLIFENACIN UNICORN unless your doctor tells you to do so. If you have further questions on the use of SOLIFENACIN UNICORN, ask your doctor or pharmacist

4. Possible side effects

SOLIFENACIN UNICORN can have side effects.

Not all side effects reported for **SOLIFENACIN UNICORN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **SOLIFENACIN UNICORN**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SOLIFENACIN UNICORN**. 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:

- Chest pain
- Angina
- Changes in the way your heart beats e.g. if you notice it beating faster
- Difficulty in breathing
- Less urine than is normal for you

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

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- Blurred vision
- Dry mouth, constipation, nausea, heartburn (dyspepsia), stomach pain

The following side effects have been reported less frequently:

- Bladder infection, inflammation of the bladder due to infection (cystitis)
- Sleepiness, impaired sense of taste (dysgeusia)
- Dry eyes

- Dry nasal passages
- Reflux disease (gastro-oesophageal reflux), dry throat, obstruction of the colon, lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- Dry skin
- Difficulty in passing urine
- Tiredness, accumulation of fluid in the lower legs (oedema),
- Hallucinations, confusion,
- Dizziness and headache,
- Vomiting
- Allergic rash, itching of the skin (pruritus), rash, reddening of patches of the skin (erythema multiforme) or hives (urticaria).

The following side effects have been reported with unknown frequency:

- Dilation of the pupils (mydriasis), difficulty in adjusting focus (cycloplegia), painful eyes with bright light (photophobia)
- Reduced secretion of the mucus of the chest
- Flushing of the skin
- Decreased appetite, high levels of blood potassium which can cause abnormal heart rhythm
- Disturbed state of mind characterised by restlessness, illusions and confusion (delirium)
- Increased pressure in the eyes (glaucoma)
- Voice disorder (dysphonia)
- A painful obstruction of the ileum or other part of the intestine, stomach discomfort
- Liver disorder
- Muscular weakness
- Kidney disorder.

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

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **SOLIFENACIN UNICORN**.

5. How to store SOLIFENACIN UNICORN:

Store at or below 25 ºC.

Store in the original packaging.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SOLIFENACIN UNICORN contains

The active ingredient is Solifenacin succinate.

SOLIFENACIN UNICORN 5: Hypromellose, lactose monohydrate, magnesium stearate, maize starch and Opadry Yellow (containing hypromellose, iron oxide yellow, macrogol, talc and titanium dioxide).

SOLIFENACIN UNICORN 10: Hypromellose, lactose monohydrate, magnesium stearate, maize starch and Opadry Pink (containing hypromellose, iron oxide red, iron oxide yellow, macrogol, talc and titanium dioxide).

What SOLIFENACIN UNICORN looks like and contents of the pack

Film-coated tablets

SOLIFENACIN UNICORN 5: Light yellow coloured, round, biconvex, film coated tablet, debossed with ‘D5’ on the one side and plain on the other side.

SOLIFENACIN UNICORN 10: Light pink coloured, round, biconvex, film coated tablet, debossed with ‘D6’ on the one side and plain on the other side.

Blister pack: Silver aluminium/Colourless transparent PVC blisters containing 10 tablets. 3 blister strips are packed into an outer carton. Pack size is 30 tablets.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle & Pontac Streets

Cape Town

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8001

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