PATIENT INFORMATION LEAFLET FOR UTROVES

SCHEDULING STATUS

S3

UTROVES 5 and 10 film coated tablets

Solifenacin succinate

UTROVES 5 contains sugar (lactose monohydrate, 54,25 mg)

UTROVES 10 contains sugar (lactose monohydrate, 108,50 mg)

Read all of this leaflet carefully before you start taking UTROVES

- 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.
- UTROVES 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 UTROVES is and what it is used for

2. What you need to know before you take UTROVES

3. How to take UTROVES

4. Possible side effects

5. How to store UTROVES

6. Contents of the pack and other information

1. What UTROVES is and what it is used for

UTROVES contains a medicine called solifenacin succinate.

The active substance of UTROVES belongs to the group of medicines called anticholinergics.

UTROVES 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 UTROVES

Do not take UTROVES:

- If you are hypersensitive (allergic) to solifenacin succinate or any of the ingredients of UTROVES (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 dialysis.
- 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 UTROVES from the body (for example, ketoconazole).
- If you have a disorder of the heart known as prolonged QT interval, whether it is inherited or acquired.
- If you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor before taking UTROVES:

Take special care with UTROVES:

- 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 UTROVES.

- 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 decrease the rate of breakdown of UTROVES 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 Torsade 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 UTROVES 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 UTROVES and inform your doctor immediately.

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

Children and adolescents

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

Other medicines and UTROVES

Always tell your health care provider if you are taking any other medicine. (This includes all 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 UTROVES.
- Metoclopramide, domperidone and cisapride, which make the digestive system work faster, as UTROVES can reduce their effect.
- Ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which UTROVES is broken down by the body. If you have severe kidney disease you should not take these medicines with UTROVES (see **section 2**).
- Rifampicin, phenytoin and carbamazepine, as they increase the rate at which UTROVES is broken down by the body.

UTROVES with food, drink and alcohol

UTROVES 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.

UTROVES is contraindicated in pregnancy and during breastfeeding.

Driving and using machines

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

UTROVES contains sugar (lactose monohydrate)

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

3. How to take UTROVES

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

Always take UTROVES 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 UTROVES is 5 mg per day. Your doctor may increase your dose to 10 mg per day if needed.

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

If you take more UTROVES 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 associated with overdose of UTROVES are headache, dry mouth, dizziness, drowsiness and blurred vision.

If you forget to take UTROVES

It is important that you do not miss any doses. If you miss a dose of UTROVES, 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 UTROVES

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

4. Possible side effects

UTROVES can have side effects.

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

If any of the following happens, stop taking UTROVES 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 reaction to UTROVES. 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 urgent 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.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

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 UTROVES.

5. How to store UTROVES

Store all medicines out of reach of children.

Store at or below 30 ºC.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What UTROVES contains:

Each UTROVES 5 film coated tablet contains 5 mg solifenacin succinate.

Each UTROVES 10 film coated tablet contains 10 mg solifenacin succinate.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch and purified water.

UTROVES 5 film coating contains opadry yellow 02F220022 (consisting of Hypromellose 5cp, iron oxide yellow (E172), macrogol 8000, talc, titanium dioxide (E171).

UTROVES 10 film coating contains opadry pink 02F240016 (consisting of hypromellose 5cp, iron oxide red (E172), iron oxide yellow (E172), Macrogol 8000, talc, titanium dioxide (E171).

What UTROVES looks like and contents of the pack

UTROVES 5: Light yellow round, biconvex film coated tablets.

UTROVES 10: Light pink, round, biconvex film coated tablets with score line on one side and plain on the other.

UTROVES film coated tablets are packed in transparent PVC/PE/PVDC aluminium blister strips or aluminium/aluminium blister strips. Blister strips containing 10, 14 or 15 tablets are packed into an outer carton.

Pack size: 30, 50 or 90 film coated tablets.

Holder of certificate of registration

Forrester Pharma (Pty) Ltd

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Rosen Heights

Rosen Park

Bellville

7530

South Africa

Registration numbers

UTROVES 5: To be allocated.

UTROVES 10: To be allocated.