

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SOLIFENACIN 5 mg UNICHEM film-coated tablets

SOLIFENACIN 10 mg UNICHEM film-coated tablets

Solifenacin succinate

Contains sugar: lactose monohydrate.

SOLIFENACIN 5 mg UNICHEM: Each film-coated tablet contains 124,9 mg lactose monohydrate.

SOLIFENACIN 10 mg UNICHEM: Each film-coated tablet contains 119,9 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking SOLIFENACIN UNICHEM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- SOLIFENACIN UNICHEM 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 UNICHEM is and what it is used for
2. What you need to know before you take SOLIFENACIN UNICHEM
3. How to take SOLIFENACIN UNICHEM
4. Possible side effects

5. How to store SOLIFENACIN UNICHEM
6. Contents of the pack and other information

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

SOLIFENACIN UNICHEM contains the active substance solifenacin succinate, which belongs to a class of medicines called 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.

SOLIFENACIN UNICHEM 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 SOLIFENACIN UNICHEM

Do not take SOLIFENACIN UNICHEM:

- If you are hypersensitive (allergic) to solifenacin succinate or any of the other ingredients of SOLIFENACIN UNICHEM listed in section 6 of this leaflet.
- If you have urinary retention (an inability to pass water or to empty your bladder completely).
- If you suffer from narrow angle glaucoma (increased pressure in the eyes, with gradual loss of eyesight).
- If you suffer from myasthenia gravis (a muscle disease which can cause an extreme weakness of certain muscles).
- If you suffer from toxic megacolon (a severe stomach or bowel condition resulting from inflammation in the colon).
- If you are undergoing kidney dialysis.
- If you have severe liver disease or problems.
- If you suffer from severe kidney disease or moderate liver disease and are being treated with

medicines called cytochrome P3A4 inhibitors, such as ketoconazole (used to treat fungal infections).

- If you have been diagnosed with a prolonged QT interval (a measurement made on an electrocardiogram used to assess some of the electrical properties of the heart).
- If you are pregnant or breastfeeding.

Warnings and precautions

Your doctor may assess you to find whether there are other causes for your need to pass urine frequently, such as heart failure or kidney disease.

Take special care with SOLIFENACIN UNICHEM:

- If you have trouble emptying your bladder or have difficulty in passing urine (such as a thin urine flow), as this increases the risk of accumulation of urine in the bladder (urinary retention).
- If you have gastrointestinal obstruction (causing stomach pain, nausea (feeling sick), vomiting (being sick), feeling bloated and 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 suffer from moderate liver disease.
- If you have a hiatus hernia (a tear in the diaphragm, the large muscle separating your abdomen and chest) or suffer from heartburn.
- If you suffer from autonomic neuropathy (a disease of the nerves that manage everyday body functions).
- If you have hypokalaemia (too low levels of potassium in your blood).

Children

Safety and efficacy of SOLIFENACIN UNICHEM in children have not yet been established.

Therefore, SOLIFENACIN UNICHEM should not be given to children.

Other medicines and SOLIFENACIN UNICHEM

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

Tell your doctor or pharmacist if you are currently taking:

- Bisphosphonates (such as alendronate, risedronate, ibandronate, zoledronic acid, used to treat bone problems and osteoporosis).
- Metoclopramide (used to treat nausea (feeling sick) and vomiting (being sick)) or cisapride (used to treat heartburn).
- Ketoconazole or itraconazole (used to treat fungal infections).
- Nelfinavir or ritonavir (used to treat human immunodeficiency virus (HIV) infection).
- Verapamil or diltiazem (used to treat high blood pressure and angina (chest pain)).
- Rifampicin (used to treat tuberculosis (TB)).
- Phenytoin or carbamazepine (used to treat epilepsy).

Tell your doctor if you are taking or planning on taking any other anticholinergic medicines, such as:

- tiotropium or ipratropium (used to treat asthma),
- cyclopentolate, homatropine or atropine (used during eye examinations),
- darifenacin, tolterodine, trospium or oxybutynin (used to treat an overactive bladder),
- flavoxate (used to treat urinary tract infection symptoms),
- hyoscyamine (used to treat stomach cramps),
- orphenadrine (used to relax skeletal muscles),
- propantheline (used to treat an overactive bladder or excessive sweating),
- tricyclic antidepressants (used to treat depression, pain or sleeplessness),
- antihistamines (first generation, used to treat sleeplessness, allergies or nausea (feeling

sick)).

Your doctor may advise you to wait 7 days after taking SOLIFENACIN UNICHEM before taking any other anticholinergic medicines.

Pregnancy and breastfeeding

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 SOLIFENACIN UNICHEM.

You should not take SOLIFENACIN UNICHEM if you are pregnant or breastfeeding. If you get pregnant while taking SOLIFENACIN UNICHEM, stop taking it immediately and tell your health care provider.

Driving and using machines

SOLIFENACIN UNICHEM can cause blurred vision, sleepiness or tiredness, dizziness or possibly hallucinations (perceiving things that are not there) which which may affect your ability to drive and use machines. Take special care before driving or operating machinery, until you know how SOLIFENACIN UNICHEM affects you.

SOLIFENACIN UNICHEM contains lactose monohydrate

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

3. How to take SOLIFENACIN UNICHEM

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

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

Adults, including the elderly

The usual dose is 5 mg once daily. Your doctor may increase your dose up to 10 mg once daily.

Your doctor will determine the correct dose for you based on your kidney function, liver function or any other medicines that you are taking at the same time.

Your doctor will tell you how long your treatment with SOLIFENACIN UNICHEM will last.

SOLIFENACIN UNICHEM should be swallowed whole with liquids.

SOLIFENACIN UNICHEM be taken with or without food, as is convenient.

If you have the impression that the effect of SOLIFENACIN UNICHEM is too strong or too weak, tell your doctor or pharmacist.

If you take more SOLIFENACIN UNICHEM than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

If you forget to take SOLIFENACIN UNICHEM

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 SOLIFENACIN UNICHEM at the next regularly scheduled time.

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

4. Possible side effects

SOLIFENACIN UNICHEM can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

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

- changes in the way your heart beats (beating faster or slower), irregular heartbeat or changes in the electrical activity of your heart (electrocardiogram (ECG));
- kidney function impairment (drowsiness, shortness of breath, fatigue, confusion, nausea, passing less urine than is normal for you);
- liver disorder (stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, nausea (feeling sick), vomiting (being sick) of blood, yellowing of skin or eyes);
- partial or complete blockage of the bowels or faecal impaction (lodging of a large amount of stool in your large intestine);
- erythema multiforme (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, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- blurred vision;
- dry mouth, nausea (feeling sick);
- constipation, indigestion, pain in your stomach area.

Less frequent side effects:

- urinary tract infection or inflammation of the bladder (strong and frequent urge to urinate, pain and burning sensation when urinating, cloudy, bloody or strong-smelling urine, abdominal pain, nausea and vomiting);
- build-up of urine in the bladder due to inability to empty the bladder, difficulty in passing urine;
- seeing or hearing things that does not exist (hallucinations) or feeling confused;
- heartburn, dry throat, vomiting (being sick);
- headache or dizziness;
- distortion of the sense of taste;
- excessive sleepiness or tiredness;
- dry eyes or dry nasal passages;
- dry skin.

Side effects with an unknown frequency:

- too high levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness);
- increased pressure in the eyes;
- abnormal results when testing your liver function;
- delirium (state of severe confusion);
- muscle weakness,
- voice disorder (causing a rough, raspy or hoarse voice);
- discomfort in your stomach area;
- decreased appetite.

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 SOLIFENACIN UNICHEM.

5. How to store SOLIFENACIN UNICHEM

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOLIFENACIN UNICHEM contains

The active substance in SOLIFENACIN UNICHEM is solifenacin succinate.

SOLIFENACIN 5 mg UNICHEM: Each film-coated tablet contains 5 mg solifenacin succinate.

SOLIFENACIN 10 mg UNICHEM: Each film-coated tablet contains 10 mg solifenacin succinate.

The other ingredients are hypromellose (E464), iron oxide red (E172) (SOLIFENACIN 10 mg UNICHEM), iron oxide yellow (E172) (SOLIFENACIN 5 mg UNICHEM), lactose monohydrate, magnesium stearate (E572), maize starch, polyethylene glycol (E1521), pregelatinised starch, talc (E553b) and titanium dioxide (E171).

What SOLIFENACIN UNICHEM looks like and contents of the pack

SOLIFENACIN 5 mg UNICHEM: Light yellow, round, biconvex, film-coated tablets, debossed with “U” on one side and “328” on the other side.

SOLIFENACIN 10 mg UNICHEM: Light pink, round, biconvex, film-coated tablets, debossed with “U” on one side and “329” on the other side.

Clear PVC/PVDC and silver aluminium blister strips, placed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

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