Package leaflet: Information for the user

Solifenacin succinate Rowex 5 mg Film-coated tablets
Solifenacin succinate Rowex 10 mg Film-coated tablets

solifenacin succinate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

ROWEX®

1 What Solifenacin succinate Rowex is and what it is used for

Solifenacin, the active substance of Solifenacin succinate Rowex 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.

Solifenacin succinate Rowex 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
- wetting yourself because you could not get to the bathroom in time.

2 What you need to know before you take Solifenacin succinate Rowex

Do not take Solifenacin succinate Rowex
if you:
- are allergic to solifenacin or any of the other ingredients of this medicine (listed in section 6)
- have an inability to pass water or to empty your bladder completely (urinary retention)
- have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- are undergoing kidney dialysis
- have severe liver disease
- 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 Solifenacin succinate Rowex from the body (for example, ketoconazole). Your doctor or pharmacist will have informed you if this is the case.

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Solifenacin succinate Rowex starts.

Warnings and precautions
Talk to your doctor or pharmacist before taking Solifenacin succinate Rowex
- 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).

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Solifenacin succinate Rowex starts.

Before starting Solifenacin succinate Rowex, 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
Solifenacin succinate Rowex is not to be used in children or adolescents under 18 years.

Other medicines and Solifenacin succinate Rowex
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

It is especially important to inform your doctor if you are taking:
- other anticholinergic medicines, effects and side effects of both medications can be enhanced
- cholinergics as they can reduce the effect of Solifenacin succinate Rowex
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin succinate Rowex can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, verapamil and diltiazem, which decrease the rate at which Solifenacin succinate Rowex is broken down by the body
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which Solifenacin succinate Rowex is broken down by the body
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

Solifenacin succinate Rowex with food and drink
Solifenacin succinate Rowex can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding
Pregnancy
You should not use Solifenacin succinate Rowex if you are pregnant unless clearly necessary.

Breast-feeding
Do not use Solifenacin succinate Rowex if you are breast-feeding as solifenacin may get into your breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Solifenacin succinate Rowex may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects do not drive or operate machinery.

Solifenacin succinate Rowex contains lactose
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 Solifenacin succinate Rowex

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

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

Swallow the tablets whole with a glass of water, without chewing or crushing them.

Solifenacin succinate Rowex 10 mg Film-coated tablets
The tablets can be divided into equal doses. Swallow the tablets or the halves with a glass of water, without chewing or crushing them.

Take the tablets at the same time each day. The tablets may be taken with or without meals.

If you take more Solifenacin succinate Rowex than you should
If you have taken too much Solifenacin succinate Rowex or if a child has accidentally taken Solifenacin succinate Rowex, contact your doctor or pharmacist immediately.

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)
- dilated pupils (mydriasis).

If you forget to take Solifenacin succinate Rowex
If you forget to take a dose at the usual time, take it as soon as you remember, unless it is time to take your next dose. Never take more than one dose per day. If you are in doubt, always consult your doctor or pharmacist.

Continued on the next page ››

If you stop taking Solifenacin succinate Rowex
If you stop taking Solifenacin succinate Rowex, your symptoms of overactive bladder may return or worsen. Always consult your doctor, if you are considering stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Solifenacin succinate Rowex and seek medical help immediately if you notice any of the following side effects:

– allergic attack **(signs may include swelling of the throat, face, lips and mouth, difficulty in breathing or swallowing),** or a severe skin reaction (e.g. blistering and peeling of the skin)

– 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 solifenacin.

Further side effects can occur with the following frequencies:

Very common, may affect more than 1 in 10 people
- dry mouth.

Common, may affect up to 1 in 10 people
- blurred vision
- constipation
- nausea
- indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia).

Uncommon, may affect up to 1 in 100 people
- urinary tract infection, bladder infection
- sleepiness, tiredness
- impaired sense of taste (dysgeusia)
- dry (irritated) eyes
- dry nasal passages
- reflux disease (gastro-oesophageal reflux)
- dry throat
- dry skin
- difficulty in passing urine
- accumulation of fluid in the lower legs (oedema).

Rare, may affect up to 1 in 1,000 people
- lodging of a large amount of hardened stool in the large intestine (faecal impaction)
- blockage in the colon
- build up of urine in the bladder due to inability to empty the bladder (urinary retention)
- dizziness, headache
- vomiting
- itching, rash.

Very rare, may affect up to 1 in 10,000 people
- hallucinations, confusion
- allergic rash.

Not known, frequency cannot be estimated from the available data.
- 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 heartbeat
- voice disorder
- liver disorder, abnormal liver function test
- muscle weakness
- renal disorder
- stomach discomfort, ileus (lack of movement in the intestines that can lead to intestinal obstruction)
- widespread reddening and scaling of skin
- delirium.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Solifenacin succinate Rowex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, bottle and blister labels after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Shelf life after first opening the polyethylene bottle is 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Solifenacin succinate Rowex contains
Solifenacin succinate Rowex 5 mg Film-coated tablets
- The **active substance** is **solifenacin succinate.**
  Each film-coated tablet contains 5 mg of solifenacin succinate equivalent to 3.8 mg solifenacin.

- The other ingredients are lactose monohydrate, hypromellose, pregelatinised starch, magnesium stearate, macrogol 6000, talc, titanium dioxide (E171), iron oxide yellow (E172).

Solifenacin succinate Rowex 10 mg Film-coated tablets
- The **active substance** is **solifenacin succinate.**
  Each film-coated tablet contains 10 mg of solifenacin succinate equivalent to 7.5 mg solifenacin.

- The other ingredients are lactose monohydrate, hypromellose, pregelatinised starch, magnesium stearate, macrogol 6000, talc, titanium dioxide (E171), iron oxide red (E172).

What Solifenacin succinate Rowex looks like and contents of the pack
Solifenacin succinate Rowex 5 mg Film-coated tablets are light yellow, round, film-coated tablets of 6 mm, debossed with 05 impressed on one side.

Solifenacin succinate Rowex 10 mg Film-coated tablets are light pink, round, film-coated tablets of 8 mm, debossed with 10 impressed on one side and a score line on the other side.

The tablet can be divided into equal doses.

PVC/Al blister packs contain 10, 20, 30, 50, 90 or 100 film-coated tablets packed in a carton box.
Polyethylene bottles (with a polypropylene screw cap/desiccant insert) contain 30, 56, 60, 84, 90, 100, 105 or 250 film-coated tablets packed in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova ulica 57, Ljubljana 1526, Slovenia.
Lek Pharmaceuticals d.d., Trimlini 2D, Lendava 9220, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Solifenacin Sandoz 5 mg filmomhulde tabletten Solifenacin Sandoz 10 mg filmomhulde tabletten
France	SOLIFENACINE SANDOZ 5 mg, comprimé pelliculé SOLIFENACINE SANDOZ 10 mg, comprimé pelliculé
Germany	Solifenacin HEXAL 5 mg Filmtabletten Solifenacin HEXAL 10 mg Filmtabletten
Hungary	Solifenacin Sandoz 5 mg filmtabletta Solifenacin Sandoz 10 mg filmtabletta
Ireland	Solifenacin succinate Rowex 5 mg Film-coated tablets Solifenacin succinate Rowex 10 mg Film-coated tablets
Italy	Solifenacina Sandoz
Netherlands	Solifenacinesuccinaat Sandoz 5 mg, filmomhulde tabletten Solifenacinesuccinaat Sandoz 10 mg, filmomhulde tabletten
Romania	Solifenacin Sandoz 5 mg comprimate filmate Solifenacin Sandoz 10 mg comprimate filmate
Slovenia	Sulfesa 5 mg filmsko obložene tablete Sulfesa 10 mg filmsko obložene tablete
Sweden	Solifenacin Sandoz 5 mg filmdragerad tablett Solifenacin Sandoz 10 mg filmdragerad tablett
United Kingdom	Solifenacin 5 mg Film-coated tablets Solifenacin 10 mg Film-coated tablets

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