Package leaflet: Information for the user

Soreca 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:

1. What Soreca is and what it is used for

The active substance of Soreca 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.

Soreca 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 Soreca

Do not take Soreca

- if you are allergic to solifenacin or any of the other ingredients of this medicine (listed in section 6)
- if you have an inability to pass water or to empty your bladder completely (urinary retention)
- if you have a severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis)
- if you suffer from the muscle disease called myasthenia gravis, which can cause an extreme weakness of certain muscles
- if you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma)
- 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 solifenacin 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 starts.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine

- 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 hiatus hernia or heartburn.
- if you have a nervous disorder (autonomic neuropathy).

Children and adolescents
This medicine is not to be used in children or adolescents under 18 years.

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

Before starting Soreca, 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).

Other medicines and Soreca
Please tell your doctor or pharmacist if you are taking or have recently taken or might take 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.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, intraconazole, verapamil and diltiazem, which decrease the rate at which solifenacin is broken down by the body
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which solifenacin is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the esophagus (oesophagitis).

Soreca with food, drink and alcohol
This medicine can be taken with or without food, depending on your preference.

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

Solifenacin should not be taken if you are pregnant unless it is absolutely necessary.

Do not take solifenacin during breast-feeding, since Solifenacin can pass into breast.

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

Soreca contains lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Soreca

Instructions for a correct use

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

You should swallow the whole tablet with some liquid. It can be taken with or without food, according to your preference. Do not crush the tablets.

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

If you take more Soreca than you should
In case of overdose or accidental ingestion, contact your doctor or pharmacist immediately, indicating the medicine and the amount taken.
Symptoms of overdose may include: headache, dry mouth, dizziness, drowsiness and blurred vision, perceiving things that are not there (hallucinations), over- excitability, seizures, difficulty breathing, elevated heart rate (tachycardia), accumulation of urine in the bladder (urinary retention) and dilated pupils (mydriasis).

If you forget to take Soreca
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.

If you stop taking Soreca
If you stop taking Soreca, 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or pharmacist immediately.

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 succinate. **If angioedema occurs, solifenacin succinate should be discontinued immediately** and appropriate therapy and/or measures should be taken.

Solifenacin may cause the following other side effects:

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), stomach discomfort

Uncommon (may affect up to 1 in 100 people)
- urinary tract infection, bladder infection,
- sleepiness,
- impaired sense of taste (dysgeusia),
- dry (irritated) eyes,
- dry nasal passages,
- reflux disease (gastro-oesophageal reflux),
- dry throat,
- dry skin,
- difficulty in passing urine,
- tiredness,
- 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)
- 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, palpitations, fast heartbeat,
- voice disorder,
- liver disorder,
- muscle weakness,
- renal disorder.

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 Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych
Al. Jerozolimskie 181C
PL-02 222 Warszawa
Tel.: + 48 22 49 21 301
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e-mail: ndl@urpl.gov.pl.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Soreca

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

There are no special precautions for storage.

Do not use Soreca after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Soreca contains
The active substance is solifenacin succinate. Each tablet contains 10 mg of solifenacin succinate (equivalent to 7.5 mg of solifenacin).

The other ingredients are lactose monohydrate, maize starch, hypromellose (E464), anhydrous colloidal silica, magnesium stearate, talc, macrogol, titanium dioxide (E171) and red iron oxide (E172).

What Soreca looks like and content of the pack
Soreca 10 mg are round, pink tablets with the inscription “E3” on one side.

Soreca 10 mg film-coated tablets are supplied in cardbox cartons containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Recordati Polska sp. z o.o.
ul. Królewska 16
00-103 Warszawa
Poland

Manufacturer
Laboratorios Lesvi, S.L.
Avda. Barcelona 69
08970 Sant Joan Despí (Barcelona), Spain

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

Germany	Solifenacin Lesvi 10 mg Filmtabletten
Italy	Solifenacina Lesvi 10 mg compresse rivestite con film
Netherlands	Solifenacinesuccinaat Lesvi 10 mg filmomhulde tabletten
Spain	Solifenacina Lesvi 10 mg comprimidos recubiertos con película
Poland	Soreca

This leaflet was las revised in: 07/2019