Package leaflet: Information for the user

<Product name> 5 mg
<Product name> 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 <Product name> is and what it is used for

The active substance Solifenacin succinate 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.

<Product name> 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 <Product name>

Do not take <Product name>
- if you are allergic to Solifenacin succinate 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 <Product name> starts.

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product name>

- 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 <Product name> starts.

Before starting <Product name>, 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).

Cildren and adolescents

<Product name> is not to be used in children or adolescents under 18 years.

Other medicines and <Product name>

Tell your doctor 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,
- 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 gullet (oesophagitis).

<Product name> with food and drink

<Product name> can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding

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

You should not use <Product name> if you are pregnant unless clearly necessary.

Do not use <Product name> if you are breast-feeding as solifenacin may get into your breast milk.

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.

<Product name> contains lactose

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

3. How to take <Product name>

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

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

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.

If you take more <Product name> than you should

If you have taken too much <Product name> or if a child has accidentally taken <Product name>, 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) and dilated pupils (mydriasis).

If you forget to take <Product name>

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 <Product name>

If you stop taking <Product name>, 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.

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, <Product name> should be discontinued immediately and appropriate therapy and/or measures should be taken.

<Product name> 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 (Torsade de Pointes), palpitations, accelerated 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 the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.
(Contact details will be implemented at national basis for each country)

5. How to store <Product name>

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

This medicinal product does not require any special storage conditions.

Do not use this medicine 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 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 <Product name> contains

- The active substance is solifenacin succinate.

  <Product name> 5 mg: each tablet contains 5 mg of solifenacin succinate, corresponding to 3.8 mg of solifenacin.

  <Product name> 10 mg: each tablet contains 10 mg of solifenacin succinate, corresponding to 7.5 mg of solifenacin.

- The other ingredients are:

  Tablet core: lactose monohydrate, maize starch, talc, magnesium stearate (E470b).

  Tablet coating:

  <Product name> 5 mg: Opadry yellow (hypromellose 6cP (E464), titanium dioxide (E171), macrogol 400, ferric oxide yellow (E172), ferric oxide red (E172)), purified water.

  <Product name> 10 mg: Opadry white (hypromellose 6cP (E464), titanium dioxide (E171), macrogol 400), Opadry brown (hypromellose 5cP (E464), titanium dioxide (E171), macrogol 6000, ferric oxide yellow (E172), ferric oxide red (E172)).

What <Product name> looks like and contents of the pack

<Product name> 5 mg: yellow round biconvex film-coated tablets, diameter 6 mm.

<Product name> 10 mg: pink round biconvex film-coated tablets, diameter 7 mm.

Pack size: 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
G.L. Pharma GmbH, 8502 Lannach, Austria

Manufacturer
G.L. Pharma GmbH, 8502 Lannach, Austria

PRO.MED.CS Praha a.s., 140 00 Prague 4, Czech Republic

This medicinal product is authorised in the Member States of the EEA under the following names
Austria: Vesisol 5/10 mg-Filmtabletten
Bulgaria: Vesisol 5/10 mg Филмирана таблетки
Czech Republic: Sofelan 5/10 mg potahovaná tablety
Poland: Vesisol
Portugal: Solifenacin G.L. Pharma 5/10 mg
Slovakia: Urokur 5/10 mg filmom obalená tablety

This leaflet was last revised in [To be completed nationally]**.**