Package leaflet: Information for the user

[nationally completed name] 5 mg film-coated tablets
[nationally completed 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 [Nationally completed name] is and what it is used for

Solifenacin, the active substance of [Nationally completed name] belongs to the group 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.

[Nationally completed 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
- wetting yourself because you could not get to the bathroom in time.

2 What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
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 [Nationally completed name] 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 [Nationally completed name] starts.

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed 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 [Nationally completed name] starts.

Before starting [Nationally completed 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).

Children and adolescents under 18 years
[Nationally completed name] is not to be used in children or adolescents under 18 years.

Other medicines and [Nationally completed name]
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 [Nationally completed name].
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. [Nationally completed name] can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, intraconazole, verapamil and diltiazem, which decrease the rate at which [Nationally completed name] is broken down by the body
- medicines like rifampicin, phenytoin and carbamazepine, as they may increase the rate at which [Nationally completed name] is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis).

[Nationally completed name] with food and drink
[Nationally completed name] can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding
Pregnancy
You should not use [Nationally completed name] if you are pregnant unless clearly necessary.

Breast-feeding

Do not use [Nationally completed name] 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
[Nationally completed name] may cause blurred vision and sometimes sleepiness or tiredness. If you suffer from any of these side effects do not drive or operate machinery.

[Nationally completed 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 medicine.

3 How to take [Nationally completed name]

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

Method of use
Swallow the tablets with a glass of water, without chewing or crushing them, at the same time each day. The tablets may be taken with or without meals.

<[Nationally completed name] 10 mg film-coated tablets>
The tablet can be divided into equal doses.

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

If you take more [Nationally completed name] than you should
If you have taken too much [Nationally completed name] or if a child has accidentally taken [Nationally completed 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)
- dilated pupils (mydriasis)

If you forget to take [Nationally completed 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 [Nationally completed name]

If you stop taking [Nationally completed 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 (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), 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. If angioedema occurs, [Nationally completed name] should be discontinued immediately and appropriate therapy and/or measures should be taken.

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 heart beat
- 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store [Nationally completed name]

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 after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Shelf life after first opening the polyethylene bottle is 6 months. This does not apply to packs with plastic/aluminium strips.

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 [Nationally completed name] contains
- 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 maize starch, magnesium stearate, macrogol 6000, talc, titanium dioxide (E 171), iron oxide yellow (E 172).

- 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 maize starch, magnesium stearate, macrogol 6000, talc, titanium dioxide (E 171), iron oxide red (E 172).

What [Nationally completed name] looks like and contents of the pack
[Nationally completed name 5 mg film-coated tablets] are light yellow, round, film-coated tablets with 05 impressed on one side.

[Nationally completed name 10 mg film-coated tablets] are light pink, round, film-coated tablets with 10 impressed on one side and score line on the other side.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Austria	Solifenacin 1A Pharma 5 mg – Filmtabletten
	Solifenacin 1A Pharma 10 mg – Filmtabletten
Bulgaria	Truzor 5 mg Film-coated tablet
Cyprus	Solifenacin Sandoz
Czech Republic	Muscarisan 5 mg
	Muscarisan 10 mg
Denmark	Solifenacin "Sandoz"
Finland	Solifenacin Sandoz 5 mg tabletti, kalvopaallysteinen
	Solifenacin Sandoz 10 mg tabletti, kalvopaallysteinen
Greece	Solifenacin/Sandoz 5 mg επικαλυμμένα με λεπτό υμένιο δισκία
	Solifenacin/Sandoz 10 mg επικαλυμμένα με λεπτό υμένιο δισκία
Norway	Solifenacin Sandoz 5 mg filmdrasjert tablett
	Solifenacin Sandoz 10 mg filmdrasjert tablett
Poland	Solifenacin Sandoz 5 mg tabletki powlekane
	Solifenacin Sandoz, 10 mg, tabletki powlekane
Slovenia	Sulfesa 5 mg filmsko obložene tablete
	Sulfesa 10 mg filmsko obložene tablete
Slovakia	Solifenacin Sandoz 10 mg
Spain	Solifenacina Sandoz 5mg comprimidos recubiertos con película EFG
	Solifenacina Sandoz 10 mg comprimidos recubiertos con película EFG

This leaflet was last revised in {MM/YYYY}.
[To be completed nationally]