PACKAGE LEAFLET: INFORMATION FOR THE USER

Solifenacin succinate 5 mg film-coated tablets
Solifenacin succinate 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 SOLIFENACIN IS AND WHAT IT IS USED FOR

The active substance of Solifenacin 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 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

Do not take Solifenacin 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.
- 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Solifenacin 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.
- have some obstruction of the digestive system (constipation).
- are at risk of your digestive system slowing down (stomach and bowel movements). Your doctor will have informed you if this is the case.
- suffer from severe kidney disease.
- have moderate liver disease.
- are being treated with medicines that may decrease the removal of solifenacin from the body (for example, ketoconazole).
- have a stomach tear (hiatus hernia) or heartburn.
- 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 starts.
Before starting solifenacin, 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 is not to be used in children or adolescents under 18 years.

Other medicines and Solifenacin
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.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin can reduce their effect.
- medicines, like ketoconazole, ritonavir, nelfinavir, itraconazole, 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).

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

Pregnancy, breast-feeding and fertility
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.

You should not use solifenacin if you are pregnant unless clearly necessary.
Do not use solifenacin 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.

Solifenacin contains lactose monohydrate.
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 SOLIFENACIN

Always take this medicine exactly as your doctor or pharmacist 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.
Try to take solifenacin at the same time each day.
Solifenacin must be swallowed whole with a drink. It can be taken with or without food, according to your preference. Do not crush the tablets.
Talk to your doctor or pharmacist if you have the impression that the effect of solifenacin is too strong or too weak.

If you take more Solifenacin than you should
If you have taken too much solifenacin or if a child has accidentally taken solifenacin, 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 Solifenacin
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 Solifenacin
If you stop taking solifenacin, 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, solifenacin 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 and heartburn (dyspepsia), stomach discomfort.

Uncommon (may affect up to 1 in 100 people):
- Urinary tract infections; bladder infection (cystitis).
- 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.
- Fatigue, swelling of the lower limbs (oedema).

Rare (may affect up to 1 in 1,000 people):
- Dizziness; headache.
- Obstruction of the gut; lodging of a large amount of hardened stool in the large intestine (faecal impaction);
- Vomiting.
- Itching; rash.
- Build-up of urine in the bladder due to inability to empty the bladder (urinary retention).

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 (hyperkalaemia).
- Delirium.
- Increased eye pressure (glaucoma).
- Irregular heartbeat (Torsade de Pointes); changes in the electrical activity of the heart (ECG); feeling your heartbeat; faster heartbeat.
- Difficulty in speaking (dysphonia).
- Blockage of the intestine (ileus); abdominal discomfort.
- Liver disorder; abnormal liver tests.
- Erythema and scaling of the skin (dermatitis exfoliative).
- Muscular weakness.
- Kidney disorder.
- Anaphylactic reaction.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine

5. HOW TO STORE SOLIFENACIN

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 and blister after "EXP". The expiry date refers to the last day of that month.
This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

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 contains:
- The active substance is solifenacin succinate.
  Solifenacin 5 mg: Each tablet contains 5 mg solifenacin succinate, corresponding to 3.8 mg solifenacin.
  Solifenacin 10 mg: Each tablet contains 10 mg solifenacin succinate, corresponding to 7.5 mg solifenacin.
- The other ingredients are:
  Core tablet: Maize starch pregelatinized; lactose monohydrate; cellulose, microcrystalline; hypromellose; magnesium stearate.
  Film coating: Macrogol 6000; talc; hypromellose; titanium dioxide (E171); Iron oxide yellow (E172) - Solifenacin 5 mg; Iron oxide red (E172) - Solifenacin 10 mg

What Solifenacin looks like and contents of the pack
Solifenacin 5 mg is a white to yellowish rounded biconvex film-coated tablet with a diameter of 8.0-8.2 mm.
Solifenacin 10 mg is a pinkish rounded biconvex film-coated tablet with a diameter of 10.0-10.2mm.
Solifenacin is supplied in blister packs of 10, 30, 50, 90 and 100 film-coated tablets.
Not all pack sizes may be marketed.

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This leaflet was last updated in June 2024

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