PACKAGE LEAFLET: INORMATION 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Solifenacin succinate is and what it is used for
2. What you need to know before you take Solifenacin succinate
3. How to take Solifenacin succinate
4. Possible side effects
5. How to store Solifenacin succinate
6. Contents of the pack and other information

1. WHAT SOLIFENACIN SUCCINATE IS AND WHAT IT IS USED FOR

The active substance of Solifenacin succinate belongs to the group 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.

Solifenacin succinate 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 SUCCINATE

Do not take Solifenacin succinate
- if you are allergic (hypersensitive) to Solifenacin succinate or any of the other ingredients of Solifenacin succinate.
- 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 succinate 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 have ever had any of the above mentioned conditions before treatment with Solifenacin succinate starts.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Solifenacin succinate

- 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 is much higher (urinary retention).
- 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 disorder of the nervous system called autonomic neuropathy.

Inform your doctor if you have or have ever had any of the above mentioned conditions before treatment with Solifenacin succinate starts.
Before starting Solifenacin succinate, 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 is not to be used in children or adolescents under 18 years.

Other medicines and Solifenacin succinate
Please tell your doctor or pharmacist or nurse if you are taking or have recently taken or might take any other medicines.
It is especially important to inform your doctor if you are taking:
- other anticholinergic medicines, as the effects and side effects of both medications could be increased.
- cholinergics, as they can reduce the effect of Solifenacin succinate.
- medicines, like metoclopramide and cisapride, which make the digestive system work faster. Solifenacin succinate can reduce their effect.
- medicines, like ketoconazole, itraconazole (medicines used to treat fungal infections), ritonavir, nelfinavir (medicines used to treat HIV infections) and verapamil, diltiazem (medicines used to treat high blood pressure and heart diseases). These medicines decrease the rate at which Solifenacin succinate is broken down by the body.
- medicines like rifampicin (medicine used to treat tuberculosis and other bacterial infections) and phenytoin, carbamazepine (medicines used to treat epilepsy). They may increase the rate at which Solifenacin succinate is broken down by the body.
- medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis). Please ask your doctor if your medicine belongs to this group.

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

Pregnancy and breast-feeding and fertility
You should not use < Product Name > if you are pregnant unless your doctor thinks it is necessary. Do not use Solifenacin succinate if you are breast-feeding as Solifenacin succinate may pass 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 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 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 SUCCINATE

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

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

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

Use in children and adolescents
Solifenacin succinate is not to be used in children or adolescents under 18 years.

If you take more Solifenacin succinate than you should
If you have taken too much Solifenacin succinate or if a child has accidentally taken Solifenacin succinate, 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 succinate
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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Solifenacin succinate
If you stop taking Solifenacin succinate, 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.

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

- allergic attack, 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 succinate

Solifenacin succinate may cause the following other side effects:

Very common side effects (may affect more than 1 in 10 people)

– dry mouth

Common side effects (may affect up to one in ten people)

– blurred vision
– constipation, nausea, indigestion with symptoms such as abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort

Uncommon side effects (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 side effects (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 side effects (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), feeling your heartbeat, faster heartbeat
– voice disorder
– liver disorder
– muscle weakness
– renal disorder

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Yellow Card Scheme
Website: 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 SUCCINATE

This medicinal product does not require any special storage conditions.

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

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Solifenacin succinate contains

The active substance is Solifenacin succinate

Each film-coated tablet contains 5 mg solifenacin succinate.
Each film-coated tablet contains 10 mg solifenacin succinate.

The other ingredients are:
Tablet core: Maize starch, Lactose monohydrate, Hypromellose (E464), Magnesium stearate
Film-coating: Hypromellose (E464), Macrogol, Talc (E553b), Titanium Dioxide (E171) and Iron Oxide Yellow (E172) (only for 5 mg)
Iron Oxide Red (E172) (Only for 10 mg)

What Solifenacin succinate looks like and contents of the pack

Solifenacin succinate 5 mg film-coated tablets are round, light yellow and marked with the code “390” on one side of the tablets.

Solifenacin succinate 10 mg film-coated tablets are round, light pink and marked with the code “391” on one side of the tablets.

Solifenacin succinate 5 mg and 10 mg film-coated tablets are supplied in blister packs of 10, 30, 50, 90 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Glenmark Pharmaceuticals Europe Limited
Laxmi House, 2B Draycott Avenue, Kenton, Middlesex
HA3 0BU
United Kingdom

Manufacturer:

Zentiva s.a.
Bd. Theodor Pallady nr 50
032266 Bucuresti
Romania

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