

Package leaflet: Information for the user

Solfisan 5 mg film-coated tablets
Solfisan 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 Solfisan is and what it is used for
2. What you need to know before you take Solfisan
3. How to take Solfisan
4. Possible side effects
5. How to store Solfisan
6. Contents of the pack and other information

1. What Solfisan is and what it is used for

The active substance of Solfisan 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.

Solfisan 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 Solfisan

Do not take Solfisan:

- 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 allergic to solifenacin or any of the other ingredients of this medicine (listed in section 6)
- 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 Solfisan 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 Solfisan starts.

Warnings and precautions

Talk to your doctor or pharmacist before taking Solfisan

- 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).

Children and adolescents

Solfisan 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 Solfisan starts.

Before starting Solfisan, 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 Solfisan

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

Solfisan with food and drink

Solfisan can be taken with or without food, depending on your preference.

Pregnancy and breast-feeding

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

Do not use Solfisan if you are breast-feeding as solifenacin may get into your breast milk.

If you 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

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

Solfisan 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 Solfisan

Instructions for proper 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. The 10 mg tablet can be divided into equal doses.

If you take more Solfisan than you should

If you have taken too much Solfisan or if a child has accidentally taken Solfisan, 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 Solfisan

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 Solfisan

If you stop taking Solfisan, 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. If angioedema occurs, Solfisan should be discontinued immediately and appropriate therapy and/or measures should be taken.

Solfisan 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 an 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, feeling your heartbeat, faster heartbeat (Torsade de Pointes)

- 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.

To report any side effect(s):

• Saudi Arabia:

-The National Pharmacovigilance and Drug Safety Centre (NPC)

oFax: +966-11-205-7662

oCall NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.

oToll free phone: 8002490000

oE-mail: npc.drug@sfd.gov.sa

oWebsite: www.sfd.gov.sa/npc

•Other GCC States:

Please contact the relevant competent authority.

5. How to store Solfisan

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

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

-Store below 30 °C

6. Contents of the pack and other information

What Solfisan contains

- The active substance is solifenacin succinate.

Solfisan 5 mg: Each Solfisan film-coated tablet contains 5 mg solifenacin succinate equivalent to 3.8 mg solifenacin.

Solfisan 10 mg: Each Solfisan film-coated tablet contains 10 mg solifenacin succinate equivalent to 7.5 mg solifenacin.

- The other ingredients are:

Lactose monohydrate

Maize starch

(Maize) starch, (partially) pregelatinised

Magnesium stearate

Water, purified

Coating

5 mg:

Hypromellose 5cp

Titanium dioxide (E171)

Macrogol 8000

Talc

Iron oxide yellow (E172)

Water, purified

What Solfisan looks like and contents of the pack

Solfisan 5 mg: light yellow, round, biconvex film coated tablets with a diameter of 5.8 mm

Solfisan 10 mg: light pink, round, biconvex film coated tablets with score line on one side and plain on the other and with a diameter of 7.9 mm. The tablet can be divided into equal halves.

Solfisan tablets are supplied in blister packs of 30 tablets.

Marketing Authorization Holder & Manufacturer:

AJA Pharmaceutical Industries Company, Ltd.

Hail Industrial City MODON, Street No 32

PO Box 6979, Hail 55414

Kingdom of Saudi Arabia

This leaflet was last revised in 05/2018

This is a Medicament

-Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

-Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

-The doctor and the pharmacist are the experts in medicines, their benefits and risks.

-Do not by yourself interrupt the period of treatment prescribed for you.

-Do not repeat the same prescription without consulting your doctor.

-Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists