

Package leaflet: Information for the patient

Urisol 5 mg Film-Coated Tablets

Urisol 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.

What is in this leaflet

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

1. What Urisol is and what it is used for

The active substance of Urisol 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.

Urisol 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 Urisol

Do not take Urisol

- 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 Urisol 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 Urisol starts.

Warnings and precautions

Talk to your doctor before taking Urisol

- 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).

If any of these apply to you, talk to your doctor.

Children and adolescents

Urisol is not to be used in children or adolescents under 18 years.

Before starting Urisol, 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 Urisol

Tell your doctor or pharmacist if you are taking or have recently taken or might take other medicines without a prescription.

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

Urisol with food and drink

Urisol can be taken with or without food.

Pregnancy and breast-feeding

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

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

Ask your doctor or pharmacist before taking this medicine.

Driving and using machines

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

Urisol contains lactose

If you have been told by your doctor that you have a rare hereditary problem of galactose intolerance, lapp lactase deficiency or glucose-galactose malabsorption you should not use this medicine.

3. How to take Urisol

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 Urisol than you should

If you have taken more of this medicine than you should or if a child has accidentally taken Urisol, contact your doctor or pharmacist immediately.

You may experience symptoms of overdose which 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 Urisol

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 Urisol

If you stop taking Urisol, 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 consult 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, Urisol should be discontinued immediately and appropriate therapy and/or measures should be taken.

Urisol may cause the following other side effects:

Very common: dry mouth.

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

Uncommon: 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: lodging of a large amount of hardened stool in the large intestine (faecal impaction); buildup of urine in the bladder due to inability to empty the bladder (urinary retention); dizziness, headache; vomiting; itching, rash.

Very rare: hallucinations, confusion; allergic rash.

Not known: 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; muscle weakness; renal disorder.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Urisol

- Keep this medicine out of the sight and reach of children.
- Do not use Urisol 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.
- Store in the original package in order to protect from light and humidity.
- Do not use any Urisol pack that is damaged.
- Do not throw away any medicines via wastewater. 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 Urisol contains

- The active substance is solifenacin succinate 5 mg or 10 mg.
- The other ingredients are starch, lactose, hypromellose (E 464), magnesium stearate, macrogol, titanium dioxide (E 171) and iron oxide (E 172).

What Urisol looks like and contents of the pack

Urisol 5 mg tablets are round, light yellow tablets.

Urisol 10 mg tablets are round, light pink tablets.

Urisol tablets are supplied in blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

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Urisol 5 mg tablets Reg N° Lebanon 150416/1

Urisol 10 mg tablets Reg N° Lebanon 150516/1

This is a medicament

- A 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 experts in medicine, its 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.