

Regurin[®] XL



PACKAGE LEAFLET: INFORMATION FOR THE USER

60 mg prolonged-release capsules, hard
Trospium chloride

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Regurin XL is and what it is used for
2. Before you take Regurin XL
3. How to take Regurin XL
4. Possible side effects
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6. Further information

1. WHAT REGURIN XL IS AND WHAT IT IS USED FOR

Regurin XL is a medicine used for the relaxation of the muscles of the bladder. It is used for the treatment of symptoms associated with involuntary loss of urine (wetting) and/or increased frequency of urination and/or urgency of urination in patients with an overactive bladder.

2. BEFORE YOU TAKE REGURIN XL

Do not take Regurin XL

- If you have ever had an allergic reaction to trospium chloride or any of the other ingredients of Regurin XL (An allergic reaction can be a rash, itchiness or shortness of breath.). For the list of ingredients in Regurin XL, please see section 6.
- If you suffer from any of the following:
 - urinary retention, i.e. blockage of the urinary tract,
 - the eye condition narrow-angle glaucoma,
 - abnormal/faster than normal heart beats,
 - myasthenia gravis (a disorder that causes muscle fatigue),
 - a severe gastro-intestinal condition, such as toxic megacolon,
 - problems with your kidneys,
 - severe problems with your liver.

Take special care with Regurin XL

If you suffer from any of the following:

- any type of stomach or bowel obstruction,
- difficulties in passing urine and/or a poor stream of urine (male prostate disorders),
- neuropathy, i.e. nerve damage,
- a hernia of the diaphragm with inflammation of the oesophagus due to reflux of gastric acid (hiatus hernia associated with reflux oesophagitis). This is usually associated with heartburn which worsens on bending or lying down,
- an overactive thyroid,
- any heart conditions, such as coronary artery disease or congestive heart failure,
- any liver problems.

Talk to your doctor before starting your treatment with Regurin XL if you think any of these might apply to you.

Patients with liver disorders

You should talk to your doctor if you have a liver disorder. Patients with severe liver disorders should not take this medicine.

Patients with kidney disorders

You should talk to your doctor if you have a kidney disorder. Patients with kidney disorders should not take this medicine.

Children under the age of 18 years

Do NOT give Regurin XL to children under 18 years of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor in particular if you are taking any of the following medicines:

- certain antidepressants e.g. amitriptyline or imipramine
- some medicines for the treatment of asthma that may accelerate the heart rate (e.g. salbutamol)
- other medicines with anticholinergic action (such as those used to treat Parkinson's disease, asthma and

stomach cramps)

- metoclopramide – medicine used for nausea and vomiting
 - medicines containing guar, colestipol or colestyramine.
- Please note that this information may also apply to medicines that you have used recently.

Pregnancy and breast-feeding

Since there is no experience with trospium chloride during pregnancy and breast feeding, Regurin XL should be taken during pregnancy and breast-feeding only if your doctor considers it absolutely necessary.

Driving and using machines

Regurin XL can cause blurred vision. If you experience this, do not drive or use any tools or machines.

Important information about some of the ingredients of Regurin XL

This medicine contains sucrose. If you know that you have an intolerance to certain sugars, please take Regurin XL only after consultation with your doctor.

3. HOW TO TAKE REGURIN XL

Please always take Regurin XL as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual dose unless otherwise prescribed by your doctor

Unless otherwise prescribed by your doctor, the usual daily dose is one Regurin XL prolonged-release capsule.

Method of administration

Swallow one prolonged-release capsule whole with a glass of water. Take the capsule one hour before a meal on an empty stomach.

Duration of administration

Your doctor will determine the duration of treatment. The need for continued treatment should be checked at regular intervals of 3 – 6 months.

Patients with a kidney disorder should consult their doctor and not take this medicine.

Patients with a liver disorder should consult their doctor before taking this medicine.

If you take more Regurin XL than you should

If you have taken too much Regurin XL you should contact your doctor or go to the nearest hospital casualty department immediately.

If you forget to take Regurin XL

If you forget to take a capsule, take your capsule as soon as you remember, but do not take more than one capsule in one day. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Regurin XL

Your symptoms may return if you stop taking Regurin XL before recommended by your doctor. Therefore, you should take Regurin XL for as long as prescribed by your doctor. Please consult your doctor if you wish to stop treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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4. POSSIBLE SIDE EFFECTS

Like all medicines, Regurin XL can cause side effects, although not everybody gets them.

The following "very rare" side effects below are important and will require immediate action if you experience them. You should stop taking Regurin XL and see your doctor immediately if the following symptoms occur:

- swelling of the face, tongue and windpipe which can cause great difficulty in breathing
- a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure.

The following side effects have been reported for Regurin XL prolonged-release capsules, hard in clinical trials:

Very common side effects, affects more than 1 user in 10

- dryness of the mouth.

Common side effects, affects 1 to 10 users in 100

- constipation, nausea, abdominal pain, indigestion,
- dry eyes, dry nose.

Uncommon side effects, affects 1 to 10 users in 1,000

- flatulence

Rare side effects, affects 1 to 10 users in 10,000

- difficulty emptying the bladder, urinary retention,
- fast heart rate, palpitations,
- difficulty seeing objects close-up,
- rash,
- general feeling of weakness.

Very rare side effects, affects less than 1 user in 10,000

- urinary tract infection,
- headache.

The following side effects have also been reported for trospium (trospium is the active ingredient of Regurin XL; it is not known if these side effects will also occur with the capsules that you have been prescribed): Difficulty in breathing, diarrhoea, chest pain, slight to moderate increase of certain liver values (serum transaminases), fast irregular heartbeat, joint or muscle pains, dizziness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE REGURIN XL

Keep out of the reach and sight of children.

Do not use Regurin XL after the expiry date which is stated on the blister and the container after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use Regurin XL if you notice that the package has been damaged or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Regurin XL contains

The active substance is: Trospium chloride.
Each prolonged-release capsule contains 60 mg trospium chloride.

The other ingredients are:

Capsule contents: Sucrose, Maize starch, Methyl acrylate-methyl methacrylate-methacrylic acid-copolymer, Ammonium hydroxide, Medium chain triglycerides, Oleic acid, Ethylcellulose, Titanium dioxide (E 171), Hypromellose, Macrogol 400, Polysorbate 80, Triethyl citrate, Talc

Capsule shell: Gelatin, Titanium dioxide (E 171), Yellow

iron oxide (E 172), Red iron oxide (E 172), Printing ink (Shellac glaze, Black iron oxide (E 172), Propylene glycol)

What Regurin XL looks like and contents of the pack

Regurin XL prolonged-release capsules, hard consist of a white-coloured and an orange-coloured part imprinted with SAN 60 and contain white to off-white pellets.

Regurin XL is available in packs containing 4 (sample), 7, 10, 14, 28, 30, 56, 60, 84, 90 and 10x28 prolonged-release capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Denmark	Spasmo-lyt Depot
Germany	Urivesc 60mg Retardkapseln
Finland	Spasmo-lyt Depot 60mg
United Kingdom	Regurin XL 60mg prolonged-release capsule, hard
Italy	Urivesc 60mg capsule rigide a rilascio prolungato
Luxemburg	Urivesc 60mg Retard- kapseln
Austria	Urivesc 60mg Retard- kapseln
Portugal	Urivesc SR
Spain	Urivesc 60mg cápsulas duras de liberación prolongada

This leaflet was last approved in August 2009.