

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Regurin® XL 60 mg prolonged-release capsules, hard trospium chloride

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. 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.

What is in this leaflet:

1. What Regurin XL 60 mg is and what it is used for
2. What do you need to know before you take Regurin XL 60 mg
3. How to take Regurin XL 60 mg
4. Possible side effects
5. How to store Regurin XL 60 mg
6. Contents of the pack and other information

1. What Regurin XL 60 mg is and what it is used for

Regurin XL 60 mg is a medicine used for the relaxation of the muscles of the urinary 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 urinary bladder.

2. What do you need to know before you take Regurin XL 60 mg

Do not take Regurin XL 60 mg:

- If you have ever had an allergic reaction to trospium chloride or any of the other ingredients of this medicine (listed in section 6). (An allergic reaction can be a rash, itchiness or shortness of breath.).

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Regurin XL 60 mg if you suffer from any of the following:

- any type of stomach or bowel obstruction,
- an impaired urine flow (e.g. in the case of benign tissue growth of the male prostate),
- neuropathy, i.e. nerve damage,
- a 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.

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 60 mg to children under 18 years of age.

Other medicines and Regurin XL 60 mg

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

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

- certain anti-depressants 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 (e.g. amantadine - used to treat Parkinson's disease)
- 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 and fertility

Since there is no experience with trospium chloride during pregnancy and breast feeding, Regurin XL 60 mg should be taken during pregnancy and breast-feeding only if your doctor considers it absolutely necessary.

Driving and using machines

Even when used as directed, this medicine can affect vision so that the ability to actively participate in road traffic, operate machines or work may be impaired. Therefore, do not drive motor vehicles, operate machines or perform other hazardous activities if you are suffering from blurred vision.

Regurin XL 60 mg contains sucrose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, such as sucrose, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say it is essentially 'sodium-free'

3. How to take Regurin XL 60 mg

Always take this medicine exactly as your doctor has told you. 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 60 mg prolonged-release capsule.

Method of administration

Swallow one prolonged-release capsule whole with a glass of water. Take the capsule at least one hour before 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 60 mg than you should

No symptoms and signs of intoxication in humans have been reported to date.

If you have taken too much Regurin XL 60 mg you should inform immediately a doctor or pharmacist who will decide on further measures.

If you forget to take Regurin XL 60 mg

Do not take a double dose to make up for a forgotten dose. Continue with the regular intake as described in the dosage directions.

If you stop taking Regurin XL 60 mg

Your symptoms may return if you stop taking Regurin XL 60 mg before recommended by your doctor. Therefore, you should take Regurin XL 60 mg 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported for Regurin XL 60 mg 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.

Other possible side effects, for which the frequency is not known

- sporadic cases of hallucination, confusion and agitation have occurred mostly in elderly patients and can be facilitated by neurological diseases and/or other drugs, with a similar mechanism of action taken at the same time.

The following side effects have also been reported for trospium (trospium is the active ingredient of Regurin XL 60 mg; 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.

The following “very rare” side effects below are important and will require immediate action if you experience them. You should stop taking Regurin XL 60 mg 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.

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.

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 (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Regurin XL 60 mg

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 and the container after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine 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. Content of the pack and other information

What Regurin XL 60 mg 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, Sodium dodecylsulphate, 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)

See section 2 ‘Regurin XL 60 mg contains sucrose and sodium.’

What Regurin XL 60 mg looks like and contents of the pack

Regurin XL 60 mg 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 60 mg is available in packs containing 4 (sample), 7, 10, 14, 28, 30, 56, 60, 84, 90, 100 and 10x28 prolonged-release capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan Products Ltd.,
Station Close,
Potters Bar,
Hertfordshire,
EN6 1TL, UK

Manufacturer

Madaus GmbH
51101 Köln
Germany

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

Denmark Spasmo-lyt Depot 60 mg
Germany Urivesc
Finland Spasmo-lyt Depot 60 mg
United Kingdom Regurin XL 60 mg prolonged-release capsule, hard
Italy Urivesc
Luxemburg Urivesc
Austria Urivesc
Portugal Urivesc
Spain Urivesc

This leaflet was last revised in September 2020