PACKAGE LEAFLET: INFORMATION FOR THE USER

Regurin® 20 mg coated tablets
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 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.

In this leaflet:

1. What Regurin is and what it is used for

Regurin is a medicine used for the relaxation 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 imperative urge of urination in patients with hyperactive urinary bladder (involuntary urge of urination and
voiding problems of unknown origin or due to nervous system disorders).

2. What you need to know before you take Regurin

Do not take Regurin
- 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Regurin
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,

- any kidney problems.

Patients with liver disorders
You should not take Regurin if you have a serious liver disorder. If you have a slight to moderate liver impairment you should talk to your doctor before taking this medicine.

Patients with kidney disorders
If you have a kidney disorder you should talk to your doctor before taking this medicine. Your doctor will, if necessary, give you a lower dose (see dosage instructions in Section 3 – How to take 'For patients with kidney disorders).

Children under the age of 12 years
Do not give Regurin to children under the age of 12 years.

Other medicines and Regurin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Inform your doctor in particular if you are taking any of the following medicines:
- certain medicines for the treatment of abnormal sadness (depression), e.g. amitriptyline or imipramine
- medicines for the treatment of asthma that may accelerate the heart rate (e.g. salbutamol)
- other medicines with anticholinergic action (e.g. amantadine)
- medicines for the stimulation of motility of the gastro-intestinal tract which are used to treat impaired gastric emptying or complaints due to reflux of gastric acid (reflux disease), e.g. metoclopramide
- medicines containing the substances guar, colestipol or cholestyramine which should not be taken simultaneously with Regurin.

Please note that this information may also apply to medicines that you have used recently.

Regurin with food and drink
As high fat diets can affect the action of Regurin, the medicine should be taken before meals on an empty stomach.

Pregnancy, breast-feeding and fertility
Since there is no experience with this medicine during pregnancy and breast-feeding, your doctor will decide if this medicine is suitable for you. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
Even when used as directed, this medicine can alter sharp-sightedness so that the ability to actively participate in road traffic, operate machines or work without secure support is impaired. Therefore, do not drive motor vehicles, operate machines or perform other hazardous activities if you are suffering from blurred vision.

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

This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems if you have coeliac disease. One tablet contains no more than 57 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.

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

3. HOW TO TAKE REGURIN

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 for adults and children over the age of 12 years is one Regurin tablet taken twice daily (equivalent to 40 mg of trospium chloride daily).

Method of administration
Swallow one tablet whole with a glass of water. Take the tablet before a meal on an empty stomach.

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

For patients with kidney disorders
If your kidney function is slightly to moderately impaired, no dose adjustment of Regurin is required.
In severely impaired kidney function, the dose should be reduced to one tablet once daily or every second day (equivalent to 20 mg of trospium chloride daily or every second day).
You should consult with your doctor about the correct dose for you.

If you take more Regurin than you should
No symptoms and signs of intoxication in humans have been reported to date.
If you have taken more Regurin than the amount prescribed you should contact a doctor or pharmacist immediately.

If you forget to take Regurin
If you miss a dose of Regurin, simply carry on with the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Regurin
Your symptoms may return if you stop the intake of Regurin before recommended by your doctor. Therefore, you should take Regurin 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The side effects occurring most frequently are typical for this kind of medicine and comprise dry mouth, dyspepsia and constipation.

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

- swelling of the face, tongue and windpipe which can cause great difficulty in breathing (affects less than 1 user in 10,000)
- a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure (frequency unknown)
- life-threatening hypersensitivity reactions with large-scale detachment of the skin and/or mucous membranes (frequency unknown).

The following side effects have been reported for Regurin:

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 (dyspepsia).

Uncommon side effects, affects 1 to 10 users in 1,000
- fast heart rate (tachycardia),
- headache,
- flatulence, diarrhoea,
- chest pain.

Rare side effects, affects 1 to 10 user in 10,000
- dizziness
- difficulty emptying of the bladder, urinary retention,
- difficulty seeing objects close-up,
- rash,
- joint and muscle pains.

Other possible side effects, for which the frequency is not known
- accelerated and irregular heart rate (tachyarrhythmia),
- difficulty in breathing,
- itchiness, nettle-rash (hives),
- general feeling of weakness (asthenia),
- slight to moderate increase of certain liver values (serum transaminases),
- 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.

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 to HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE REGURIN

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

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

Storage conditions
This medicinal product does not require any special storage conditions.

Do not use Regurin if you notice that the pack or any of the tablets are damaged.

Do not throw away medicines 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. Contents of the pack and further information

What Regurin contains

The active substance is trospium chloride.

Each coated tablet contains 20 mg trospium chloride.

The other ingredients are:
Tablet core: Wheat starch, microcrystalline cellulose, lactose monohydrate, povidone (K29-32), croscarmellose sodium, stearic acid, silica colloidal anhydrous, talc.
Tablet coating: Sucrose, carmellose sodium, talc, silica colloidal anhydrous, calcium carbonate (E 170), macrogol 8000, titanium dioxide (E 171), iron oxide hydrate yellow (E 172), white beeswax, carnauba wax.
See section 2 'Regurin contains lactose, sucrose, wheat and sodium'.

What Regurin looks like and contents of the pack
Regurin tablets are brownish-yellow, glossy coated tablets with a diameter of approximately 7 mm.

Regurin is available in packs containing 2, 20, 28, 30, 40, 50, 56, 60, 90, 100, 120, 150, 200, 500, 600, 1000, 1200 and 2000 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Viatris Healthcare Limited
Damastown Industrial Park
Mulhuddart
Dublin 15,
DUBLIN,
Ireland

The medicine is authorised in the Member States of the EEA under the following names:

Denmark	Spasmo-lyt
Germany	Urivesc 20 mg
Finland	Spasmo-lyt plus 20 mg
France	Chlorure de Trospium Madaus 20 mg
Greece	Urivesc
United Kingdom	Regurin 20 mg tablets
Ireland	Regurin 20 mg tablets
Italy	Urivesc
Luxemburg	Urivesc 20 mg
Austria	Urivesc 20 mg-Dragées
Portugal	Urivesc BID

This leaflet was last approved in January 2023