

PACKAGE LEAFLET: INFORMATION FOR THE USER

Regurin® 20mg coated tablets

(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.

The name of your medicine is Regurin 20mg coated tablets but will be referred to as Regurin throughout this leaflet.

In this leaflet

1. What Regurin is and what it is used for
2. Before you take Regurin
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4. Possible side effects
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1. WHAT REGURIN IS AND WHAT IT IS USED FOR

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

2. 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 Regurin (An allergic reaction can be a rash, itchiness or shortness of breath). For the list of ingredient of Regurin, please see section 6.
- If you suffer from any of the following
 - Urinary retention i.e. blockage of the urinary track,
 - The eye condition narrow-angle glaucoma,
 - Abnormal/faster than normal heart beat,
 - Myasthenia gravis (a disorder that causes muscle fatigue),
 - A severe gastro-intestinal condition, such as a toxic megacolon.

Take special care with Regurin

If you suffer from any of the following:

- Any type of stomach or bowel obstruction
- difficulties in passing urine and /or 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,
- any kidney problems.

If any of the above apply to you, it is important that you speak to your doctor or pharmacist before taking Regurin and they will decide what to do.

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 disorder').

Children under the age of 12 years

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

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 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 (such as those used to treat Parkinson's disease, asthma and stomach cramps)
- 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 substance guar, colestipol or cholestyramine which should not be taken simultaneously with Regurin.

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

Taking 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 and breast-feeding

Please tell your doctor if you are pregnant, think you might be pregnant, or are breast-feeding. Your doctor will decide if the medicine is suitable for you.

Driving and using machines

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

Important information about some of the ingredient of Regurin

This product contains lactose (milk sugar) and sucrose (sugar). If you have been told by your doctors that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

This product also contains wheat starch. If you suffer from wheat allergy (different from coeliac disease) you should not take this product. Regurin is suitable for patients with coeliac disease.

3. HOW TO TAKE REGURIN

Always take Regurin exactly 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 for adults and children over the age of 12 years is one Regurin tablets taken twice daily (equivalent to 40mg 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 moderate 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 20mg 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

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

If you forget to take Regurin

If you forget to take a tablet, take your tablet as soon as you remember, but do not take more than two tablets in one day (unless prescribed otherwise)

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The side effects occurring most frequently are typical for this kind of medicine and compromise 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)
- Serious reactions with severe blistering and peeling of the skin and/or mucous membranes like for example in the lips, eyes, mouth, nose and genitals. This may be accompanied by a fever and chills, aching muscles and generally feeling unwell (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, affect 1 to 10 users in 1000

- fast heart rate (tachyarrhythmia)
- headache
- flatulence, diarrhoea
- chest pain

Rare side effects, affect 1 to 10 users 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 on weakness (asthenia)
- slight to moderate increase of certain live 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.

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

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

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 contains

Each coated tablet contains 20mg trospium chloride as the active ingredient.

The other ingredients are:

Tablet core: wheat starch, microcrystalline cellulose, lactose monohydrate, povidone, croscarmellose sodium, stearic acid, silica colloidal anhydrous, talc

Tablet coating: sucrose, carmellose sodium, talc, silica colloidal anhydrous, calcium carbonate (E170), macrogol 8000, titanium dioxide (E171), yellow iron oxide (E172), white bees wax, and carnauba wax.

Note for diabetics: One tablet corresponds to 0.06g carbohydrate (equivalent to 0.005 bread units).

What Regurin looks like and contents of the pack

The tablets are circular, biconvex, brownish-yellow, glossy coated and unprinted.

This product is available in blister packs containing 60 tablets.

Manufactured by: Madaus GmbH, 51101 Cologne, Germany.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

Regurin® 20mg Coated Tablets
PPA: 1328/207/001

Leaflet date: 09.08.2013

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