

Package Leaflet: Information for the user

Trospium 20mg film-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 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. See section 4.

What is in this leaflet:

1. What Trospium 20mg film-coated tablets are and what they are used for
2. What you need to know before you take Trospium 20mg film-coated tablets
3. How to take Trospium 20mg film-coated tablets
4. Possible side effects
5. How to store Trospium 20mg film-coated tablets
6. Contents of the pack and other information

1. What Trospium 20mg film-coated tablets are and what they are used for

Trospium 20mg film-coated tablets 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 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 Trospium 20mg film-coated tablets

Do not take Trospium 20mg film-coated tablets

- if you are allergic 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 your pharmacist before taking Trospium 20mg film-coated tablets 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 (see “Patients with liver disorders” below)
- any kidney problems (see “Patients with kidney disorders” below).

Patients with liver disorders

You should not take Trosipium 20mg film-coated tablets 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 Trosipium 20mg film-coated tablets – *Patients with kidney disorders*”).

Children under 12 years of age

Do not give this medicine to children under 12 years of age.

Other medicines and Trosipium 20mg film-coated tablets

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 Trosipium 20mg film-coated tablets.

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

Trosipium 20mg film-coated tablets with food and drink

As high fat diets can affect the action of Trosipium 20mg film-coated tablets, this medicine should be taken before meals on an empty stomach.

Pregnancy and breast-feeding

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.

Since there is no experience with trosipium chloride during pregnancy and breast-feeding, Trosipium 20mg film-coated tablets should be taken during pregnancy and breast-feeding only if your doctor considers it absolutely necessary.

Driving and using machines

This medicine can cause blurred vision. Do not drive motor vehicles, operate machines or perform other hazardous activities if you suffer from blurred vision after taking this medicine.

Trosipium 20mg film-coated tablets contain lactose (milk sugar) and sucrose (sugar).

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

3. How to take Trospium 20mg film-coated tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose for adults and children over 12 years of age is one film-coated tablet twice a day (equivalent to 40 mg of trospium chloride per day), unless otherwise prescribed by your doctor.

Patients with kidney disorders

If your kidney function is slightly to moderately impaired, no dose adjustment 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.

Use in children

Do not give this medicine to children under 12 years of age.

Method of administration (How to take the tablets)

Swallow one film-coated tablet whole with a glass of water. Take the tablet before a meal on an empty stomach.

Duration of treatment

Your doctor will want to assess your treatment every 3 to 6 months, to decide whether this medicine is still the best one for you.

If you take more Trospium 20mg film-coated tablets than you should

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

If you have taken more Trospium 20mg film-coated tablets than the amount prescribed, you should contact a doctor or pharmacist immediately.

If you forget to take Trospium 20mg film-coated tablets

If you miss a dose of Trospium 20mg film-coated tablets, 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 Trospium 20mg film-coated tablets

Your symptoms may return if you stop the intake of Trospium 20mg film-coated tablets before recommended by your doctor. Therefore, you should take this medicine 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 below are **serious and will require immediate action** if you experience them. **Stop taking Trospium 20mg film-coated tablets and see your doctor immediately if the following symptoms occur:**

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

The following side effects have also been reported for Trospium 20mg film-coated tablets:

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):

- indigestion (dyspepsia)
- constipation
- abdominal pain
- feeling sick (nausea)

Uncommon side effects (affects 1 to 10 users in 1,000):

- fast heart beat (tachycardia)
- headache
- wind (flatulence)
- diarrhoea
- chest pain

Rare side effects (affects 1 to 10 users in 10,000):

- dizziness
- difficulty seeing objects close-up / blurred vision
- difficulty emptying the bladder, urinary retention
- rash
- joint pain (arthralgia)
- muscle pain (myalgia)

Other possible side effects, for which the frequency is unknown (cannot be estimated from the available data)

- accelerated and irregular heart rate (tachyarrhythmia)
- difficulty in breathing (dyspnoea)
- itchiness, nettle rash (hives, urticaria)
- general feeling of weakness (asthenia)
- slight to moderate increase of certain liver values (serum transaminases)
- sporadic cases of hallucinations, 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 via:

HPRA Pharmacovigilance
Earlsfort Terrace

IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trospium 20mg film-coated tablets

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

Do not use Trospium 20mg film-coated tablets after the expiry date which is stated on the blister and on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. 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 Trospium 20mg film-coated tablets contain

- The active substance is trospium chloride. Each film-coated tablet contains 20 mg trospium chloride.
- The other ingredients are :
Core: Cellulose Microcrystalline, Lactose monohydrate, Maize starch, Povidone, Croscarmellose sodium, Silica Colloidal Anhydrous, Magnesium Stearate;
Coating: Sucrose, Copovidone, Titanium Dioxide (E171), Macrogol 6000, Macrogol 400, Talc, Hypromellose (E464), Iron Oxide Yellow (E172), Iron Oxide Red (E172).

What Trospium 20mg film-coated tablets look like and contents of the pack

Trospium 20mg film-coated tablets are supplied as:
brownish yellow to light brown, round, biconvex film-coated tablets, debossed with “L” on one side and “1” on other side.

Trospium 20mg film-coated tablets are available in PVC/PVDC-Aluminium blisters of 30, 50, 60, 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited
Laxmi House, 2B Draycott Avenue
Harrow, Middlesex HA3 0BU, UK

Manufacturers:

Glenmark Pharmaceuticals s.r.o
Fibichova 143,566 17 Vysoké Mýto,
Czech Republic

Glenmark Pharmaceuticals Europe Limited

Building 2, Croxley Green Business Park,
Croxley Green, Hertfordshire, WD18 8YA,
United Kingdom

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

France	Trospipharm 20mg comprimé pelliculé
Germany:	Trospiumchlorid Glenmark 20mg Filmtabletten
Ireland	Trospium 20mg film-coated tablets
United Kingdom	Trospium chloride 20mg film-coated tablets

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