Trospium chloride 20mg Film-coated Tablets

Patient Information Leaflet

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

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

Trospium chloride 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 chloride 20mg film-coated tablets

Do not take Trospium chloride 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 chloride 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 Trospium chloride 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 Trospium chloride 20mg film-coated tablets – *Patients with kidney disorders*”).

Children under 12 years of age
The safety and efficacy of Trospium chloride 20mg film-coated tablets in children under 12 years of age has not been established. No data are available.

Other medicines and Trospium chloride 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 Trospium chloride 20mg film-coated tablets.

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

Trospium chloride 20mg film-coated tablets with food and drink
As high fat diets can affect the action of Trospium chloride 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 trospium chloride during pregnancy and breast-feeding, Trospium chloride 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.

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

If you forget to take Trospium chloride 20mg film-coated tablets
If you miss a dose of Trospium chloride 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 chloride 20mg film-coated tablets
Your symptoms may return if you stop the intake of Trospium chloride 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 chloride 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 chloride 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Trospium chloride 20mg film-coated tablets
- Keep out of the sight and reach of children.
- Do not use after the expiry date printed on the carton and blister label after 'EXP'. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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) Contents of the pack and other information
What Trospium chloride 20mg film-coated tablets contain:
The active substance is trospium chloride. Each film-coated tablet contains 20mg 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, talc, Opadry yellow 03B82720 (hypromellose, macrogol 400, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172)).

What Trospium chloride 20mg film-coated tablets look like and contents of the pack
Trospium chloride 20mg Film-coated tablets are brownish yellow to light brown, round, biconvex film-coated tablets, debossed with "L" on one side and "1" on other side.

They are available in blister packs containing 30 and 60 tablets.

PL 46420/0310 Trospium chloride 20mg Film-coated tablets **POM**

Who makes and repackages your medicine?
Your medicine is manufactured by Glenmark Pharmaceuticals Europe Limited, Building 2, Croxley Green Business Park, Croxley Green, Hertfordshire, WD18 8YA, United Kingdom
or
Glenmark Pharmaceuticals s.r.o., Fibichova 143, 566 17 Vysoke Myto, Czech Republic.
Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 18.05.2026

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