

## PATIENT INFORMATION LEAFLET

## TROSPIUM CHLORIDE 20 MG FILM-COATED TABLETS

Read all of this leaflet carefully 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What is Trospium Chloride and what is it used for?
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**1. What is Trospium Chloride and what is it used for?**

The name of this medicine is Trospium Chloride 20 mg Film-Coated Tablets. Trospium Chloride 20 mg Film-Coated Tablets are used to treat the symptoms of overactive bladder conditions.

For example, needing to go to the toilet frequently, needing to suddenly rush to the toilet and/or having difficulty getting there in time and wetting yourself.

**2. Before you take Trospium Chloride**

**Do not take Trospium Chloride if your doctor has told you that you have:**

- An allergic reaction to Trospium Chloride or any of the ingredients listed in section 6. (An allergic reaction can be a rash, itchiness or shortness of breath).
- Urinary retention i.e. urination occurs less frequently than normal.
- The eye condition glaucoma.
- Abnormal/faster than normal heart beats.
- Myasthenia gravis (a disorder which causes muscle fatigue).
- A severe gastro-intestinal condition, such as toxic megacolon.

**Do NOT give this product to children under 12 years of age.**

**Special Precautions**

Check with your doctor or pharmacist before taking your medicine if you suffer from any of the following:

- Any type of stomach or bowel obstruction.
- Blockage of the urinary tract.
- 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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

**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. Taking some medicines together can be harmful.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Amantadine (used in the treatment of Parkinson's disease or as protection against influenza).
- Tricyclic antidepressants.
- A 'sympathomimetic' (one of a class of drugs which can increase the heart rate).
- Metoclopramide (a drug which increases the rate of movement of digested food through your gastro-intestinal system).
- Guar gum (sometimes used in a type of diabetes).
- Cholestyramine or colestipol (drugs used to reduce the levels of certain fats in your bloodstream).

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

**Pregnancy and breast feeding**

If you are pregnant or breast feeding talk to your doctor before taking Trospium Chloride.

**Driving and using machines**

Trospium Chloride does not affect your ability to drive or use machines.

**Important information about some of the ingredients of Trospium Chloride**

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

**3. How to take Trospium Chloride**

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with them if you are not sure. Trospium Chloride should be taken orally.

**Adults and children 12 years or over:**

The usual dose for adults is one tablet twice a day. Doctors may prescribe different doses to this. For example, patients with kidney problems may take a reduced dose of one tablet per day or one tablet every second day. Read the pharmacist's label it will tell you exactly how many you should take.

The tablets should be swallowed whole with a glass of water, **before meals** on an empty stomach.

If symptoms persist, contact your doctor or pharmacist. Your doctor will want to **assess your treatment every 3 to 6 months**, to decide whether this medicine is the best one for you.

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**Children under 12 years of age:**

This product should not be taken by children under 12 years of age.

**If you take more Trospium Chloride than you should:**

It is always important to follow the recommended dose on the label. If too many tablets are taken by accident, contact your doctor or hospital immediately.

**If you forget to take Trospium Chloride:**

Take the dose as soon as you remember to take it and then continue on as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Trospium Chloride can have side effects, although not everybody gets them.

The side effects occurring most frequently are typical for this kind of medicine and comprise of dry mouth, dyspepsia and constipation.

To give you an idea of how many patients might get side effects, they have been listed as very common, common, uncommon, rare, very rare and other side effects. These mean the following:

Very common	More than 1 in 10 people.
Common	Up to 1 in 10 people.
Uncommon	Up to 1 in 100 people.
Rare	Up to 1 in 1,000 people.
Very rare	Fewer than 1 in 10,000 people.
Other side effects	The frequency is not known.

The following side effects below are serious and will require immediate action if you experience them. You should **stop taking Trospium Chloride 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 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).

Less serious side effects:

**Very Common:**

- Dry mouth

**Common:**

- Constipation
- Nausea
- Abdominal pain
- Indigestion (dyspepsia)

**Uncommon:**

- Fast heart rate (tachycardia)
- Headache
- Flatulence
- Diarrhoea
- Chest pain

**Rare:**

- Dizziness
- Difficulty emptying the bladder
- Urinary retention
- Difficulty seeing objects close-up
- Rash
- Joint and muscle pains

**Other Side Effects:**

- 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 enzyme levels
- 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom  
Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Ireland  
HPRA Pharmacovigilance,  
Earlsfort Terrace, IRL – Dublin 2  
Tel: +353 1 6764971 Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie) E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

**5. Storing Trospium Chloride**

Keep all medicines out of the reach and sight of children.

Do not use Trospium Chloride after the expiry date on the carton and blister. The expiry date refers to the last day of that month.

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 Trospium Chloride contains:**

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

The tablets also contain maize starch, lactose monohydrate, microcrystalline cellulose, povidone K30, sodium starch glycolate, magnesium stearate, macrogol 400, hypromellose and iron oxide yellow (E172).

**What Trospium Chloride looks like and contents of the pack:**

Trospium Chloride tablets are round yellow tablets.

Trospium Chloride tablets are available in boxes of 20 or 60 tablets. Not all pack sizes may be marketed.

**Marketing authorisation holder:**

Auden Mckenzie (Pharma Division) Ltd.  
Whiddon Valley, Barnstaple,  
North Devon, EX32 8NS, UK

**Manufacturer:**

Tiofarma  
Benjamin Franklinstraat 9, 3261 LW  
Oud-Beijerland, Netherlands

This leaflet was last revised in January 2016.

**For information in large print, on tape, on CD or in Braille, phone +44 (0)1271 385 257.**