# PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

**The medicine is dispensed with a doctor's prescription only**
**TroSpas 15 mg**
**TroSpas 30 mg**
**Tablets**
**The active ingredient and its quantity:**
Trospium Chloride 15 mg
Trospium Chloride 30 mg
For a list of inactive ingredients and allergens in the preparation see section 6.
**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
**This medicine is intended for adults and children above 12 years of age.**

## 1. What is the medicine intended for?

This medicine is used for treatment of impaired function of the urinary bladder, manifested by urgency and/or frequency and/or urinary incontinence.
**Therapeutic group:** anticholinergic, antimuscarinic.

## 2. Before using the medicine:

**☒ Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – additional information).

You are suffering from:
- Urinary retention (urination is less frequent than usual).
- Narrow-angle glaucoma.
- Arrhythmia (rapid and irregular heartbeat).
- Myasthenia gravis.
- Severe chronic inflammatory bowel disease (Crohn's disease, ulcerative colitis).
- Toxic megacolon.
- Renal disease requiring dialysis (creatinine clearance < 10 ml/min/1.73 $m^2$).

**Special warnings regarding the use of the medicine**
**❗ Before starting treatment with TroSpas tell the doctor if you are suffering or have suffered in the past from:**
- An obstruction in the digestive system (e.g. due to narrowing of the pylorus - pyloric stenosis).
- Urine outflow obstruction or disturbance that may cause residual urine.
- Hiatus hernia with an inflammation of the esophagus.
- Disorders of the autonomic nervous system (autonomous neuropathy).
- Situations in which a rapid heart rate is not desirable, such as overactive thyroid, impaired function of the heart and/or blood vessels, coronary heart disease, narrowing of the coronary arteries, heart failure.

If you are suffering from a serious liver disease, you should refrain from taking TroSpas. If you are suffering from a mild to moderate liver disease, talk to your doctor about it before taking this medicine.
Trospium chloride is excreted mainly via the kidneys. Elevated blood levels of the medicine have been observed in patients with severely impaired renal function. Therefore, even when kidney function is moderately impaired, treatment with this medicine should be commenced with caution.
**Tests that should be performed before using the medicine:**
A doctor's examination is required in order to determine the source of the bladder's dysfunction and to rule out organic causes such as heart or kidney disorders, chronic thirst (polydipsia), infections and tumors in the urinary system.
**Children**
TroSpas is not intended for children under 12 years of age.
**❗ If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist.**
The following effects may occur when taking the following medicines:
- An increase in the anticholinergic effect: amantadine (for Parkinson's disease), antidepressants (tricyclic), quinidine and disopyramide (antiarrhythmics), antihistamines (for allergies).
- An increase in the tachycardic effect: ß-sympathomimetics (used as cardiac medicines, medicines for asthma and contractions inhibitors).
- A reduction in the effect of the medicine: metoclopramide (for treatment of nausea) and cisapride (used to treat digestive disorders and reflux).

**❗ Other drug interactions**
Since TroSpas affects the digestive system (secretion of digestive juices), one cannot rule out the potential of TroSpas to affect drugs taken at the same time with TroSpas.
Taking medicines that contain substances such as Guar, Colestyramine and Colestipol at the same time with TroSpas is not recommended since the absorption of TroSpas may be reduced.
Metabolic interactions have only been investigated in vitro, but without findings. Considering the metabolism of the medicine, no metabolic interactions are expected.
**❗ Use of the medicine and food**
The medicine should be taken before a meal, on an empty stomach.
**❗ Use of the medicine and alcohol consumption**
During treatment with TroSpas, alcohol consumption should be avoided as much as possible.
**❗ Pregnancy, breastfeeding and fertility**
Animal studies have not provided any evidence of inducing congenital abnormalities as a result of using the medicine. Since there is no experience of use during pregnancy and lactation in humans, TroSpas should be used during pregnancy and lactation only after careful evaluation of the medicine's necessity.
If you are pregnant or breastfeeding, thinking you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking any medicine.
**❗ Driving and operating machinery**
Using the medicine may cause blurry vision, and so requires care when driving vehicles or operating dangerous machinery and in any activity that requires alertness. This effect is evident particularly in the beginning of treatment, following a change or increase in dosage and when taking this medicine with alcohol.
**❗ Important information about some ingredients of the medicine**
This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

## 3. How should you use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only.
The recommended dosage:
15 mg (one TroSpas 15 mg tablet or half a TroSpas 30 mg tablet), 3 times a day (morning, noon and evening).
Or
30 mg in the morning (two TroSpas 15 mg tablets or one TroSpas 30 mg tablet) and 15 mg in the evening (one TroSpas 15 mg or half a TroSpas 30 mg tablet).
Patients with impaired kidney function:
With severe renal failure (creatinine clearance 10-30 ml/min/ 1.73 $m^2$), do not exceed a maximal daily dosage of 15 mg.
Patients with impaired liver function:
There is no need to adjust the dosage in cases of mild and moderate impairment of liver function. The treatment is not recommended in cases of severe impairment in liver function.
Children: Treatment is not recommended for children under 12 years of age, due to lack of data about this age group.
**Do not exceed the recommended dose.**
**Method of administration:**
TroSpas 15 mg: swallow the tablet whole with a sufficient amount of water, at least one hour before a meal, on an empty stomach.
TroSpas 30 mg: swallow the tablet or half the tablet whole with a sufficient amount of water, at least one hour before a meal, on an empty stomach. Only TrosPas 30 mg tablets can be halved.
There is no information regarding crushing, pulverization or chewing of the tablets.
**Duration of treatment:**
Follow the treatment as recommended by the doctor. Consult the doctor every 3-6 months about continuing treatment with the medicine.
**If you have accidentally taken a higher dosage**, contact the doctor immediately. Possible signs of an overdose (anticholinergic symptoms) are: visual disturbances, increased heartbeat, extremely dry mouth and reddening of the skin, which can be treated with parasympathomimetic drugs such as neostigmine. In cases where increased intraocular pressure (glaucoma) occurs, pilocarpine drops can be used.
If you have taken an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor!
If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
If you stop taking the medicine: do not stop taking TroSpas without consulting a doctor.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

## 4. Side effects

As with any medicine, using TroSpas may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
**Discontinue treatment and contact a doctor immediately if any of the following occur:**
- Rash, itching, angioedema (swelling, usually in the face), breathing difficulties - since these symptoms may indicate an allergy to the medicine.
- Anaphylactic reaction due to sensitivity to the active ingredient - discontinue treatment and contact the doctor immediately.
- Difficulties in urination or urinary retention, weakness or chest pains.
- There are very few reports of severe skin reactions accompanied by bleeding and formation of blisters. It cannot be determined whether there is an association between these effects and TroSpas. If you experience one of these symptoms, contact a doctor immediately.

**Contact a doctor as soon as possible** if you experience blurred vision, disorders in liver function, rapid heart rate, palpitations (pounding heart) or irregular heart rate.
**Additional side effects:**
- Very common side effects (appear in more than one user out of ten) – dry mouth.
- Common side effects (appear in 1-10 users out of 100) – gastrointestinal disorders, constipation, abdominal pain and nausea.
- Uncommon side effects (appear in 1-10 users out of 1,000) – diarrhea, flatulence.

The following side effects have been observed in other products containing the active ingredient (trospium chloride): dry eyes, disturbed vision, dry nose, urinary tract infections, muscle and joint pains.
If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Storage: store at a temperature lower than 25°C.

## 6. Additional information

**In addition to the active ingredient the medicine also contains:**
Microcrystalline Cellulose PH101, Microcrystalline Cellulose PH102, Croscarmellose Sodium, Povidone K-25, Magnesium Stearate.
Coating: Hypromellose 2910, Titanium Dioxide, Macrogol 8000
**What does the medicine look like and what are the contents of the package:**
TroSpas 15 mg: A round, film-coated, white tablet embossed with "T" on one side.
TroSpas 30 mg: A round, film-coated, white tablet with a deep score line on one side.
TroSpas 15 mg and TroSpas 30 mg are marketed in a package containing 7, 10, 20, 30, 60 or 100 tablets. 7 or 10 tablets in every blister. Not all package sizes may be marketed.
**Marketing authorization holder, manufacturer and address:** CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.
This leaflet was revised in January 2022 in accordance with the Ministry of Health guidelines.
**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
TroSpas 15 mg: 159-75-34856
TroSpas 30 mg: 159-76-34857

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