

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

The medicine is dispensed with a doctor's prescription only

TROSMOLYT 20 mg

Film-Coated tablets

The active ingredient:

Tropium Chloride 20 mg

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and section 2 "Important information about some ingredients of the medicine".

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 treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for children under the age of 12.

1. What is the medicine intended for?

Trosmolyt 20 mg contains the active ingredient trospium chloride and is used for relaxation of the bladder.

The medicine is given for treatment of symptoms related to urinary incontinence (wetting) and/or frequent urination and urinary urgency in patients suffering from overactive bladder (overactivity of the bladder muscle from a nerve source or an unknown source).

Therapeutic class: Anticholinergic antimuscarinic.

2. Before using the medicine:

Do not use this medicine if:

- There is known sensitivity to one of the medicine's ingredients (sensitivity to the medicine may be manifested in rash, itching or shortness of breath) - for a list of inactive ingredients, see section 6.
- You are suffering from urinary retention (urination occurs less frequently than normal).
- You are suffering from narrow-angle glaucoma.
- You are suffering from a faster heart rate than normal.
- You are suffering from a severe muscle weakness (Myasthenia Gravis).
- You are suffering from severe problems in the digestive system, such as toxic megacolon.

Special warnings regarding the use of the medicine: Before treatment with Trosmolyt 20 mg, inform the doctor if:

- You are suffering from any type of gastric or intestinal obstruction.

- You are suffering from urinary tract obstruction and/or impaired urine flow (prostate disorders in men).
- You are suffering from neuropathy (nerve damage).
- You are suffering from hiatal hernia with esophageal reflux, which is usually accompanied by heartburn which worsens when lying down or bending over.
- You are suffering from overactivity of the thyroid.
- You are suffering from heart problems such as coronary heart disease or heart failure.
- You are suffering from a condition in which rapid heartbeat may be dangerous for you, such as overactive thyroid gland (hyperthyroidism).
- You are suffering from liver problems.
- You are suffering from kidney problems.

Patients with impaired hepatic function

Do not use the medicine if you are suffering from a severe liver disorder. Refer to your doctor before starting to use the medicine if you are suffering from mild to moderate liver impairment.

Patients with impaired kidney function

If you are suffering from kidney problems, tell your doctor before starting to use the medicine. Your doctor will prescribe you a lower dosage, if needed (see section 3 – "How should you use the medicine?"), under "In patients suffering from kidney problems").

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

Especially if you are taking:

- Medicines for treatment of depression conditions (e.g. amitriptyline or imipramine).
- Medicines for treatment of asthma which may increase heart rate (e.g. salbutamol).
- Other medicines with anticholinergic activity (for example medicines used for treatment of Parkinson's disease, asthma and stomach cramps).
- Medicines for stimulating the activity of the digestive system which are used for treatment of delayed gastric emptying or gastroesophageal reflux of stomach acid (such as metoclopramide).
- Medicines that contain the substances guar, colestipol or colestyramine, which should not be used concomitantly with Trosmolyt 20 mg.

Use of Trosmolyt 20 mg may cause other medicines to not work properly.

If you are uncertain regarding the type of medicines you are taking, consult with the doctor or pharmacist.

Use of the medicine and food

Fat-rich diet may affect the activity of Trosmolyt 20 mg. The tablet should be taken before a meal on an empty stomach.

Pregnancy and breastfeeding

Inform the doctor if you are pregnant, think you are pregnant or are breastfeeding. The doctor will decide if this medicine is appropriate for you.

Driving and operating machinery

Use of Trosmolyt 20 mg may cause blurry vision. If you experience this effect do not drive or operate machinery.

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 generally accepted dosage is:

For adults and children over 12 - one tablet twice a day (which is equal to 40 mg of trospium chloride per day).

In patients suffering from kidney problems, the doctor may adjust the dosage.

- If your kidney function disorder is mild to moderate, there is no need to adjust the dosage.
- If your kidney function disorder is severe, the doctor will adjust the dosage and decrease it to one tablet per day or one tablet every other day.

You should consult with the doctor regarding the dosage that is appropriate for you.

Do not exceed the recommended dose.

The tablet should be swallowed whole with a glass of water before a meal on an empty stomach.

Duration of treatment

The doctor will determine the duration of treatment. The necessity of continuing the treatment will be checked by the doctor in fixed time intervals of three to six months.

If you accidentally take a higher dosage

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time,

take the medicine as soon as you remember, but do not take more than two tablets per day unless your doctor indicates otherwise.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

If you decide to discontinue treatment with Trosmolyt 20 mg before the period of time determined by the doctor is over, the symptoms may return. It is recommended to continue taking Trosmolyt 20 mg for the entire duration of treatment prescribed by the doctor. It is recommended to consult with the doctor if you would like to discontinue

the treatment.

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 the use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Trosmolyt 20 mg 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.

The characteristic side effects for this type of medicine which occur frequently include dry mouth, indigestion and constipation.

The following side effects are serious and if they occur an immediate response is necessary.

Stop using this medicine and refer to a doctor immediately if the following side effects appear:

- Swelling of the face, tongue and wind-pipe, which may cause breathing difficulties (occurs in less than 1 user in 10,000).
- A sudden allergic reaction accompanied by shortness of breath, rash, wheezing and drop in blood pressure (occurs with unknown frequency).
- A serious hypersensitivity reaction accompanied by serious blisters, peeling of the skin and/or mucosal tissues, such as: lips, eyes, mouth, nose and genitals. This may be accompanied by the following symptoms: fever, chills, muscle pains and malaise (occurs with unknown frequency).

Very common side effects - side effects that occur in more than one out of ten users:

- dry mouth

Common side effects - side effects that occur in 1-10 out of 100 users:

- constipation, nausea, abdominal pains and indigestion
- Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- Fast heartbeat (tachycardia)
- Headaches
- Flatulence, diarrhea
- Chest pains

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

- Dizziness
- Difficulty with bladder emptying, urinary retention
- Difficulty seeing objects up-close
- Rash
- Muscle and joint pain

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Fast and irregular heartbeat (tachyarrhythmia)

- Breathing difficulties
- Itching and rash
- General feeling of weakness
- A mild to moderate increase in certain hepatic values (serum transaminase)
- Isolated cases of hallucinations, confusion and agitation were mostly observed in the elderly population of patients, probably due to neurological conditions and/or as a result of taking other medicines with a similar mechanism of action concomitantly

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not indicated in the leaflet, consult with the doctor.

Reporting side effects:

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.
- Store at a temperature below 25°C.

6. Additional information:

In addition to the active ingredient the medicine also contains:

Microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate.

Coating:

Hypromellose, titanium dioxide, polydextrose, talc, maltodextrin, medium chain triglycerides, iron oxide.

What does the medicine look like and what are the contents of the package?

Round, light yellow-brown, biconvex tablets in blister packs of 30, 50 or 100 tablets. Not all package sizes may be marketed.

License holder/manufacturer and the address: CTS Chemical Industries Ltd., Kiryat Malachi.

This leaflet was revised in March 2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

159-44-35071-00

