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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:
Trosipium Chloride 20 mg.
For inactive ingredients 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 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?
Trosmolylt is a medicine that 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 neural 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.
- Do not use in children under the age of 12.

❗ Before treatment with Trosmolylt, inform the doctor if:

- You are suffering from gastric or intestinal obstruction.
- You are suffering from urinary tract obstruction.
- 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 liver problems.
- You are suffering from kidney problems.

❗ 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 of the tricyclic antidepressants family (e.g. amitriptyline or imipramine).
- Medicines for treatment of asthma which may increase heart rate (e.g. salbutamol).
- Sympathomimetic medicines (medicines that stimulate the sympathetic nervous system) which may increase heart rate.
- Other medicines with anticholinergic activity (e.g. amantadine for treatment of Parkinson's disease).
- Medicines used for stimulating the activity of the digestive system e.g. metoclopramide.
- Medicines containing Guar gum which are sometimes used for treatment of diabetes.
- Medicines used for lowering lipid blood levels, e.g. colestipol or colestyramine.

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

❗ Use of the medicine and food
Since fat-rich diet may affect Trosmolylt's activity, the tablet should be taken on an empty stomach, before a meal.

❗ Use of the medicine and alcohol consumption
During treatment with Trosmolylt 20 mg, alcohol consumption should be avoided as much as possible.

❗ 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
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.

❗ Use in children
Trosmolylt is not intended for use in children under the age of 12.

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 trosipium chloride per day). In patients suffering from kidney problems, the doctor may adjust the dosage and decrease it to one tablet per day or one tablet once a day 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 cup of water before a meal on an empty stomach.

The tablet should not be crushed/halved/chewed, since the tablets are coated.

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 the medicine on time, continue taking the medicine as usual. Do not take a double dose to make up for a forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine
If you decide to discontinue treatment with Trosmolylt before the period of time determined by the doctor is over, the symptoms may return. It is recommended to continue taking Trosmolylt for the entire duration of treatment prescribed by the doctor. It is recommended to consult with the doctor if you are interested in discontinuing 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.

4. Side effects:
As with any medicine, using Trosmolylt may cause side effects in some users. If the side effects do not go away, if they are bothersome or if they worsen, consult your doctor. 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 one user in 10,000).
- A sudden allergic reaction accompanied by shortness of breath, rash, wheezing and drop in blood pressure (occurs in an 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.

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.
- Problems with bladder emptying, urinary retention.
- Problem with seeing objects up-close.
- Rash.
- Muscle and joint pain.

Additional 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.

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 lower than 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 a 30-tablet, 50-tablet or 100-tablet blister. Not all package sizes may be marketed.
- License holder/manufacturer and the address: CTS Chemical Industries Ltd., Kiryat Malachi.
- This leaflet was checked and approved by the Ministry of Health in: 10/2017
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 159-44-35071-00