

**Patient leaflet in accordance with
the Pharmacists' Regulations
(Preparations) - 1986**

The dispensing of this medicine requires a physician's prescription

Spasmo-lyt 20 mg

Film-coated tablets

Each tablet contains:

Active ingredient:

Tropium chloride 20 mg

For a full list of ingredients see the section 'Additional Information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your physician or 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 to yours.

This medicine is not intended for children under 12 years old.

What is this medicine intended for?

Spasmo-lyt 20 mg is a medicine that is indicated for treatment of symptoms associated with involuntary urine leakage (wetting) and/or frequent urination and a strong urge to urinate in patients with an overactive bladder (overactive bladder muscle due to a neurological condition or an unknown cause).

Therapeutic group

Anticholinergic - antimuscarinic

Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (An allergic reaction can be a rash, itchiness or shortness of breath) (for information about this medicine's ingredients please see the section 'Additional Information')

- If you suffer from:

- urinary retention (urination occurs less frequently than normal)
- narrow-angle glaucoma
- an unusually rapid heart rate
- severe muscle weakness (myasthenia gravis)
- severe gastro-intestinal disorders, such as toxic megacolon (toxic expansion of the colon)
- This medicine is not intended for children under 12 years old.

Special warnings about using this medicine

Before using Spasmo-lyt 20 mg, tell your physician if you suffer from:

- A stomach or bowel obstruction.
- Blockage of the urinary tract.
- Neuropathy (nerve damage).
- A hiatus hernia associated with reflux esophagitis. This is usually associated with heartburn which gets worse when you bend or lie down.
- An overactive thyroid.
- Heart conditions, such as coronary artery disease or congestive heart failure.
- Liver problems.
- Kidney problems.

If you suffer from any of the problems listed above, before you start treatment with **Spasmo-lyt 20 mg**, consult your physician or pharmacist who will advise you as appropriate.

If you are taking or have recently taken other medicines, including nonprescription medicines and nutritional supplements, tell your physician or pharmacist.

In particular if you are taking:

- Tricyclic antidepressants.
- Sympathomimetic medicines (medicines which stimulate the sympathetic nervous system) which can increase the heart rate.
- Other medicines with anticholinergic activity, such as medicines for treating Parkinson's disease, for example Amantadine.
- Medicines which simulate the activity of the gastro-intestinal system, such as Metoclopramide.
- Medicines that contain guar gum, which sometimes used to treat diabetes.
- Medicines used to reduce the levels of fats in your bloodstream, such as Cholestyramine or Cholestipol.

If you are not sure which type of medicines you are taking, consult your physician or pharmacist.

Children

This medicine is not intended for children under 12 years old.

Using the medicine and alcohol consumption

As far as possible, avoid drinking alcoholic beverages during treatment with **Spasmo-lyt 20 mg**.

Pregnancy and breastfeeding

If you are pregnant, plan to become pregnant or are breastfeeding, consult your physician or pharmacist before taking this medicine.

Driving and using machines

Using this medicine can cause blurred vision so exercise caution when driving a car or operating dangerous machines, and when engaged in any other activity that requires alertness. This effect particularly occurs at the beginning of the treatment, when increasing or adjusting the dose, and when taking the medicine concomitantly with alcohol.

Important information about some of this medicine's ingredients

This medicine contains lactose (milk sugar) and sucrose (sugar). If you have been told that you have an intolerance to certain sugars, tell your physician before taking this medicine.

This medicine contains wheat starch. Do not use this medicine if you are sensitive to wheat (not celiac disease).

How to use this medicine?

Always use according to the physician's instructions. Check with your physician or pharmacist if you are not sure.

The recommended dose is usually:

Adults and children over 12 years old:

One tablet of **Spasmo-lyt 20 mg** twice a day.

In patients with kidney problems, the physician may adjust the dose and reduce it to one tablet a day or one tablet every other day.

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

The duration of the treatment will be decided by your physician. Your physician will assess the need for continuing the treatment every 3 to 6 months.

If you decide to stop treatment with **Spasmo-lyt 20 mg** before you have completed the course of treatment prescribed by your physician, your symptoms may recur.

It is recommended to continue taking **Spasmo-lyt 20 mg** for the entire period of treatment prescribed by your physician. It is recommended to consult your physician if you are interested in cessation of the treatment.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some of this medicine, refer immediately to a physician or hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take your next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

If you have any further questions regarding the use of this medicine, consult your physician or the pharmacist.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

Side effects

Like all medicines, using **Spasmo-lyt 20 mg** may cause side effects in some patients. Do not be alarmed while reading the list of side effects, you may not experience any of them.

Frequent side effects are typical for this type of medicine including dry mouth, indigestion and constipation.

The following side effects are severe and demand immediate action if occurs (rare side effects). Stop the treatment with **Spasmo-lyt 20 mg** and refer to your physician immediately if the following symptoms occur:

- Swelling of the face, tongue and windpipe which can cause difficulty breathing.
- Sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure.
- Serious hypersensitivity reaction with severe blistering and peeling of the skin and/or mucous membranes (in the lips,

eyes, mouth, nose and genitals). You may also feel the following symptoms: fever, chills, aching muscles and generally feeling unwell.

Very common side effects (effects that appear in more than one user out of 10):

- Dry mouth

Common side effects (effects that appear in 1-10 users out of 100):

- Constipation
- Nausea
- Stomach ache
- Indigestion

Uncommon side effects (effects that appear in 1-10 users out of 1,000):

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

Rare side effects (effects that appear in 1-10 users out of 10,000):

- Dizziness
- Difficulty emptying the bladder
- Urinary retention
- Difficulty seeing objects close-up
- Rash
- Muscle and joint pain

Additional side effects:

- Accelerated and irregular heart rate (tachyarrhythmia)
- Breathing difficulties
- Itching
- Hives
- General feeling of weakness
- Slight to moderate increase in levels of certain liver enzyme (serum transaminase)
- Sporadic cases of hallucination, confusion and nervousness have been observed mostly in elderly patients, possibly due to neurological diseases and other medicines that work the same way that were taken at the same time.

If side effect occurs, if one of the side effects worsen or when you experience a side effect that is not mentioned in this leaflet, consult your physician.

Reporting side effects:

Side effects can be reported to the Ministry of Health (MoH) by following the link 'Reporting side effects due to medication therapy' on the MoH home page (www.health.gov.il) which refers to an online form for reporting side effects, or by clicking the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Do not store above 30°C.

Additional information

In addition to the active ingredient Tropium chloride this medicine also contains:

Wheat starch; Microcrystalline cellulose; Lactose monohydrate; Povidone (K-value 29-32); Croscarmellose sodium; Stearic acid; Silica, Colloidal anhydrous; Talc.

Tablet coating:

Sucrose; Caramellose sodium; Talc; Silica, Colloidal anhydrous; Calcium carbonate (E 170); Macrogl 8000; Titanium dioxide (E 171); Iron oxide hydrate yellow (E 172); Beeswax, white; Carnauba wax.

• What the medicine looks like and what are the contents of the package:

Spasmo-lyt 20 mg contains round, brownish-yellow glossy-coated tablets. The tablets are packaged in blister trays in boxes of 30, 50 or 100 tablets.

Not all package sizes may be available.

- Registration holder's name and address: MegaPharm Ltd., POB 519 Hod Hasharon 4510501.
- Manufacturer name and address: Madaus GmbH, Cologne, Germany for Meda Pharma GmbH & Co. KG., Bad Homburg, Germany.
- This leaflet was reviewed and approved by the Ministry of Health in March 2017.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 145-82-33117-00.