

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### SPASMEX FORTE

5mg tablets

TROSPIUM

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What SPASMEX FORTE is and what it is used for
2. Before you take SPASMEX FORTE
3. How to take SPASMEX FORTE
4. Possible side effects
5. How to store SPASMEX FORTE
6. Further information

#### 1. WHAT SPASMEX FORTE IS AND WHAT IS IT USED FOR

Trospium belongs to a group of medicines called antispasmodics (that reduce the smooth muscle tone).

This medicine is prescribed for the treatment of

- smooth muscles spasm muscle of the gastrointestinal tract, bladder, bile ducts, the urinary system and the genital;
- smooth muscles spasm of the gastrointestinal tract, bladder, bile ducts, the urinary system and the genital that occur after surgery;
- symptoms of the overactive bladder (frequent urination, sudden need to urinate and / or difficulty reaching the toilet in time and wetting oneself).

#### 2. BEFORE YOU TAKE SPASMEX FORTE

##### **Do not take SPASMEX FORTE**

- if you are hypersensitive to Trospium or to any of the other ingredients of the medicine
- if you suffer from urinary retention

- if you have raised pressure in the eye (narrow angle glaucoma)
- if you have a fast, irregular heartbeat (tachyarrhythmia)
- if you have myasthenia gravis (muscle weakness)
- if you suffer from severe ulcerative colitis or Crohn's disease
- if you have severe kidney failure (if you are on dialysis)
- if you have megacolon (an extremely enlarged colon)

Do not use in children under 12 years.

### ***Take special care with SPASMEX FORTE***

Tell your doctor if you:

- have difficulties in passing urine and/or a poor stream of urine
- suffer from neuropathy (nerve damage)
- have any heart conditions
- suffer from reflux esophagitis
- have an overactive thyroid gland
- suffer from mechanical narrowing of the digestive tract (Pyloric stenosis)
- have liver or kidney problems
- If you suffer from a herniated diaphragm

Before starting treatment, the doctor should rule out organic causes of frequent urination, heart and kidney disease, frequent hydration, as well as infections or tumors of the urinary system.

Special caution during treatment with trospium chloride is required in elderly patients with heart or lung disease (however, only reports on intravenous administration of the medicine are available).

### ***Taking other medicines***

Talk to your doctor or pharmacist before taking these tablets if you are taking any of the following medicines:

- Amantadine (for the treatment of Parkinson's disease)
- Tricyclic antidepressants (medicines to treat depression)
- Quinidine (used to treat irregular heartbeat)
- Disopyramide (used to treat irregular heartbeat)
- Antihistamines (allergy medicine)
- Beta-sympathomimetics (medicines that are commonly used in the treatment of asthma, heart disease, eye disease, nasal cavities)
- Metoclopramide (medicine that increases the rate of movement of digested food through the gastrointestinal system)
- Guar gum (used as a laxative, sometimes used in diabetes)
- Cholestyramine and colestipol (medicines that bind the bile in the gastrointestinal tract to prevent its reabsorption)

The absorption of medicines that are administered simultaneously with Spasmex can be altered, because of the effects of trospium chloride on the contraction of the digestive tract and the secretion of digestive juices.

### ***Taking Spasmex with food and drink***

Take Spasmex with a glass of water, at least one hour before a meal.

### ***Pregnancy and breastfeeding***

Talk to your doctor before taking this or any other medicine if you are pregnant.

During pregnancy and breastfeeding, avoid the application of trospium chloride. Your doctor will decide whether the application is necessary. Closely follow doctor's instructions.

### ***Driving and using machines***

Trospium chloride may cause visual disturbances that can affect the performance in the traffic. In case of visual disturbances do not drive or use machines.

***Important information about some of the ingredients of SPASMEX FORTE***

**SPASMEX FORTE** tablets contain Lactose-monohydrate. If your doctor told you that you have intolerance to some sugars, consult your doctor before taking this medicine.

**3. HOW TO TAKE SPASMEX FORTE**

SPASMEX FORTE tablets are administered orally.

The recommended daily dose is 1 to 2 tablets (5 to 10 mg) 3 times a day (equivalent to 15 to 30 mg trospium chloride per day), or 4 tablets twice a day (equivalent to 40 mg trospium chloride per day).

The maximum daily dose is 45 mg.

If you are a patient with renal impairment, your doctor will adjust the dose.

Take Spasmex with a glass of water, at least one hour before a meal.

If symptoms persist, contact your doctor or pharmacist. Your doctor will want to assess your treatment every 3-6 months, in order to decide whether this Medication is right for you.

Do not use Spasmex in children under 12 years.

***If you take more SPASMEX FORTE than you should***

If you have taken a higher dose of Spasmex tablets than you should, tell your doctor or visit a hospital, and show them a box of medicine.

***If you forget to take SPASMEX FORTE***

If you forget to take a dose, take it as soon as you remember. Do not take a double dose next time, but continue taking the medicine as prescribed by your doctor or as indicated in the package leaflet.

Talk to your doctor or pharmacist if you have any additional questions.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Spasmex can cause severe allergic reactions. If during the administration of this medicine you experience following symptoms, tell your doctor or visit the emergency department of the nearest hospital:

- Sudden difficulty in breathing, swallowing or speaking
- Swelling of the lips, face and neck
- Explicit dizziness or fainting
- Skin rash that itches

**Other side effects:**

**Very common (in more than 1 in 10 patients):**

- Dry mouth

**Common (1 to 10 per 100 patients):**

- Headache with fatigue
- Visual disturbances
- Abdominal pain
- Nausea
- Diarrhea

- Flatulence
- Discomfort in the stomach after a meal
- Constipation
- Disorders of emptying of the bladder (residual urine production)
- Difficulty or pain when urinating
- Malaise

**Uncommon (1 to 10 per 1,000 patients):**

- Rapid heartbeat
- Breathing difficulties
- Exanthema (rash)
- Dry skin

**Rare (1 to 10 in 10,000 patients)**

- Rapid and irregular heartbeat
- Increased LFTs

Tropium chloride can cause chest pain, blurred vision, pupil dilation, reflux of stomach acid into the esophagus, it can inhibit the secretion of mucus in the respiratory tract, reduce the secretion of saliva and sweat glands function.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## 5. HOW TO STORE SPASMEX FORTE

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP".

Store below 25 °C.

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 SPASMEX FORTE contains***

The active ingredient is tropium chloride. 1 tablet contains 5 mg of tropium chloride.

The other ingredients are anhydrous, colloidal silicon dioxide, microcrystalline cellulose, starch, lactose monohydrate, magnesium stearate, and talc (E553b).

### ***What SPASMEX FORTE looks like and contents of the pack***

The tablets are white to off-white, round and flat with beveled edges.

Spasmex is available in boxes of 20 tablets (2 blisters of 10 tablets).

### ***Regime of dispensing***

The medicine is issued on prescription.

### ***Manufacturer***

Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Slovenia

***Manufacturer of the medicinal product:***

Lek farmacevtska družba d.d., Verovškova 57, Ljubljana, Slovenia