Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

The medicine is sold with a doctor's prescription only

SPASMEX® 15
SPASMEX® 30

Active ingredient and its quantity:
Each tablet of Spasmex 15 contains: Trospium chloride 15 mg
Each tablet of Spasmex 30 contains: Trospium chloride 30 mg
This medicine contains lactose. For further information, see section 6.
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you only. 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 adolescents over 12 years old.

1. What is the medicine intended for?

This medicine is used for the treatment of impaired function of the urinary bladder, accompanied by urgency and/or frequency and/or urinary incontinence.
Therapeutic group: Anticholinergic, Antimuscarinic.

2. Before using the medicine

X Do not use this medicine if:

•You are sensitive (allergic) to the active ingredient or any of the other ingredients of this medicine (see section 6 – "further information").
You suffer from:
• urinary retention (urination is less frequent than usual).
• narrow-angle glaucoma.
• arrhythmia (increased 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 use of the medicine

! Before starting the treatment with Spasmex tell the doctor if you suffer 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 fast heart rate is not desirable e.g. overactivity of the thyroid gland, impaired function of the heart and/ or blood vessels, coronary heart disease, narrowing of the coronary arteries, cardiac insufficiency.

If you suffer from a serious liver disease, you should not take Spasmex. If you suffer from a mild to moderate liver disease, talk to your doctor before taking this medicine. Trospium chloride is excreted mainly via the kidneys. In patients with severely impaired renal function, elevated blood levels of the medicine were observed.

Therefore, even when kidney function is only mildly impaired, treatment should only be commenced with caution.

Medical examinations prior to using this medicine:
Prior to starting treatment, 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 tumours in the urinary system.

Children
Spasmex is not recommended for children under 12 years old.

! If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist.
The following effects can occur when taking following drugs:
• An increase in the anticholinergic effect: amantadine (for Parkinson's disease), antidepressants (tricyclic), quinidine and disopyramide (antiarrhythmic), 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 Spasmex: metoclopramide (Pramin) and cisapride (used to treat digestive disorders and reflux).

! Other possible drug interactions:
Since Spasmex influences the digestive system (secretion of digestive juices), one cannot rule out the potential of Spasmex to affect drugs taken at the same time with Spasmex.
Taking medicines that contain substances such as Guar, Colestyramine and Colestipol at the same time with Spasmex is not recommended since the absorption of Spasmex may be reduced.
Metabolic interactions have only been investigated in vitro, but without findings. Due to the metabolism of the medicine, no metabolic interactions are to be expected.

! Use of Spasmex and food
The medicine should be taken before a meal, on an empty stomach.

! Use of Spasmex and alcohol consumption
Drinking alcohol should be avoided as much as possible during the use of Spasmex.

! Pregnancy and breast-feeding
Animal studies have not provided any evidence of inducing congenital abnormalities as a result of using the medication. Since there is no experience of use during pregnancy and lactation in humans, Spasmex should be used during pregnancy and lactation only after strict evaluation of the drug's necessity.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking any medicine.

! Driving and using machines
Use of this medicine may cause blurred vision, therefore caution should be exercised when driving a car, operating dangerous machinery or when engaged in any other activity which requires alertness.
This effect particularly occurs at the beginning of therapy, after an increase or change of dose as well as when taken concomitantly with alcohol.

! Important information regarding some of the ingredients of the medicine
This medicine contains lactose. If a doctor has told you that you are sensitive to certain sugars, consult your doctor before taking this medicine (see section 6 - further information).

3. How to use this medicine?

Always use according to doctor's instructions. Check with the doctor or pharmacist if you are not sure. The dosage and manner of treatment will be determined by the doctor only.

The recommended dosage:
15 mg (one Spasmex 15 tablet or half a Spasmex 30 tablet), 3 times a day (morning, noon and evening).
Or
30 mg in the morning (two Spasmex 15 tablets or one Spasmex 30 tablet) and 15 mg in the evening (one Spasmex 15 or half a Spasmex 30 tablet).

Patients with impaired kidney function: with severe impaired kidney function (Creatinine clearance 10-30 ml/ min/ 1.73 m^2), do not exceed the 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 use in children under 12 years of age, due to the lack of data about this age group.

Do not exceed the recommended dose.

Method of administration:
Spasmex 30: 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.
Spasmex 15: swallow the tablet whole with a sufficient amount of water, at least one hour before a meal, on an empty stomach.
Spasmex 30 tablet may be halved.
There is no information regarding crushing or chewing of the tablets.

Duration of treatment:
Continue treatment as recommended by the doctor. Consult the doctor about further treatment with the medication every 3-6 months.

If you have accidentally taken a higher dosage, refer immediately to a doctor. 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 if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor!

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

If you stop taking the medicine: Do not stop taking Spasmex without consulting a doctor.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, use of Spasmex may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Discontinue treatment and refer to a doctor immediately if any of the following occur:
•Rash, itching, angioedema (swelling, usually in the face), breathing difficulties, since these symptoms might indicate an allergy to the medicine.
• Anaphylactic reaction due to sensitivity to the active ingredient - discontinue treatment and proceed to the doctor immediately.
• In cases of difficulties in urination or urinary retention, weakness or chest pains.
• There are very few reports of severe skin reactions accompanied with bleeding and formation of blisters. It cannot be determined whether there is an association between these effects and Spasmex. If you experience one of these symptoms, proceed to a doctor immediately.
Refer to a doctor as soon as possible if you experience blurred vision, disorders in the 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, stomach ache and nausea.
• Uncommon side effects (appear in 1-10 users out of 1,000) - diarrhoea, 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, sore muscles and joints.

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

Side effects can be reported to the Ministry of Health via the link “Report Side Effects of Drug Treatment” found on the homepage of the Ministry of Health’s website (www.health.gov.il), which refers to the online form for reporting side effects, or by clicking on the link:
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffetMedic@moh.gov.il

5. How to store Spasmex?

•Avoid poisoning! This medicine and any medicine must be stored in a safe 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 doctor.

••Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
••Storage conditions: Store below 30°C, in a dry place.

6. Additional information

In addition to the active ingredient the tablets also contain:

Inactive ingredients
Lactose Monohydrate, Microcrystalline Cellulose, Maize Starch, Sodium Starch glycolate Type A, Stearic Acid, Colloidal Anhydrous Silica, Povidone (K25), Hypromellose, Titanium Dioxide.

Each tablet contains 100 mg Lactose Monohydrate.

What does the medicine look like and what does the package contain?

White, round tablets with a breaking notch. Spasmex 15 mg tablets are imprinted with "O" on the other side to enable a clear distinction between the dosages.
The tablets are packed in blisters of 10 tablets, marketed in packs of 10, 30 or 100 tablets.
Not all package types may be marketed.

Registration holder and address:

Tec-O-Pharm Libra Ltd., P.O.B. 45054
Jerusalem 91450

Manufacturer:

DR. PFLEGER ARZNEIMITTEL GMBH, GERMANY

Medicine registration number of the medicine in the National Drug Registry of the Ministry of health:

Spasmex 15: 132-49-30583
Spasmex 30: 142-14-31805

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