

SPASMOLYT TABLET

Tropium chloride (20mg)

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What Spasmolyt is used for

Spasmolyt is a medicine used for the relaxation of the urinary bladder. It is used for the treatment of symptoms associated with involuntary loss of urine (wetting) and/or increased frequency of urination and imperative urge of urination in people with hyperactive urinary bladder (due to unknown origin or nervous system disorders).

How Spasmolyt Works

The anticholinergic effect of tropium chloride exerts a relaxing action on smooth muscle tissue and organ functions mediated by muscarinic receptors. In clinical experiments, tropium chloride diminishes the contractile tone of smooth muscle in the gastrointestinal and genitor-urinary tract.

Before you use Spasmolyt

- When you must not use it

Spasmolyt must not be taken if you have:

1. Hypersensitivity to the active ingredients or to any of the other constituents of the medicine

2. Retention of urine (e.g. blockage of the urinary tract)
3. Narrow-angle glaucoma (increased pressure in the eye)
4. Tachyarrhythmia (accelerated irregular heart rate)
5. Myasthenia gravis (disease that causes fatigue and weakness of the muscle)
6. Severe gastrointestinal condition including toxic megacolon (colonic enlargement)
7. Severe liver impairment
8. Sugar intolerance
9. Renal failure requiring dialysis.

Caution should be exercised while using Spasmolyt if you are pregnant or breastfeeding women.

- Before you start to use it

Spasmolyt should be used with caution in people with:

- narrowing (obstruction) of the gut, e.g. pyloric stenosis
- nerve damage (autonomic neuropathy)
- hiatus hernia with heartburn
- undesirable accelerated pulse rate e.g. in overactive thyroid gland, heart conditions such as coronary disease and congestive heart failure.

In people with mild to moderate liver impairment caution should be exercised.

Spasmolyt is mainly eliminated by kidney. Therefore people with mild to moderate renal impairment caution should be exercised.

Before commencing therapy your doctor may arrange some tests to diagnose other diseases. Spasmolyt contains lactose-Monohydrate and sucrose. People with rare hereditary

problems of sugar intolerance, should not take this medicine. Apart from that, Spasmolyt is suitable for people with coeliac disease (autoimmune disorder of the small intestine).

- Taking other medicines

Please inform doctors if you are taking:

- amantadine (a medicine for Parkinson's disease), tricyclic antidepressants
- beta-sympathomimetics (used as heart stimulant, anti-asthmatic)
- metoclopramide commonly used in the treatment of disorders of stomach emptying or reflux disease)
- cholestyramine and colestipol used for cholesterol lowering

Other medications as Spasmolyt may influence gastrointestinal movement and secretion, and may affect the absorption of other concurrent medicines.

How to use Spasmolyt

- How much to use

1 coated tablet twice daily (equivalent to 40 mg of tropium chloride per day).

In people with severe renal impairment the recommended dosage is: 1 coated tablet per day or every second day (equivalent to 20 mg of tropium chloride per day or every second day).

Use in children under 12 years of age is not recommended.

A reduction in dosage is required for people with impaired kidney function. The daily dose should not exceed 20 mg of tropium chloride.

- When to use it

Use as directed by your doctor

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Trospium chloride (20mg)

or pharmacist.

- How long to use it

Your doctor may arrange appointments at regular intervals of 3-6 months.

- If you forget to use it

Do not take a double dose to compensate for a missed tablet.

- If you use too much (overdose)

After the administration of a maximum single dose of 360 mg trospium chloride to healthy volunteers, dry mouth, increased heart rate and urination disorder, urinary retention were observed.

No symptoms and signs of intoxication in humans have been reported to date.

While you are using it

- Things you must do

Spasmolyt must be swallowed whole with a glass of water before meals.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Spasmolyt

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Spasmolyt to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick,

dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Very common (>10%)

-gastrointestinal system: dry mouth

Common (>1%)

- gastro-intestinal system (indigestion, constipation, abdominal pain, nausea)

Uncommon (<1%):

- gastrointestinal system: flatulence, diarrhoea,

- heart: increased heart rate

- general disorders: chest pain

- nervous system: headache

Rare (<0.1%):

- urinary system: urination disorders (e.g. formation of residual urine), urinary retention, muscles and

- connective tissues: muscle pain, joint pain

- nervous system: dizziness

- vision disorder: difficulty seeing objects close-up

- skin: rash

Very rare(<0.01%):

- skin: swelling of the skin

Not known:

- Heart: tachyarrhythmia

- Respiratory: difficulty in breathing,

- Skin: itchiness, nettle-rash (hives) hypersensitivity

reactions with severe skin reactions such as blister and skin detachment.

- general feeling of weakness

body as a whole: severe life-threatening allergic reaction

with shortness of breath, rash, wheezing and drop of blood

pressure, slight to moderate increase of certain liver enzyme

level

- nervous system: hallucination*, agitation*, confusion.

*These adverse effects occurred mostly in elderly and can be facilitated by neurological diseases and/or concomitant intake of other anticholinergic medicines.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (*Consumers* → *Reporting*).

Storage and Disposal of Spasmolyt

- Storage

Store below 30°C in dry place. The expiry date applies to the correctly stored product in the intact package.

Keep out of the reach and sight of children.

Do not use Spasmolyt after the expiry date which is stated on the label folding carton and on the tube.

- Disposal

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.

Product Description

- What it looks like

Brownish-yellow, glossy coated biconvex tablets with a diameter of approximately 7mm.

- Ingredients:

Active ingredient: Trospium chloride 20mg

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Inactive ingredients: Calcium carbonate, white beeswax, stearic acid, purified water, microcrystalline cellulose, croscarmellose sodium, carnauba wax, titanium dioxide, wheat starch, sucrose, colloidal anhydrous silica, carmellose sodium, lactose monohydrate, iron oxide yellow, talc, isopropanol, povidone K29-K32 and macrogol 8000.

- MAL number
MAL20081733A.

Manufacturer

Madaus GMBH
Luetticher Str. 5
53842, Troisdorf
51101, Koln
Germany.

Product Registration Holder

Antah Pharma Sdn Bhd
No. 3, Jalan 19/1, 46300,
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18 January 2016.

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