SPASMEX® 30 mg film-coated tablets

Name of the medicinal product

SPASMEX® 30 film-coated tablets

Qualitative and Quantitative composition

1 film-coated tablet contains 30 mg Trospium Chloride.

Excipients: Lactose, for full list, please see below.

Pharmaceutical form

White, round film-coated tablet, convex on one side with a special breaking-notch (SNAP-TAB) easing the division into 2 halves.

CLINICAL particulars

Therapeutic indications

For the treatment of detrusor instability or detrusor hyperreflexia accompanied by the symptoms of pollakisuria, Imperative urinary urgency and urge urinary incontinence.

Posology and method of administration

1/2 film-coated tablet should be taken three times a day (corresponding to 15 mg trospium chloride), or 1 film-coated tablet in the morning (corresponding to 30 mg trospium chloride) and in the evening ½ film-coated tablet (corresponding to 15 mg trospium chloride).

In patients with severely impaired renal function (Creatinine clearance between 10 and 30 ml/min/1.73 m^2), a daily dose of 20 mg should not be exceeded.

Mode and duration of treatment

The film-coated tablets should be swallowed whole with a sufficient quantity of liquid before a meal on an empty stomach. The necessity of a continuation of treatment should be mentioned at regular intervals of 3-6 months.

Contraindications

SPASMEX® is contra-indicated in patients with:

- Hypersensitivity to the active ingredient trospium chloride or any of the excipients.
- Urinary retention
- Narrow-angle glaucoma
- Tachyarrhythmia
- Myasthenia gravis
- Severe chronic inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- Toxic megacolon
- Renal impairment requiring dialysis (Creatinine clearance < 10ml/min/ 1.73 m^2).

Special warnings and precautions for use

Special care should be taken with trospium chloride in patients with:

- Obstruction in the gastro-intestinal tract (e.g. pyloric stenosis)
- Obstructed passage of urine outflow with the risk of residual urine
- Autonomous neuropathy
- Hiatus hernia with reflux oesophagitis
- As well as in patients where a fast heart rate is not desired e.g. those with thyroid hyperactivity, coronary heart disease and heart insufficiency.
- Children below the age of 12 years

The use of trospium chloride is not recommended in patients with impaired liver function, as there is no available data.

Trospium chloride is mainly excreted via the kidneys. In patients with severely impaired renal function notable increases in plasma levels were observed. Therefore in this patient group, even by only mild to moderately impaired kidney function, treatment should only be commenced with caution.

Before starting treatment, organic causes for pollakisuria and urge symptomatology should be excluded, such as heart or kidney disorders, polydipsia, as well as infections and tumours in the urinary organs.

Patients suffering from the rarely observed hereditary galactose intolerance, lactose deficiency or glucose-galactose-malabsorption should not take SPASMEX®

Interaction with other medicinal products and other forms of interaction

The following interactions may occur:

- Increase in the anticholinergic effect of amantadine, tricylic antidepressants, quinidine, antihistamines and disopyramide as well as increase in the tachycardiac effect of ß-sympathomimetics.
- Decrease in the effect of prokinetics (e.g. metoclopramid and cisaprid).

Because trospium chloride influences the gastro-intestinal motility and secretion, it can not be ruled out that the ingestion of concurrently taken drugs will not be changed.

During concurrent intake of medicines that contain substances such as Guar, colestyramine and colestipol, it can not be ruled out that the resorption of trospium chloride will not be reduced; therefore the concurrent use of medications which contain these substances is not recommended.

Investigations into metabolic interactions connected with trospium chloride were examined in vitro using cytochrome P-450 enzymes which are involved in the metabolism of drug substances (P450 1A2, 2A6, 2C6, 2C9, 2C19, 2D6, 2E1, 3A4). Thereby no influence by trospium chloride could be determined on the metabolic activities.

Due to the fact that trospium chloride is only metabolised to a small extent, and that an ester hydrolysis represents the only relevant metabolic pathway, no interactions as a consequence of metabolism are to be expected.

In addition, neither clinical studies nor pharmacovigilance have revealed data which indicate clinically relevant interactions.

Pregnancy and lactation

SPASMEX® falls under C of pregnancy categories.

SPASMEX® should only be used during pregnancy or when breast- feeding after close examination of the indication due to the lack of experience with this drug in humans during pregnancy and lactation.

Effects on ability to drive and use machines

Due to accommodation disturbances the ability to drive or operate machines may be impaired.

Undesirable effects:

During the evaluation of side effects, the following frequencies have been defined:

Very common	≥ 10%
Common	≥ 1 % - <10%
Uncommon	≥ 0.1 % - < 1 %
Rare	≥0.01 % - < 0.1 %
Very rare	< 0.01 % or unknown

Immune system disorders

Rare: angiooedema, anaphylaxis

Eye disorders

Uncommon: accommodation disorders (especially in patients who are hyperop not sufficiently corrected)

Cardiac disorders

Uncommon: tachycardia

Rare: tachyarhythmia

Respiratory, thoracic and mediatinal disorders

Uncommon: dysponea

Gastrointestinal disorders

Common: dry mouth, dyspepsia, constipation, stomach ache and nausea

Uncommon: diarrhoea, flatulence

Hepatobiliary disorders

Rare: mild to moderate increase of transaminases

Skin and subcutaneous tissue disorders

Uncommon: skin rashes

Renal and urinary tract disorders

Uncommon: disturbance in urination (e.g. formation of residual urine)

Rare: Urinary retention

General disorders

Uncommon: weakness or chest pains

Overdose:

The highest single dose of trospium chloride which has been given to humans orally is 360 mg .Dry mouth, tachycardia and micturition disturbances were observed. Cases of severe overdose or intoxication with trospium chloride have not been reported up till now.

Expected signs of an overdose are increased anticholinergic symptoms such as visual disturbances, tachycardia, dry mouth and reddening of the skin.

Upon presentation of an overdose, the following measures should be taken:

- Gastric lavage and impairment of resorption (e.g. activated charcoal)
- Local application of pilocarpine in patients with glaucoma
- Catheterization by urinary retention
- In severe cases, administration of a parasympathomimetic (e.g. neostigmine).
- Administration of beta-ß-blockers in cases of insufficient response, manifest tachycardia and/ or circulatory instability (e.g. starting with 1 mg Propanolol i.v. under ECG and blood pressure surveillance).

Pharmaceutical particulars.

List of excipients

Sodium starch glycolate (Type A) (PH. Eur.), hypromellose, lactose-monohydrate, maize starch, microcrystalline cellulose; povidon K25; colloidal silicium dioxide; stearic acid (Ph.Eur.), titanium dioxide (E171).

Incompatibilities

Not applicable

Shelf life

See outer carton

Special precautions for storage

Do not store above 30° C.

Manufacturer:

Dr. R.Pfleger Chemische Fabrik GmbH

Bamberg, Germany

Marketing Authorization Holder

Ferring GmbH

Kiel, Germany

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