

Spasmo-Canulase®

Spasmolytic combination

Composition

1 bitab contains:

Active ingredients

Core: Cellulasum corresp. 0,9 U. FIP; Pancreatis Pulvis corresp. Amylasum 2100 U. Ph. Eur., Lipasum 1200 U. Ph. Eur., Proteasum 80 U. Ph. Eur.; Dimeticonum 20 mg; Natrii Dehydrocholas 20 mg. Outer layer: Metixeni hydrochloridum 1 mg; Pepsini Pulvis corresp. 120 U. Ph. Eur.; Dimeticonum 20 mg; Acidi glutamici hydrochloridum 100 mg; excipient. *Excipients:* colorant E 127.

Properties/Effects

The outer layer of the tablet contains metixene hydrochloride, a synthetic parasympatholytic which inhibits gastrointestinal hypermotility; glutamic acid hydrochloride, which releases hydrochloric acid in the stomach; pepsin, the principal proteolytic enzyme of gastric juice. The other ingredients are contained in the core of the tablet: sodium dehydrocholate, which promotes bile secretion; pancreatin, which contains enzymes for the digestion of proteins, carbohydrates and fats; cellulase, which, by hydrolyzing cellulose, counteracts bacterial fermentation and the resulting formation of intestinal gas.

Both the external layer and the core also contain dimeticone, a surfactant with intensive antifoaming activity that counteracts meteorism.

Pharmacokinetics

The Spasmo-Canulase bitabs are composed of an external layer that dissolves quickly and a core that is resistant to gastric juice (see Composition). Thanks to this principle, the various ingredients exert their full therapeutic effect at the precise point in the digestive tract where their action is required.

Metixene: metixene hydrochloride is almost entirely absorbed from the gastrointestinal tract. Peak plasma levels are reached after 2-4 hours. Metixene is metabolised rapidly and extensively; it is particularly eliminated in the stools (about 80%), with only a small fraction in the urine (about 20%), principally in the form of nitrate, sulphate, demethylated sulphate and phenolic derivatives.

None of the detected metabolites is more toxic or pharmacologically more active than metixene itself. The plasma half-life is 4-6 hours and elimination is in the order of 55-70% in 24 hours.

Indications/Method of use

Irritable colon accompanied by complaints such as distension, sensation of bloating, and diffuse or colic-like abdominal pain.

Meteorism associated with enzyme deficiencies, aerophagia, and dyspepsia due to fermentation or putrefaction.

Dyspepsia following biliary disorders and digestive disorders of nervous origin.

Dosage/Directions for use

1 bitab to be swallowed whole before each meal. In the case of acute abdominal discomfort, take 2 bitabs together.

Restrictions on use

Contraindications

Hypersensitivity to any of the ingredients.

(As with all anticholinergics): narrow-angle glaucoma, prostate hypertrophy with mictional disorders, intestinal atony, myasthenia gravis. Biliary tract occlusion (obstructive icterus), acute hepatitis and other functional hepatic disorders, gall bladder empyema, hepatic coma.

Precautions

No particular precautions are required when used as instructed.

Pregnancy, breast-feeding

There have been no controlled studies performed in animals or in pregnant women. Consequently, the medicine may be administered only if the potential benefit is considered to outweigh the risk to the foetus.

It is not known whether the product passes into breast milk.

Undesirable side effects

Anticholinergics administered at therapeutic doses may cause undesirable side effects in sensitive subjects; these effects are well known and principally include dry mouth, urine retention, disturbances of vision, tachycardia, palpitations, mydriasis and disturbances of visual accommodation.

Interactions

No interactions have been reported so far.

Overdosage

Overdosage induces toxic reactions of the atropinic type. Increased intestinal motility and elimination has also been observed. These symptoms disappear after withdrawal of the treatment.

Further remarks

Note

The relatively strong odour of bitabs is normal; it comes from the natural enzymes contained in the medicine.

Like all medicines, Spasmo-Canulase should be kept out of the reach of children.

Storage

The product may be used up to the date «EXP» shown on the pack.

Store below 25 °C. Protect from moisture and light.

Packaging

Pack of 20 bitabs.

Novartis Consumer Health SA Nyon Switzerland

Information updated: April 1994.