

SPASMOMEN®

Otilonium bromide 40 mg

COMPOUND DESCRIPTION

SPASMOMEN (otilonium bromide) is an original compound endowed with an elective and intense spasmolytic action on digestive tract smooth muscle and is thus indicated in hyperkinetic or spastic situations which are due to pathological contraction of the smooth muscle fibrocells.

CLINICAL PHARMACOLOGY

Otilonium bromide is a potent spasmolytic agent, which acts predominantly by modifying Ca^{++} fluxes from cellular and extracellular sites. Otilonium bromide binds Ca^{++} channels, muscarinic and tachykinin receptors and therefore has a composite mechanism of action.

Otilonium bromide inhibits the basal or stimulated gastrointestinal motility in response to contracting agents of different nature either chemical or physical in humans. The spasmolytic activity of Otilonium bromide on the gastrointestinal tract is evident at doses which do not affect gastric secretion or produce the typical atropine-like side effects.

CLINICAL PHARMACOKINETICS

The drug is poorly absorbed in the systemic circulation.

INDICATIONS

Irritable bowel, pain and spasm of the distal enteric tract.

DOSAGE AND ADMINISTRATION

1 Tablet 2-3 times a day, according to the physician's judgement.

CONTRAINDICATIONS

Known hypersensitivity to the product.

PRECAUTIONS

To be used with caution in subjects with glaucoma, prostatic hypertrophy, pyloric stenosis.

Although no hembryotoxic, teratogenic or mutagenic effects on animals have been reported, like for all drug products during pregnancy and lactation, it should be administered only in cases of need and under medical supervision.

ADVERSE EFFECTS

At the therapeutic doses, the product does not cause side effects; namely it does not cause atropine-like effects.

DRUG INTERACTIONS

None.

PRESENTATION OF THE DRUG

Cardboard box containing 30 tablets in blister.

Each coated tablet contains:

Active ingredient: Otilonium bromide 40 mg.

Excipients: Lactose, rice starch, sodium starch glycolate, magnesium stearate, hydroxypropylmethyl cellulose, titanium dioxide, polyethylene glycol, talc.

SPECIAL PRECAUTIONS FOR STORAGE

None

Keep out of the reach of children.

Marketing Authorisation Holder:

A. Menarini Industrie Farmaceutiche Riunite s.r.l. - Florence, Italy

Further information are available on request:

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