PHYSICIAN'S PRESCRIBING INFORAMTION

SPASMOMEN TABLET

QUALITATIVE AND QUANTITATIVE COMPOSITION
Each Spasmomen tablet contains 40 mg of otilonium bromide.

PHARMACEUTICAL FORM:
Round coated tablets.

CLINICAL PARTICULARS
Therapeutic Indications: Treatment of irritable bowel, pain and spasm of the distal enteric tract.
Contraindications: Known hypersensitivity to the product.
Undesired effects: At the therapeutic doses, the product does not cause atropine-like effects. Headache and dizziness are reported occasionally following oral otilonium bromide 40 mg three times daily. Gastrointestinal effects such as nausea, vomiting, epigastric pain and abdominal discomfort have occurred occasionally in patients receiving oral otilonium bromide 40 mg three times daily.
Special precautions for use: To be used with caution in subjects with glaucoma, prostatic hypertrophy, pyloric stenosis.
Pregnancy and lactation: 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.
Interactions with other medicaments and other forms of interaction: None
Posology and method of administration: 1 Tablet 2-3 times a day, according the physician's judgement. If otherwise not specified, treatment duration should be 5-7 days and up to 4 weeks, depending on severity of condition. Longer treatments of up to 1-2 years have been done if needed
Overdose: In the animal, otilonium bromide was proven practically devoid of toxicity. Consequently also in the human, no particular overdosage-related problems should appear. In case of overdose a possible symptomatic and support therapy is recommended.
Warnings: Keep out of the reach of children
Effects on ability to drive vehicles and use machinery: Nothing to be reported

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties: Otilonium bromide is endowed with a marked spasmolytic action on the smooth muscle of the digestive tract.
Pharmacokinetic properties: Experimental data evidenced that following oral administration, absorption is very low and most of the absorbed quota is disposed by biliary route.
Preclinical safety data: Acute toxicity: per os, no mortality up to 1500 mg/kg in the rat and up to 1000 mg/kg in the dog. Chronic toxicity: in the experimental animals, oral otilonium bromide at the dose of 80 mg/kg given for 180 days, did not cause any alteration of hematochemical and histological exams. Teratology: no hembryo-toxic or teratogen effect in the rat or rabbit, also up to doses of 60 mg/kg. Mutagenesis: no mutagenetic effect in numerous tests performed.

PHARMACEUTICAL PARTICULARS
List of excipients: Rice Starch, Lactose, Sodium Starch Glycolate, Magnesium Stearate, Hydroxypropylmethylcellulose, Titanium Dioxide, Polyethylene Glycol, Talc. Celiac patients: the product contains gluten.
Incompatibilities: Not known
Special precautions for storage: None
Nature and contents of container: Blister/s of 10 or 30 tablets; packed in cardboard box containing 30 tablets.
Instructions for use/handling: None stated.

Israeli Drug License number: 125.63.30456.00
Manufactured for: A. Menarini Manufacturing Logistics & Services S.r.l., Italy by Berlin-Chemie AG, Germany.
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Last revised: 7.11.2005