

MODULON

Tablets

Composition

Each coated tablet contains Mebeverine hydrochloride 135 mg.

Action

Mebeverine is a musculotropic antispasmodic that acts directly on the smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility. Since this action is not mediated by the autonomic nervous system, anticholinergic side effects are absent. Modulon is suitable for patients with prostatic hypertrophy and glaucoma.

Pharmacokinetics

Mebeverine is rapidly absorbed after oral doses with peak plasma concentrations occurring in 1 to 3 hours. It is 75% bound to albumin in plasma. Mebeverine is completely metabolised by hydrolysis to veratric acid and mebeverine alcohol, the latter of which may then be conjugated. The metabolites are excreted in the urine.

Indications

Treatment of irritable bowel syndrome and conditions included in this grouping such as chronic irritable colon, spastic constipation, mucous colitis and spastic colitis. Modulon is effectively used to treat the symptoms of these conditions, such as colicky abdominal pain and cramps, persistent non-specific diarrhea (with or without alternating constipation) and flatulence.

Gastrointestinal spasm secondary to organic diseases.

Contraindications

Hypersensitivity to any ingredient in the product

Warnings

Pregnancy

The usual precautions concerning the administration of any drug during pregnancy should be observed.

Paediatric Use

Use of this drug in children under 10 years of age is not recommended.

Adverse Reactions

Although adverse effects appear rare, gastrointestinal disturbances, dizziness, headache, insomnia, anorexia, and decreased heart rate have been reported in patients receiving mebeverine. Cases of hypersensitivity, including erythematous rash, urticaria, and angioedema, have also been reported.

Precautions

Mebeverine should be avoided in patients with paralytic ileus. Based on theoretical concerns, it should be used with care in patients with marked hepatic or renal impairment, and those with cardiac disorders such as heart block.

It was recommended that antispasmodics such as mebeverine should not be used for the symptomatic treatment of distal intestinal syndrome in cystic fibrosis.

Mebeverine considered unsafe in patients with porphyria because it has been shown to be porphyrinogenic in in-vitro systems.

Dosage and Administration

Adults and Children over 10 Years of Age

One tablet 3 times a day, preferably 20 minutes before meals. The dosage may be gradually reduced after a period of several weeks, once the desired effect has been obtained.

Elderly

Same as for adults

Over Dosage

On theoretical grounds, it may be predicted that CNS excitability will occur in cases of over dosage. No specific antidote known, gastric lavage and symptomatic treatment is recommended.

Presentation

Box of 20 tablets.