BEVACOL®

DESCRIPTION

BEVACOL is the trade name of Mebeverine hydrochloride, an antispasmodic drug.

Each Coated **BEVACOL 135** Tablet contains 135mg Mebeverine hydrochloride.

CHEMISTRY

Mebeverine hydrochloride is: Dimethoxy-3,4 benzoate of [N-ethyl (methoxy-4 phenyl)-2 methyl-1 ethylamino]-4 butyl, hydrochloric acid.

CLINICAL PHARMACOLOGY

Mebeverine is a musculotropic antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility. Mebeverine is devoid of anticholinergic side effects because its action is not mediated by the autonomic nervous system. Accordingly, Mebeverine is suitable for patients with prostatic hypertrophy and glaucoma.

Mebeverine is rapidly and completely absorbed after oral administration. It is hydrolyzed in liver and is mostly eliminated in urine. A small part is excreted in bile. Mebeverine is totally eliminated within 24 hours.

INDICATIONS

- **BEVACOL** is indicated in the symptomatic treatment of abdominal pain and discomfort related to irritable bowel syndrome.
- Treatment of gastro-intestinal spasm secondary to organic diseases.

Note

Because Mebeverine lacks atropine-like effects, it is suitable for patients with prostatic hypertrophy and glaucoma.

DOSAGE

Adults and children over 10 years

one **BEVACOL 135** Tablet, three times daily, approximately 20 minutes before meals.

ADVERSE EFFECTS

Rare effects: Nausea, vertigo, headache and allergic reactions (including rash, urticaria, and angioedema).

USE IN PREGNANCY

Animal experiments have not indicated any teratogenic or embryotoxic effects with Mebeverine. However, due to lack of human clinical data, the risk is not known. Accordingly, it is prudent to avoid using the drug during the first trimester if possible.

USE IN LACTATION

Mebeverine is not excreted in milk of lactating women after therapeutic doses. However, because there are no adequate studies, avoid the drug during lactation.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

Not documented.

DRUG INTERACTIONS

None Known.

CONTRAINDICATIONS

- Hypersensitivity to Mebeverine.
- Paralytic ileus.

WARNINGS

Not documented.

OVERDOSE

According to animal experiments, hyperexcitability of the central nervous system could be predicted of in case of Mebeverine overdose.
There is no specific antidote to Mebeverine. Gastric lavage and symptomatic treatment are recommended in case of overdose.

PRECAUTIONS

Mebeverine should be avoided in porphyria.

HOW SUPPLIED

- Boxes of 48 blistered **BEVACOL135** Tablets.
- Boxes of 32 blistered **BEVACOL135** Tablets.
- Hospital packs of different presentations.

Store according to conditions specified on the package.
Do not use after the expiry date shown on the package.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request

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