

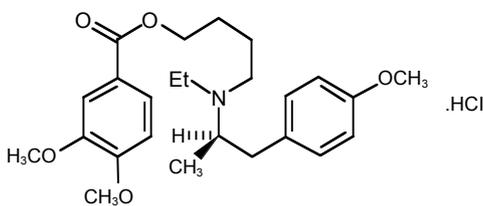
MebeverTM

(Mebeverine HCl Capsules) MR

CAPSULE 200mg

DESCRIPTION

MEBEVER MR contains mebeverine HCl which is a musculotropic antispasmodic with a direct action on smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility. Chemically, mebeverine hydrochloride is (RS)-4-[ethyl (4-methoxy- α -methylphenethyl) amino] butyl vertrate hydrochloride. The molecular formula is C₂₅H₃₅NO₅. HCl and the structural formula is:



QUALITATIVE AND QUANTITATIVE COMPOSITION

MEBEVER MR (Mebeverine HCl) is available for oral administration as:

MEBEVER MR Capsules 200mg

Each modified-release capsule contains: Mebeverine hydrochloride as extended-release pellets equivalent to mebeverine hydrochloride BP.....200mg

CLINICAL PHARMACOLOGY

Mechanism of Action

Mebeverine has a direct non-specific relaxant effect on vascular, cardiac and other smooth muscle. Mebeverine is also an inhibitor of calcium-depot replenishment. Therefore, mebeverine has dual mode of action which normalizes the small bowel motility.

PHARMACOKINETICS

Mebeverine is rapidly and completely absorbed after oral administration with peak plasma concentrations occurring in 1 to 3 hours. It is 75% bound to albumin in plasma. Mebeverine is not excreted as such, but metabolised completely. Mebeverine is completely metabolised by hydrolysis to veratric acid and mebeverine alcohol. Both the veratric acid and mebeverine alcohol are excreted into the urine, the latter partly as the corresponding carboxylic acid and partly as the demethylated carboxylic acid.

THERAPEUTIC INDICATIONS

MEBEVER MR (Mebeverine HCl) is indicated for the symptomatic relief of irritable bowel syndrome.

DOSAGE AND ADMINISTRATION

MEBEVER MR (Mebeverine HCl) capsules should be swallowed whole and should not be broken, crushed or chewed.

Adults (including the elderly):

The recommended dose of MEBEVER MR (Mebeverine HCl) capsules is one capsule twice a day, preferably 20 minutes before meals.

Children:

MEBEVER MR (Mebeverine HCl) capsules are not recommended for children.

ADVERSE REACTIONS

In general mebeverine is well tolerated. Although adverse reactions appear rare, gastrointestinal disturbances, fever, polyarthritis, dizziness, headache, insomnia, anorexia, thrombopenia, allergic reactions particularly erythematous rash, urticaria, maculopapular rash and angioedema and decreased heart rate have been reported in patients taking mebeverine.

CONTRAINDICATIONS

Mebeverine HCl is contraindicated:

- In patients who are hypersensitive to any component of the product.
- In patients with paralytic ileus (paralysis or inactivity of the muscles in intestines, which stops normal passage of food through intestine).
- In children.

PRECAUTIONS

- Use with caution in those persons who have porphyria.
- It is recommended that antispasmodics such as mebeverine should not be used for the symptomatic treatment of distal intestinal syndrome in cystic fibrosis.

Pregnancy

The medicine should be used with caution during pregnancy, and only if the expected benefit to the mother is greater than any possible risk to the fetus.

Nursing Mothers

Mebeverine is excreted in milk of lactating women after therapeutic doses, but the amount is considered too small to be harmful to a nursing infant.

OVERDOSE:

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

STORAGE

Store below 30°C.
Protect from sunlight and moisture.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED

MEBEVER MR (Mebeverine HCl) 200mg capsules are available in blister packs of 10's.

Keep out of reach of children.

To be sold on a prescription of a registered medical practitioner.

**Please read the contents carefully before use.
This package insert is continually updated
from time to time.**



Manufactured by: Getz Pharma (Pvt.) Limited, 29-30/27, K.I.A., Karachi - 74900, Pakistan.

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