

Colospas MR Capsules کولواسپاس ایم آر کپسولز

(MEBEVERINE HCl) (میبیورین ہائیڈروکلورائیڈ)

COMPOSITION: Each capsule contains:
Mebeverine HCl as extended release pellets eq. to Mebeverine HCl ... 200mg.
NQ Specs.

DESCRIPTION: Colospas MR (Mebeverine HCl) 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 veratrate hydrochloride. The molecular formula is $C_{25}H_{35}NO_5$ HCl.

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 (estrases) hydrolysis to veratric acid and Mebeverine alcohol. Both the veratric acid and Mebeverine alcohol are excreted into the urine, the later partly as the corresponding carboxylic acid and partly as the demethylated carboxylic acid.

THERAPEUTIC INDICATIONS: Colospas MR (Mebeverine HCl) is indicated for the symptomatic relief of Irritable Bowel Syndrome (IBS).

DOSAGE AND ADMINISTRATION: Colospas MR (Mebeverine HCl) capsules should be swallowed whole and should not be broken, crushed or chewed.

Adults (including the elderly): The recommended dose of Colospas MR (Mebeverine HCl) capsules is one capsule twice a day, preferably 20 minutes before meals.

Children: Colospas 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.

CONTRA-INDICATIONS: Mebeverine HCl is contra-indicated in patients who are hypersensitive to any component of the product and in patients with paralytic ileus (paralysis or inactivity of the muscles in intestines, which stops normal passage of food through intestine).

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. Although problems have not been documented. Colospas MR capsules should not be given to woman who is breast feeding unless the anticipated benefits outweigh possible risks.

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.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION: Colospas MR (Mebeverine HCl) 200mg Capsules are available in a pack of 10's.

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔



Manufactured by:

NABIQASIM INDUSTRIES (PVT) LTD.

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