

LEZPAIN

FILM COATED TABLET 135MG

Ingredient(s):

Each tablet contains:

Mebeverine Hydrochloride 135mg

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):

Mebeverine is a musculotropic antispasmodic, with a direct action 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, the usual anticholinergic side effects may be absent. Mebeverine is suitable for patients with prostatic hypertrophy and glaucoma.

Mebeverine is rapidly and completely absorbed after oral administration. Mebeverine is metabolised completely. The 1st step in the metabolism is hydrolysis, leading to a veratric acid and mebeverine alcohol.

Veratric acid is excreted into the urine, mebeverine alcohol is also excreted into the urine, partly as the corresponding carboxylic acid and partly as the dimethylated carboxylic acid.

Indications:

For the symptomatic treatment of abdominal pain and cramps, bowel disturbances and intestinal discomfort related to irritable bowel syndrome.

Dosage and Administrations:

Adults and children over 10 years: 135mg 3 times daily preferably 20 minutes before meals.

Route of Administration:

To be taken orally.

Contraindications:

In patients with hypersensitivity to any component of this product.

Side Effect / Adverse Reactions:

Side effects reported include allergic reactions mainly but not exclusively limited to the skin, immune system disorder such as hypersensitivity (anaphylactic reactions) and skin and subcutaneous tissue disorders such as urticaria, angioedema, face oedema and exanthema.

Precautions / Warnings:

Effects on the ability to drive or operate machinery: When taken as prescribed, mebeverine has no effect on psychomotor skills associated with driving and operating machinery.

Patient with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this product.

Interaction with Other Medicaments

None known.

Pregnancy and Lactation:*Pregnancy*

There are no or limited amounts of data for the uses of mebeverine in pregnant women. Mebeverine is not recommended during pregnancy.

Lactation

It is unknown whether mebeverine or its metabolites are excreted in human milk. Mebeverine should not be used during breast-feeding.

Symptoms and Treatment For Overdosage, and Antidotes:

Theoretically, it may be predicted that CNS excitability will occur in cases of overdosage. No specific antidote is known. Gastric lavage is recommended. Treatment should consist of symptomatic and supportive therapy.

Shelf-life:

3 years from the date of manufacture.

Storage Conditions:

Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Product description and Packing(s):

A white color film coated round tablet

Blister packing of 10's x 10 and 10's x 100.



Manufacturer and Product Registration Holder:
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