

Colonext

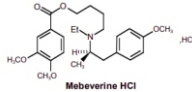
(BP Specification)

Mebeverine HCl 135mg

(BP Specification)

DESCRIPTION

COLONEXT contains mebeverine HCl which is a muscolotropic antispasmodic with a direct action on smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility. Chemically, mebeverine hydrochloride is (R)-4-[ethyl (4-methoxy-methylphenethyl) amino] butyl veratrate hydrochloride. The molecular formula is $C_{21}H_{26}NO_4 \cdot HCl$ and the structural formula is:



QUALITATIVE AND QUANTITATIVE COMPOSITION

COLONEXT Tablets 135mg

Each film-coated tablet contains: Mebeverine hydrochloride... 135mg

(BP Specification)

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

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

DOSAGE AND ADMINISTRATION

COLONEXT (Mebeverine HCl) Tablets should be swallowed whole and should not be broken, crushed or chewed.

Adults (including the elderly):

The recommended dose of COLONEXT (Mebeverine HCl) tablets is one tablet three times a day, preferably 20 minutes before meals.

Children:

COLONEXT (Mebeverine HCl) tablets are not recommended for children.

ADVERSE REACTIONS

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

CONTRAINDICATIONS Mebeverine HCl is contraindicated:

- In patients who are hypersensitive to Mebeverine or 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

Mebeverine 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 at 20°C-25°C

Protect from light and moisture.

(Excursions permitted between 15°C-30°C).

HOW SUPPLIED

COLONEXT (Mebeverine HCl) Tablets 135mg are available in blister pack of 30 Tablets.

KEEP OUT OF THE REACH OF CHILDREN.

TO BE SOLD ON PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY

Contains Lactose But Gluten Free

NEXT
PHARMACEUTICAL

Manufactured by:
NEXT Pharmaceutical Products (Pvt.) Ltd.
Plot no. 44-A&B, Sunder Industrial Estate Lahore-Pakistan

کولونیکسٹ

(میویرین)

135 ملی گرام

فلم کوڈ گولیاں

خوراک و ہدایات:

بزرگ و بچوں کی دوا کے مطابق استعمال کریں۔

صرف متھڑا کرنے کے مطابق ہی دواؤں کو خوراک کی جائے۔

تمام ادویات بچوں کی پہچان سے دور رکھیں۔

دوا کو 25°C-20°C درجہ حرارت پر رکھی اور دینی سے محفوظ رکھیں۔

(درجہ حرارت کی حد 15°C سے 30°C ہے۔)