Coliver 200mg Capsule
(Mebeverine HCl)

کولیور ۲۰۰ ملی گرام کیپسول
(میبی ویرین ہائیڈروکلورائیڈ)

COMPOSITION
Coliver Capsule 200mg
Each capsule contains:
Sustained release pellets of Mebeverine hydrochloride (MS) equivalent to Mebeverine hydrochloride.....200mg
Product complies Innovator's specs.

DESCRIPTION
Coliver 200mg sustained released capsule contain Mebeverine HCl which is an antispasmodic agent with direct action on the smooth muscle of the gastrointestinal tract.

MECHANISM OF ACTION
Mebeverine is a musculotropic antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract, without affecting normal gut motility. The exact mechanism of action is not known, but multiple mechanisms, such as a decrease in ion channel permeabilities, blockade of noradrenaline reuptake, a local anesthetic effect, changes in water absorption as well as weak anti-muscarinergic and phosphodiesterase inhibitory effect might contribute to the local effect of mebeverine on the gastrointestinal tract. Systemic side-effects as seen with typical anti-cholinergics are absent.

INDICATIONS
For the symptomatic relief of irritable bowel syndrome.

DOSAGE AND ADMINISTRATION
One capsule of 200 mg twice daily, to be given one in the morning and one in the evening preferably 20 minutes before meals.
Paediatric Population:
Mebeverine 200 mg modified release capsules are not recommended for use in children and adolescents below 18, due to insufficient data on safety and efficacy.
Duration of use is not limited. If one or more doses are missed, the patient should continue with the next dose as prescribed; the missed dose(s) should not be taken in addition to the regular dose.
Special Population:
No posology studies in elderly, renal and/or hepatic impaired patients have been performed. No specific risk for elderly, renal and/or hepatic impaired patients could be identified from available post-marketing data. No dosage adjustment is deemed necessary in elderly, renal and/or hepatic impaired patients.

METHOD OF ADMINISTRATION
Adults (including the elderly):
The capsules should be swallowed with a sufficient amount of water (at least 100 ml water). They should not be chewed because the coating is intended to ensure a prolonged release mechanism.

PHARMACOKINETICS
Absorption:
Mebeverine is rapidly and completely absorbed after oral administration of tablets. The modified release formulation permits a twice daily dosing scheme.
Distribution:
No significant accumulation occurs after multiple doses.
Biotransformation:
Mebeverine hydrochloride is mainly metabolized by esterases, initially splitting the ester bonds into veratric acid and mebeverine alcohol. The main metabolite in plasma is DMAC (Demethylated carboxylic acid). The steady state elimination half-life of DMAC is 5.77h. During multiple dosing (200 mg b.i.d.) the Cmax of DMAC is 804 ng/ml and tmax is about 3 hrs. The relative bioavailability of the modified release capsule appears to be optimal with a mean ratio of 97%.
Elimination:
Mebeverine is not excreted as such, but metabolised completely; the metabolites are excreted nearly completely. Veratric acid is excreted into the urine; mebeverine alcohol is also excreted into the urine, partly as the corresponding carboxylic acid (MAC) and partly as the demethylated carboxylic acid (DMAC).

Paediatric population:
The safety and efficacy of the product has only been evaluated in adults.

WARNINGS AND PRECAUTIONS
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltese insufficiency should not take this medicine.

SIDE EFFECTS
Allergic reactions mainly but not exclusively limited to the skin have been observed.

Immune system disorders:
Hypersensitivity (anaphylactic reactions)
Skin and subcutaneous tissue disorders:
Urticaria, angioedema, face oedema, exanthema.

DRUG INTERACTIONS
No interaction studies have been performed, except with alcohol. In vitro and in vivo studies in animals have demonstrated the absence of any interaction between mebeverine hydrochloride and ethanol.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy:
There are no or limited amounts of data from the use of mebeverine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Mebeverine is not recommended during pregnancy.
Breastfeeding:
It is unknown whether mebeverine or its metabolites are excreted in human milk. The excretion of mebeverine in milk has not been studied in animals. Mebeverine should not be used during breast-feeding.
Fertility:
There are no clinical data on male or female fertility; however, animal studies do not indicate harmful effects of mebeverine.

OVERDOSE
Theoretically CNS excitability may occur in cases of overdose. In cases where mebeverine was taken in overdose, symptoms were either absent or mild and usually rapidly reversible. Observed symptoms of overdose were of a neurological and cardiovascular nature.
No specific antidote is known and symptomatic treatment is recommended.
Gastric lavage should only be considered in case of multiple intoxication or if discovered within about one hour. Absorption reducing measures are not necessary.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients.

STORAGE & INSTRUCTIONS
Store between 15-25°C.
Protect from sunlight, heat and moisture.
Keep out of the reach of children.
To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED
Coliver Capsule 200mg
10 capsules.

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
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