PYXATALIN RETARD

MEBEVERINE HYDROCHLORIDE CAPSULES 200 MG

Composition :

Each hard gelatin capsule contains :
Mebeverine Hydrochloride BP 200 mg
(As Prolonged Release Pellets)
Excipients: Q.S.

Approved colours used in hard gelatin capsule shells:

Pharmaceutical Form: Capsule

Therapeutic indications:
For the symptomatic relief of irritable bowel syndrome.
Posology and 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 (see 5.2).
One capsule of 200 mg twice daily, to be given one in the morning and one in the evening.
Paediatric Population: Pyxatalin Retard (Mebeverine 200 mg) prolong 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 contin

ue with the next dose as prescribed; the missed dose(s) should not be taken in addition to the regular dose.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use: None

Interaction with other medicinal products and other forms of interaction:
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.

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.

Lactation: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

Undesirable effects: The following adverse reactions have been reported spontaneously during postmarketing use. A precise frequency cannot be estimated from available data.
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

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.

Pharmacodynamic properties
Pharmacotherapeutic group: Synthetic anticholinergics, esters with tertiary amino group, ATC-Code: A03AA04Mebeverine 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.
"***Clinical efficacy and safety***:All formulations of mebeverine were generally safe and well tolerated in the recommended dose regimen.

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

Pharmacokinetic properties
Absorption:Mebeverine is rapidly and completely absorbed after oral administration of Capsules.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.

Storage: Store below 30° C. Protect from light and moisture.
Keep medicine out of reach of children.

Presentation: 30 Capsules

Marketed by:

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