Duspatalin® retard 200 mg modified release capsules, hard

200 mg mebeverine hydrochloride

Abbott

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Duspatalin retard 200 mg modified release capsules are opaque white, hard gelatine capsules, with the standard imprint 245 on the surface. They are to be taken orally (by mouth). Each capsule contains 200 mg of mebeverine hydrochloride.

Excipients (non-medicinal ingredients):
Capsule content (granules):
Magnesium stearate, polyacrylate dispersion 30%, talc, hypromellose, methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30%, glycerol triacetate

Capsule shell:
Gelatine, titanium dioxide (E171), printing inks: shellac (E904), black iron oxide (E172), propylene glycol, strong ammonia solution, potassium hydroxide.

Indications

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

Treatment of gastro-intestinal spasm secondary to organ diseases.

Dosage and administration

Adults

Take one capsule twice daily, once in the morning and once in the evening.

Swallow the capsules with at least 100 ml of water, do not chew.

Always take Duspatalin retard exactly as your doctor has prescribed. If you have any questions, check with your doctor or pharmacist.

If you forget to take your tablet(s), do not take a double dose to compensate for it. If you require further information, please ask your doctor or pharmacist for advice.

Paediatric Population

Duspatalin retard 200 mg capsules are not recommended for use in children and adolescents below 18, due to insufficient data on safety and efficacy.

Contraindications

Do not take this medicine if you are allergic (hypersensitive) to the active substance or to any of the excipients

Warnings and special precautions for use

Not applicable.

Interactions with other medications

No interaction studies have been performed.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy.

No clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition (giving birth) or postnatal development.

If you are pregnant, consult your doctor before taking this medicine

There is insufficient information on the excretion of mebeverine in human breast milk. However, certain studies indicate that mebeverine is likely excreted in breast milk and a risk to the suckling child cannot be excluded. Therefore you should not take Duspatalin retard during breast-feeding.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Undesirable effects

Like all medicines, Duspatalin retard may have side effects. If you notice any side effects not mentioned in this leaflet, or if any of the side effects become serious, please inform your doctor or pharmacist.

Allergic reactions mainly but not exclusively limited to the skin have been observed, however the frequency of such reactions cannot be estimated from the available data.

Undesirable effects by system organ class:

Immune system disorders:
Hypersensitivity (allergy)

Skin and subcutaneous tissue disorders:
Urticaria (hives), angioedema (sudden onset of face, neck or limb swelling), face edema (swelling), exanthema (skin eruption, rash).

Overdose

Theoretically central nervous system 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. No specific antidote is known; gastric lavage and symptomatic treatment is recommended.

Pharmacodynamics

Pharmacotherapeutic group: Synthetic anticholinergics, esters with tertiary amino group.

Mebeverine is a musculotropic antispasmodic with a direct effect on the smooth muscle of the gastro-intestinal tract, relieving spasm without affecting normal gut motility. Since this effect is not mediated by the autonomic nervous system, the typical anti-cholinergic side-effects are absent.

Pharmacokinetics

Mebeverine is rapidly and completely absorbed after oral administration. This formulation permits a twice daily dosing scheme. Mebeverine is not excreted as such, but metabolized completely. The first step in the metabolism is hydrolysis, leading to veratric acid and mebeverine alcohol. Both veratric acid and mebeverine alcohol are excreted into the urine, the latter as the corresponding carboxylic acid (MAC) and partly as the demethylated carboxylic acid (DMAC).

In plasma, DMAC is the main circulating metabolite. The steady state elimination half-life of DMAC is approximately 5.77 h. The relative bioavailability appears to be optimal with a mean (dose-normalized) AUC ratio of 97%. During multiple dosing (200 mg twice daily) the C_{max} of DMAC is 804 ng/ml, and t_{max} is about 3 hrs.

This formulation of mebeverine has extended release properties as seen by its relatively low C_{max}, longer time to t_{max} and long elimination half life, while the bioavailability is optimal.

No significant accumulation occurs after multiple doses of this medication.

Incompatibilities

Not applicable.

Shelf life and storage conditions

This product can be stored for up to 3 years.

Do not use the medicine after the expiry date stated on the carton.

Do not store above 25°C.

Do not refrigerate or freeze.

Store in the original package.

Keep this medicine out of the reach and sight of children.

Pack sizes

Duspatalin retard 200 mg modified release capsules are supplied in packages containing 2, 4, 6, 8, 10, 12, 14, 15, 20, 28, 30, 50, 60, 100, 150 or 500 capsules per pack (not all pack sizes may be marketed).

The blisters are made of PVC with aluminum lidding foil.

Further information

Any unused product or waste material should be disposed of in accordance with local requirements.

The information in this leaflet is limited. For further information, please contact your doctor or pharmacist.

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Manufactured by: Abbott Healthcare SAS
01400 Châtillon-sur-Chalaronne - FRANCE

For: Abbott Healthcare Products B.V.,
THE NETHERLANDS

THIS MEDICATION

is a product which affects your health and its use contrary to instructions is dangerous to you.
Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medication.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not interrupt the period of treatment prescribed.
- Do not repeat the same prescription without first consulting your doctor.
- Keep all medications out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.