Mascherina

Packaging & Label Management

INVOLVED PLANT: Chatillon

PRODUCT NAME: Duspatalin Retard 200mg, capsules

AFFILIATE ORIGINATOR: Singapore; Sri Lanka

ORIGINATING FROM LCR / MKPR Number: LCR-16898-2021-DEV

COMMODITY CODE: 50078780 COMMODITY TYPE: Package Insert

CUTTING GUIDES / SIZE: Flat - 158x315mm - SPE 97885

PHARMACODE: 4377 (IIIXIIIXXIXI)

COLORS: P. Process Black U - Cutting Die (Not Printed)

FONT STYLE / MINIMUM FONT SIZE FOR TEXT: Helvetica Neue / 10.5 pt

NOTES: N.A.

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Abbott

Duspatalin® retard 200 mg,

modified release capsules, hard

200 mg mebeverine hydrochloride

Read this entire 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 imprint 245 on one side. The capsules are for oral administration only (to be taken by mouth). Each capsule contains 200 mg 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 ink: shellac (E904), black iron oxide (E172), propylene glycol, concentrated 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, one in the morning and one in the evening.
The capsules should be swallowed with a sufficient amount of water (at least 100 ml of water). They should not be chewed because the coating is intended to ensure a prolonged release mechanism.

Treatment Duration
Duration of use of Duspatalin Retard is not limited but symptom relief occurs after a minimum of 2 to 4 weeks of treatment and greater effects can be observed after a prolonged therapy of 6 to 8 weeks.

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

In case of one or more dose(s) is (are) missed, you should continue with the next dose as prescribed; the missed dose(s) is (are) not to be taken in addition to the regular dose.

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.

Special Population
No posology studies in elderly, renal and/or hepatic impaired patients have been performed. However, 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 these patients.

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

Warnings and special precautions for use
None.

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

No interaction studies have been performed with the exception of alcohol. *In vitro* and *in vivo* studies in animals have demonstrated the absence of any interaction between Duspatalin retard and ethanol.

Fertility, pregnancy and lactation
Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Pregnancy
There is no or limited amount of data from the use of mebeverine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Duspatalin retard 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. Duspatalin retard should not be used while breast-feeding.

Fertility
There is no clinical data regarding impact on male or female fertility; however, available animal studies do not indicate harmful effects of mebeverine.

Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed. The pharmacodynamic and pharmacokinetic profile as well as post-marketing experience do not indicate any harmful effect of mebeverine on the ability to drive or to use machines.

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 immediately.

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The following adverse events have been reported spontaneously during post-marketing use. A precise frequency cannot be estimated from the available information.

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

Skin and subcutaneous tissue disorders:
Hives (urticaria), sudden onset of face swelling (edema), neck or limb swelling (angioedema), skin eruptions/rash (exanthema).

Immune system disorders:
Hypersensitivity (anaphylactic reactions).

Overdose
If you have taken too many capsules of Duspatalin contact a doctor. In cases where Duspatalin was taken in overdose, symptoms were either absent or mild and usually rapidly reversible.

Symptoms
Theoretically, central nervous system (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 neurological and cardiovascular nature.

Treatment
No specific antidote is known and symptomatic treatment is recommended. Gastric lavage should only be considered in case of multiple intoxication within about one hour. Absorption reducing measures are not necessary.

Pharmacodynamics
Pharmacotherapeutic group: Synthetic anticholinergics, esters with tertiary amino group.
ATC-Code: A03AA04

The following is a detailed description of how the active ingredient of Duspatalin works. For further explanations please consult your doctor.

Mechanism of action and pharmacodynamic effects
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.

Pharmacokinetic Properties
The following is a detailed description of how the active ingredient of Duspatalin is metabolized by the body. For further explanations please consult your doctor.

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, which split the ester bonds into veratric acid and mebeverine alcohol firstly.

The main metabolite in plasma is DMAC (demethylated carboxylic acid). The steady state elimination half-life of DMAC is 5.77 h. During multiple dosing (200 mg b.i.d.) the C_{max} of DMAC is 804 ng/ml, and t_{max} 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 metabolized 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
No pharmacokinetic studies have been conducted in children with any formulation of mebeverine.

Incompatibilities
Not applicable.

Shelf life and Special precautions for storage
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 30°C and not below 5°C.
Store in the original package.
Keep this medicine out of the reach and sight of children.

Pack sizes
Duspatalin 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 press-through blister strips are made of aluminum.

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

Date of information
01 Oct 2020 -(RDCCDS000239 version 7)

Manufactured by
Mylan Laboratories SAS,
Route de Belleville, Lieu-dit-Maillard
01400 Châtillon-sur-Chalaronne – FRANCE
For
Abbott Healthcare Products B.V.,
The Netherlands

Abbott
50078780 CL 4377

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