

Mascherina**Packaging & Label Management**

INVOLVED PLANT: Chatillon

PRODUCT NAME: Duspatalin 135mg 5x10Tab

AFFILIATE ORIGINATOR: Indonesia

ORIGINATING FROM LCR / MKPR Number: LCR-15168-2020-DEV

COMMODITY CODE: 50076484

COMMODITY TYPE: Leaflet

CUTTING GUIDES / SIZE: Flat - 158x315 mm - SPE 97885

PHARMACODE: 4268 (IIIXIXIXXIX)

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

FONT STYLE / MINIMUM FONT SIZE FOR TEXT: Helvetica Neue / 12 pt

NOTES: N.A.

 1st draft
Date 15/04/2021
Operator/Dev. Santosh N 2nd draft
Date
Operator/Dev.
 6th draft
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Operator/Dev.
 11th draft
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Operator/Dev. 3rd draft
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 7th draft
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 12th draft
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DUSPATALIN

Mebeverine HCl

COMPOSITION

Each sugar coated tablet contains 135 mg mebeverine hydrochloride

MECHANISM OF ACTION

Mebeverine hydrochloride the active principle in Duspatalin, is a musculotropic spasmolytic with a direct action on the smooth muscle spasm of the gastrointestinal tract, relieving spasm without affecting normal gut motility.

INDICATIONS

Adjunct in gastro intestinal disorders characterized by smooth muscle spasm.

DOSAGE

Adult: 1 tablet 3 times daily, preferably 20 minutes before meals.

When the desired effect has been obtained the dosage may be reduced gradually after a few weeks.

CONTRAINDICATIONS

Hypersensitivity to mebeverine.

SIDE EFFECTS

Indigestion, heartburn, dizziness, insomnia, anorexia, headache, decrease in pulse rate, constipation, general malaise.

SPECIAL WARNING AND PRECAUTIONS FOR USE

- Though experiments in rats and rabbits have shown that Duspatalin is not teratogenic in these animal species, administration of Duspatalin is to be discouraged during pregnancy.
- Duspatalin tablet should be used with caution in patients with the following conditions on the basis of potential clinical significance (possible reason in parenthesis where appropriate).
 - Cardiac dysrhythmia, in particular patients with partial or complete atrioventricular heart block, and/or angina or severe ischaemic heart disease.
 - Hepatic dysfunction, i.e. patients with advanced liver disease, e.g. cirrhosis (because of metabolic pathway). Liver function test may be indicated if patients develops gastrointestinal symptoms or jaundice suggesting hepatic sensitivity.
 - Advanced renal disease (because of excretory pathway)
- The product is not recommended in children below the age of 3 years because no clinical trials have been carried out with mebeverine in this age group.

PACKING

Box of 5 blisters @ 10 sugar coated tablets.

Reg. No. : DKI1327000616A1

STORAGE

Do not store above 30°C. Do not freeze.

Store in the original package.

SHELF LIFE

3 years

ON MEDICAL PRESCRIPTION ONLY HARUS DENGAN RESEP DOKTER

Manufactured by Mylan Laboratories SAS,
F-01400 Chatillon-sur-Chalaronne – FRANCE

Imported by PT. Abbott Indonesia,
Jl. Raya Jakarta - Bogor, Km. 37, Depok, Indonesia



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Abbott
50076484 CL 4268

DISETUVI OLEH BPOM: 10/03/2023

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