SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Duspatalin 135 mg, coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One coated tablet contains
135 mg mebeverine hydrochloride.

Excipients with a known effect:

79 mg sucrose and
97 mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Round, white sugar-coated tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults and children over the age of 10 years
Symptomatic treatment of irritable bowel syndrome.

4.2 Posology and method of administration

For oral use.

The coated tablets must be taken with a sufficient quantity of water (at least 100 ml). They must not be chewed because of the unpleasant taste.

Adults and children over the age of 10 years
Three times daily 1 tablet of 135 mg, to be taken approximately 20 minutes before a meal.
There are no safety risks for a duration of use up to 1 year. However, when the desired effect has been achieved after a few weeks, the dose may be reduced gradually.
If one or more doses have not been taken, the patient must continue with the next dose as prescribed; the missed dose should not be taken on top of the usual dose.

Paediatric population
Duspatalin 135 mg should not be used in children below the age of 10 years because

the safety and efficacy have not been established in this target group.

Elderly patients and patients with kidney and/or liver disorders
No dose studies have been performed in elderly patients and patients with kidney and/or liver disorders.

4.3 Contraindications
Hypersensitivity to mebeverine or one of the excipients (see section 6.1).

4.4 Special warnings and precautions for use
Because Duspatalin 135 mg coated tablets contain lactose, patients with rare hereditary disorders, such as galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, should not use

this medicinal product.

Because Duspatalin 135 mg coated tablets contain sucrose, patients with rare hereditary disorders, such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency, should not use this medicinal product.

4.5 Interactions with other medicinal products and other forms of interactions
As far as known, mebeverine has no interactions with other medicinal products.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of mebeverine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). The use of Duspatalin 135 mg is not recommended during pregnancy.

Breast-feeding
It is unknown whether mebeverine or one of its metabolites is excreted in human milk. Excretion of mebeverine in breast milk has not been investigated in animals. Duspatalin 135 mg should not be used during breast-feeding.

Fertility
No clinical data are available on the fertility in men or women; however, animal studies do not indicate damaging effects from Duspatalin 135 mg (see section 5.3).

4.7 Effects on ability to drive and use machines
No studies have been carried out into the effect on the ability to drive and use machines. Neither the pharmacodynamic and pharmacokinetic profiles, nor the post-marketing experience indicate an adverse effect of mebeverine on the ability to drive and use machines.

4.8 Undesirable effects
The following undesirable effects have been reported spontaneously during post-marketing use. No exact frequency can be determined from the available data.

The observed allergic reactions are mainly, but not exclusively, limited to the skin.

Skin and subcutaneous tissue disorders
Urticaria, angioedema, facial oedema, exanthem

Immune system disorders
Hypersensitivity (anaphylactic reactions)

Report of suspected undesirable effects
It is important to report suspected undesirable effects after approval of the medicinal product. In this way the relationship between benefits and risks of the medicinal product can be constantly monitored. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

Symptoms
Very little is reported in the literature about symptoms after mebeverine overdose. In cases of mebeverine overdose, the symptoms were either absent or mild and usually quickly reversible. Observed overdose symptoms are of a neurological nature.

Treatment
There is no known specific antidote; symptomatic treatment is recommended. Measures to decrease absorption are not necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: synthetic anticholinergics, esters with tertiary amino group. ATC code: A03AA04.

Mechanism of action and pharmacodynamic effects
Mebeverine is a musculotropic spasmolytic agent with a direct effect on the smooth muscles of the gastrointestinal tract without affecting the normal intestinal motility. Because this effect is not brought about via the autonomous nervous system, the typical anticholinergic adverse effects do not occur.

5.2 Pharmacokinetic properties
Absorption
Mebeverine is quickly and fully absorbed after oral administration of tablets.

Distribution
No significant accumulation occurs after multidosage use.

Biotransformation
Mebeverine hydrochloride is mainly metabolised by esterases, which first split ester compounds 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 2.45 hours. With multidosage use, the C_{max} of DMAC is 1670 ng/ml and the t_{max} is 1 hour for the coated tablets with 135 mg.

Elimination
Mebeverine is not excreted as such but excreted fully metabolised; the metabolites are excreted almost completely. Veratric acid is excreted in the urine; mebeverine alcohol is also excreted in the urine, partly as the corresponding carboxylic acid (MAC) and partly as the demethylated carboxylic acid (DMAC).

Paediatric patients
No clinical investigations in children have taken place with any form of mebeverine.

5.3 Preclinical safety data

Effects in repeat-dose studies after oral and parenteral doses were indicative of central nervous involvement with behavioral excitation, mainly tremor and convulsions. In the dog, the most sensitive species, these effects were seen at oral doses equivalent to 3 times the maximum recommended clinical dose of 400mg/day based on body surface area (mg/m2) comparisons.

The reproductive toxicity of mebeverine was not sufficiently investigated in animal studies. There was no indication of teratogenic potential in rats and rabbits. However, embryotoxic effects (reduction in litter size, increased incidence of resorption) were noticed in rats at doses equivalent to twice the maximum daily clinical dose. This effect was not observed in rabbits.
No effects on male or female fertility were noted in rats at doses equivalent to the maximum clinical dose.
In conventional *in vitro* and *in vivo* genotoxicity tests mebeverine was devoid of genotoxic effects. No carcinogenicity studies have been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Tablet core: lactose monohydrate, starch, povidone, talc and magnesium stearate. Tablet coating: talc, sucrose, gelatin, acacia and carnauba wax.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
5 years.

6.4 Special precautions for storage
Store below 30°C.
Store in the original packaging.

6.5 Nature and contents of container
Blister strips of 20 tablets, three strips per pack. The blister strips are made of PVC/PVDC-aluminium foil or of PVC-aluminium foil.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

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8. MARKETING AUTHORISATION NUMBER

FDA/SD.255-040621

9. DATE OF FIRST AUTHORISATION OR RENEWAL

04/28/2025

10. DATE OF REVISION OF THE TEXT

07/2025