SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mebeverine Tablets 135 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 135 mg of Mebeverine Hydrochloride.

Excipient(s) with known effect
Contains approximately 36 mg of lactose per tablet. Also contains sucrose and methyl parahydroxybenzoate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet.
White or almost white, biconvex sugar-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Mebeverine tablets are indicated for the treatment of irritable bowel syndrome and other conditions usually included in this grouping such as; chronic irritable colon, spastic constipation, mucous colitis and spastic colitis. Mebeverine is effectively used to treat the symptoms of these conditions, such as: colicky abdominal pain and cramps, persistent, non-specific diarrhoea (with or without alternating constipation) and flatulence.

4.2 Posology and method of administration

For oral administration.

Adults (including the elderly):

The usual dosage is 135 mg three times daily, preferably 20 minutes before the ingestion of food. After a period of several weeks, when the desired effect has been obtained, the dosage may be gradually reduced.

Paediatric Population
Mebeverine Tablets are not recommended for use in children and adolescents below 18, due to insufficient data on safety and efficacy.

4.3 Contraindications

Mebeverine tablets are contra-indicated in paralytic ileus, and in hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Avoid in acute porphyria.

Excipient(s)

Lactose
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Sucrose
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

Methyl parahydroxybenzoate
May cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

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 or postnatal development (see section 5.3).

Caution should be exercised when prescribing to pregnant women.

There is insufficient information on the excretion of mebeverine in human or animal breast milk. Physico-chemical and available pharmacodynamic data on mebeverine point to excretion in breast milk and a risk to the suckling child cannot be excluded. Mebeverine should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Allergic reactions mainly but not exclusively limited to the skin have been observed (a frequency cannot be estimated from the available data.).

Immune system disorders:
Hypersensitivity

Skin and subcutaneous tissue disorders
Urticaria, angioedema, erythematous rash

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Theoretically CNS excitability may occur in cases of overdose. In cases where mebeverine was taken in overdose symptoms were either absent or mild, e.g. abdominal discomfort and flatulence, and usually rapidly reversible.

No specific antidote is known; gastric lavage and symptomatic treatment is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: A03A A04 (Synthetic anticholinergics, esters with tertiary amino group).

Mebeverine hydrochloride is a musculotropic antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility. In addition, it has lowered blood pressure in animals, probably on account of its peripheral vasodilatory activity.

5.2 Pharmacokinetic properties

Mebeverine hydrochloride is rapidly and completely absorbed after oral administration in the form of tablets or suspension. It is not absorbed from the stomach and absorption has been shown to commence as soon as the drug enters the duodenum. Mebeverine hydrochloride is not excreted as such, but metabolised 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 partly as the corresponding carboxylic acid and partly as the demethylated carboxylic acid. The urine is the only route of elimination – on the basis of radio-tracer studies it has been stated that absorption of mebeverine in rats and rabbits after intra-muscular or oral administration is essentially complete since virtually all the label was recovered in the urine.

5.3. Pre-clinical Safety Data

Preclinical information has not been included because the safety profile of mebeverine has been established after many years of clinical use. Please refer to Section 4.

6.1. List of Excipients

The tablets contain:
Lactose Monohydrate
Potato Starch
Sodium Starch Glycollate
Povidone K30
Purified Talc (E553)
Magnesium Stearate (E572)

Tablet coating contains:
Sucrose
Purified Talc
Calcium Carbonate

Titanium Dioxide (E171)
Acacia
Magnesium Stearate
Macroglycerol Ricinoleate
Methylparahydroxybenzoate (E218)
White Beeswax (E901)

6.2. Incompatibilities

None known.

6.3. Shelf-Life

24 months

6.4 Special precautions for storage

Store at or below 25°C. Store in the original package or keep blister in outer carton.

6.5. Nature and Content of Container

HDPE or polypropylene containers with caps in packs of 30 or 100 tablets.

Blister strips in packs of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160 or 168 tablets.

Not all pack sizes may be marketed.

6.6. Instructions for Use, Handling and Disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford, WF10 5HX,
United Kingdom.

8. MARKETING AUTHORISATION NUMBER(S)

PL 0289/0095

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

Date MA granted: 15th March 1991

10 DATE OF REVISION OF THE TEXT

07/08/2025