SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mebeverine hydrochloride 50mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml dose contains 50mg of mebeverine hydrochloride (as pamoate complex in the drug product).

Also contains the following excipients with known effects

Sodium benzoate	10 mg per 5ml dose
Sodium	20.5 mg per 5ml dose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Yellow coloured banana flavoured suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. For the symptomatic treatment of irritable bowel syndrome and other conditions usually included in this grouping, such as chronic irritable colon, spastic constipation, mucous colitis, 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.

2. For the symptomatic treatment of gastro-intestinal spasm secondary to organic diseases.

4.2 Posology and method of administration

Adults (including the elderly) and children 10 years and over: 15 ml (150 mg) three times a day, preferably 20 minutes before meals.

After a period of several weeks when the desired effect has been obtained, the dosage may be gradually reduced.

Children under 10 years. Not applicable.

4.3 Contraindications

Hypersensitivity to any component of the product.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interaction

None Known.

4.6 Pregnancy and lactation

Animal experiments have failed to show any teratogenic effects. However, the usual precautions concerning the administration of any drugs during pregnancy should be observed.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Immune system disorders
Very rare: hypersensitivity

Skin and subcutaneous tissue disorders
Very rare: urticaria, angioedema, face oedema, exanthema/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.

4.9 Overdose

On theoretical grounds it may be predicted that CNS excitability will occur in cases of over dosage. No specific antidote is known; gastric lavage and symptomatic treatment is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: A03AA04

Pharmacotherapeutic group: Synthetic anticholinergics, esters with tertiary amino group
Mebeverine is a musculotropic antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract, relieving spasm without affecting normal gut motility.

5.2 Pharmacokinetic properties

Mebeverine is rapidly and completely absorbed after oral administration in the form of tablets or suspension. Mebeverine 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.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Pamoate
Microcrystalline cellulose
Carmellose sodium
Citric acid monohydrate

Polysorbate 20
Sodium benzoate
Trisodium citrate dehydrate
Macrogol glycerol hydroxystearate
Saccharin sodium
Simethicone emulsion
Banana flavour

6.2 Incompatibilities

None Known

6.3 Shelf life

36 months
After first opening: 14 days

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

300ml Amber coloured glass bottle with 28mm white click-lock tamper evident cap.

6.6 Special precautions for disposal

Shake well before use. Dilution and subsequent storage not recommended. Mebeverine does not produce false positive reactions in standard diagnostic urine tests.

7 MARKETING AUTHORISATION HOLDER

Kinedexe UK Limited
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UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 44710/0024

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/03/2018

10 DATE OF REVISION OF THE TEXT

26/03/2018