

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Mebeverine 50mg/5ml Sugar Free Oral Suspension

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5 ml oral suspension contains 50 mg mebeverine hydrochloride (as pamoate).

Excipient(s) with known effect

Each 5 ml oral suspension contains 1 mg polyoxyl 40 hydrogenated castor oil, 10 mg sodium benzoate and 20.5 mg sodium.

For the full list of excipients, see Section 6.1.

### **3 PHARMACEUTICAL FORM**

Oral suspension

Yellow sugar free suspension with a flavour of banana.

### **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 the active substance or to any of the excipients listed in section 6.1.

#### **4.4 Special warnings and precautions for use**

##### Sodium benzoate

This medicinal product contains 30 mg sodium benzoate in each 15 ml spoonful of oral suspension which is equivalent to 2 mg/ml.

##### Polyoxyl 40 hydrogenated castor oil

This medicinal product contains 3 mg polyoxyl 40 hydrogenated castor oil in each 15 ml spoonful of oral suspension which is equivalent to 0.2 mg/ml. Castor oil may cause stomach upset and diarrhoea.

##### Sodium

This medicinal product contains 61.5 mg of sodium in each 15 ml spoonful of oral suspension, equivalent to 3% of the WHO recommended daily intake of 2 g sodium for an adult.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Fertility, pregnancy and lactation**

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

#### **4.7 Effects on ability to drive and use machines**

Mebeverine has no or negligible influence on the ability to drive and use machines

#### **4.8 Undesirable effects**

##### Immune system disorders

Very rare (<1/10,000): hypersensitivity

#### Skin and subcutaneous tissue disorders

Very rare (<1/10,000): 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9. Overdose**

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

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Synthetic anticholinergics, esters with tertiary amino group, ATC code: A03A A04

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**

Microcrystalline cellulose  
Carboxymethylcellulose sodium  
Citric acid monohydrate  
Sodium citrate  
Polysorbate 20  
Polyoxyl 40 hydrogenated castor oil  
Disodium pamoate monohydrate  
Sodium benzoate (E 211)  
Saccharin sodium  
Banana flavour  
Simethicone emulsion  
Purified water.

### **6.2. Incompatibilities**

Not applicable.

### **6.3 Shelf life**

5 years.

### **6.4 Special precautions for storage**

Do not store above 30°C. Keep bottle in the outer carton.

### **6.5 Nature and contents of container**

Amber glass bottle with polyethylene tamper evident cap. Each bottle contains 300 ml.

### **6.6 Special precautions for disposal and other handling**

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

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

**7      MARKETING AUTHORISATION HOLDER**

Chemidex Pharma Limited  
8a Crabtree Road  
Egham  
Surrey TW20 8RN  
United Kingdom

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 17736/0084

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

21 May 1997

**10     DATE OF REVISION OF THE TEXT**

15/02/2025