IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA1161/003/001
Case No: 2041246

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Chemidex Pharma Limited T/A Essential Generics

Chemidex House, **Egham Business Village**, **Crabtree Road, Egham**, **Surrey TW20 8RB**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Mebeverine 50mg/5ml Sugar Free Oral Suspension

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **02/12/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mebeverine 50mg/5ml Sugar Free Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mebeverine pamoate equivalent to 50 mg mebeverine hydrochloride per 5 ml.

The sodium content is 20.5mg per 5ml.

The polyoxyl 40 hydrogenated castor oil content is 1mg per 5ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.
A yellow, thixotropic, banana flavoured, sugar free oral suspension with a sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of irritable bowel syndrome, (particularly gastrointestinal spasm).

4.2 Posology and method of administration

Oral route.

Adults (including the elderly) and children 10 years and over:

15 ml (150 mg) three times daily, 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:

Mebeverine 50mg/5 ml Sugar Free Oral Solution is not recommended for use in children below age 10 years (due to a lack of data on safety and efficacy).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Prior to treating patients with mebeverine, care should be taken to exclude organic disease of the bowel, particularly malignancy.

This product contains saccharin 10 mg/5 ml.

The sodium content is 20.5 mg/5 ml - to be taken into consideration by patients on a controlled sodium diet.

Mebeverine Oral Suspension contains poloxyl 40 hydrogenated castor oil which may cause stomach upset and diarrhoea.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Although studies in animals have not shown any teratogenic effect which can definitely be attributed to mebeverine, the safety of mebeverine in human pregnancy has not been established. On basic principles therefore, its use is not recommended.

4.7 Effects on ability to drive and use machines

Mebeverine 50 mg/5 ml Sugar Free Oral Solution has no ifluence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders
Very rare: hypersensitivity.

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

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: Drugs for functional bowel disorders, Synthetic anticholinergics, esters with tertiary amino group.

ATC code: A03AA04

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 and carboxymethylcellulose sodium
Citric acid monohydrate
Sodium citrate
Polysorbate 20
Polyoxyl 40 hydrogenated castor oil
Disodium pamoate monohydrate
Sodium benzoate (E211)
Saccharin sodium
Banana flavour
Simethicone emulsion
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 30°C. Keep the 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Shake well before use. Dilution and subsequent storage not recommended.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited
Trading as: Essential Generics
Chemidex House
Egham Business Village
Crabtree Road
Egham
Surrey
TW20 8RB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1161/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 January 1983

Date of last renewal: 07 January 2008

10 DATE OF REVISION OF THE TEXT

December 2008