IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1410/043/001
Case No: 2043419

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

Transferred from PA0021/066/001.

Bayer Limited

The Atrium, **Blackthorn Road**, **Dublin 18**, **Ireland**

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

Delsym (Controlled Release) 30mg/5ml 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 **21/11/2008**.

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

Delsym (Controlled Release) 30mg/5 ml Oral Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of suspension contains dextromethorphan resin complex * equivalent to 30 mg of dextromethorphan hydrobromide.

*Dextromethorphan resin complex as coated dextromethorphan polistirex and uncoated dextromethorphan polistirex.

Excipients: Each 5ml contains sucrose (granulated sugar) 600mg, sunset yellow (E110) 0.115mg, methyl paradroxybenzoate (E218) 7.5 mg, propyl parahydroxybenzoate (E216) 1.5mg and high fructose corn syrup 1.5g.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release oral suspension
Uniform oral suspension of opaque orange colour and a characteristic orange odour and flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the temporary relief of cough due to minor throat and bronchial irritation as may occur with the "common cold" or with inhaled irritants.

4.2 Posology and method of administration

For oral administration only. Shake well before using. Use the spoon provided.

Adults:

1 x 5 ml teaspoonful every 12 hours. Do not exceed 3 x 5 ml teaspoonful in 24 hours.

Children:

6-12 years: 1 x 5 ml teaspoonful every 12 hours. Do not exceed 2 x 5 ml teaspoonful in 24 hours.

2-5 years: half x 5 ml teaspoonful (= 2.5 ml) every 12 hours. Do not exceed 1 x 5 ml teaspoonful in 24 hours.

Children under 2 years:

Not recommended.

4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

Use in children under 2 years of age.

4.4 Special warnings and precautions for use

Delsym should only be used under medical supervision for persistent or chronic cough such as occurs with smoking, asthma or emphysema, or where cough is accompanied by excessive secretions.

Patients experiencing high fever, rash or persistent headache or no improvement in their condition within seven days, should seek medical advice.

Persons who are taking other medications and are under the care of a physician, should consult their doctor before taking the product.

Do not exceed the recommended dosage schedules.

Keep this and all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

This product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Delsym may cause drowsiness, if affected do not drive or operate machinery and avoid alcohol.

4.8 Undesirable effects

Dextromethorphan occasionally causes drowsiness, dizziness, excitation, mental confusion, gastrointestinal disturbances, bronchoconstriction and dyspnoea.

4.9 Overdose

In general, the management of overdosage with dextromethorphan involves supportive and symptomatic therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dextromethorphan is the d isomer of the codeine analog of levorphanol; however, unlike the l isomer, it has no analgesic or addictive properties. The drug acts centrally to elevate the threshold for coughing. Its effectiveness in patients with pathological cough has been demonstrated in controlled studies; its potency is nearly equal to that of codeine. Compared to codeine, dextromethorphan produces fewer subjective and gastrointestinal side-effects. In therapeutic dosage, the drug does not inhibit ciliary activity, and its antitussive effect persist for 5-6 hours. Its toxicity is quite low, but extremely high doses may produce CNS depression.

Dextromethorphan is well absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted as unchanged dextromethorphan and demethylated morphinan compounds.

5.2 Pharmacokinetic properties

None.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

High fructose corn syrup
Granulated sugar (sucrose)
Propylene glycol
Powdered tragancanth gum (E413)
Xanthan gum (E415)
Methyl p-hydroxybenzoate (E218)
Anhydrous citric acid (E330)
Polysorbate 80 (E433)
Propyl p-hydroxybenzoate (E216)
Orange flavour
Sunset yellow (E110)
Purified water
Coated dextromethorphan polistirex
(containing Amberlite IRP70 (polacrilin potassium), polyethylene glycol 300, vegetable oil and ethylcellulose)
Uncoated dextromethorphan polistirex
(containing, Amberlite IRP70 sodium washed)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30^{o}C.

6.5 Nature and contents of container

Amber glass bottles of 89 ml with a plastic cap, presented in an outer carton.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1410/43/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 4th May 1984

Date of last renewal: 11th November 2007

10 DATE OF REVISION OF THE TEXT

November 2008