IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0172/033/001
Case No: 2043317

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

Whitehall Laboratories Limited

T/A Wyeth Consumer Healthcare, **Huntercombe Lane South**, **Taplow, Maidenhead**, **Berkshire,SL6 0PH SL6 0PH**, **United Kingdom**

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

Robitussin Junior 3.75 mg/5ml Oral Solution

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 **14/01/2008** until **17/12/2010**.

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

Robitussin Junior 3.75mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of liquid contains:

Dextromethorphan Hydrobromide 3.75 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral Solution
A clear, red liquid with the characteristic odour and taste of cherry/grenadine.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a cough suppressant for the relief of non-productive irritant cough.

4.2 Posology and method of administration

Taken orally.

Children:	**6 - 12 years:**	10 ml 3 to 4 times daily.
	2 - 6 years:	5 ml 3 to 4 times daily.
	Under 2 years:	Not to be used.

4.3 Contraindications

Known hypersensitivity to any of the active ingredients.

4.4 Special warnings and precautions for use

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

Patients who are taking other medication and/or are under the care of a physician, should consult their doctor before taking the product.

Do not exceed the recommended dose schedule.

If symptoms persist for more that 7 days or you have a recurrent cough, consult your doctor or pharmacist.

Not for use in children under 2 years old.

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Use with caution in patients receiving monoamine oxidase inhibitors, or within two weeks of stopping treatment.

4.6 Pregnancy and lactation

- Although Dextromethorphan has been in wide spread use for many years without apparent ill consequence, there are no specific data on its use during pregnancy.

- It is not known whether dextromethorphan or its metabolites are excreted in human milk. Caution should therefore be exercised by balancing the potential benefit of treatment against any possible hazards.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects with dextromethorphan hydrobromide are rare and may include dizziness and gastrointestinal upset.

4.9 Overdose

Excitation, confusion, and respiratory depression may occur after overdosage.
Gastric lavage and supportive measures should be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dextromethorphan hydrobromide is a cough suppressant, which has a central action on the cough centre in the medulla. It has no analgesic properties and little sedative activity.

5.2 Pharmacokinetic properties

Dextromethorphan hydrobromide is well absorbed from the GI tract. It is metabolised in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites of dextromethorphan which have some cough suppressant activity.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sodium Carboxymethyl Cellulose
Sodium Benzoate
Disodium Edetate
Maltitol Liquid
Citric Acid Anhydrous

Amaranth E123
Caramel E150
Levomenthol
Cherry / Grenadine Flavour
Sorbitol Solution (70%) (E420)
Sodium Cyclamate
Acesulfame Potassium Salt
Purified Water
Ethanol (96% v/v)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottle filled to 100 ml with tamper evident jar type lid.
Supplied with measuring cup.

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

Whitehall Laboratories Ltd
Trading as:
Wyeth Consumer Healthcare
Huntercombe Lane South
Taplow
Maidenhead
Berkshire
SL6 0PH
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 172/33/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 December 1985

Date of last renewal: 18 December 2005

10 DATE OF REVISION OF THE TEXT

December 2006