Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Robitussin Dry Cough 7.5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of liquid contains;

Active ingredient:
Dextromethorphan Hydrobromide 7.5 mg

Excipients with known effect:

Ethanol (96%)	103.9 mg
Amaranth	0.165 mg
Maltitol Liquid	242 mg
Sorbitol, liquid (non-crystallising) 70% Sodium benzoate (E211)	1.454 mg 6 mg

For a full list of ingredients, see 6.1

3 PHARMACEUTICAL FORM

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

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. Shouldnot be used with other cough and cold medicines.

Adults and children over 12 years: 10 ml, 3 to 4 times daily.

Children under 12 years: Do not use

Medicaladvice should be sought before use in patients with severe renal impairment.

4.3 Contraindications

Use in children under 12 years of age.

Use in patients taking a prescription selective serotonin reuptake inhibitor (SSRI). Do not use if you are taking or have taken within the past two weeks fluoxetine or any monoamine oxidase inhibitors (MAOIs), usually used to treat depression.Severe and sometimes fatal reactions have been reported after use of dextromethorphan in patients receiving MAOIs.

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

Use in patients with, or at risk of developing, respiratory failure (e.g. those with chronic obstructive airways disease or pneumonia, or during an asthma attack or an exacerbation of asthma).

4.4 Special warnings and precautions for use

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

Cases of dextromethorphan abuse and dependence have been reported. Caution is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.

Dextromethorphan is metabolised by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10% of the general population are poor metabolisers of CYP2D6. Poor metabolisers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and/or prolonged effects of dextromethorphan. Caution should therefore be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors (see also section 4.5).

If the product is abused by patients they may become dependent on it.

Concomitant use of other cough and cold medicines should be avoided.

Concomitant use of alcohol should be avoided.

There have been no specific studies of Robitussin Dry Cough in renal or hepatic dysfunction. Due to the extensive hepatic metabolism of dextromethorphan, caution should be exercised in the presence of hepatic impairment. Medical advice should be sought before taking dextromethorphan in patients with severe renal impairment.

Do not exceed the recommended dose.

If symptoms persist for more than 7 days, you have a recurrent cough or is accompanied by fever, rash or persistent headaches, consult your doctor or pharmacist. These could be signs of a serious condition.

Serotonin Syndrome
Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)) and CYP2D6 inhibitors. Serotonin syndrome may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. If serotonin syndrome is suspected, treatment with Robitussin Dry Cough should be discontinued.

Excipient warnings:
- Patients with rare hereditary problems of fructose intolerance should not take this medicine because this product contains sorbitol and maltitol.
- This medicine contains 2094 mg sorbitol per 10 ml dose which is equivalent to 209.4 mg/ml. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This product contains amaranth (E123), which may cause allergic reactions.
- This medicine contains 208 mg of alcohol (ethanol 96%) in each 10 ml dose which is equivalent to 21 mg/ml (2.08% w/v). The amount in 10 ml of this medicine is equivalent to less than 6 ml beer or 3ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains 12.0 mg sodium benzoate in each 10 ml dose which is equivalent to 1.2 mg/ml.
- This medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Anti-depressants
Fluoxetine / Paroxetine: Hallucinations and serotonin syndrome may occur.

MAOI or SSRI
Do not give to patients taking a prescription selective serotonin reuptake inhibitor (SSRI) or tricyclic antidepressants (TCAs). Do not use if you are taking or have taken in the past two weeks, monoamine oxidase inhibitors (MAOI's), usually used to treat depression. Concomitant use of dextromethorphan with an MAOI drug is contraindicated as it can result in serotonin

syndrome, with symptoms including hypertension, hyperpyrexia, arrhythmia or myoclonus. Severe and sometimes fatal reactions have been reported after use of dextromethorphan in patients receiving MAOIs.
The pharmacological mechanism for the interaction may be that of 1) dextromethorphan blocking the neuronal reuptake of serotonin, and 2) MAOI drug decreasing the breakdown of serotonin.

Anti-arrhtyhmics
Quinodine and Amiodarone can increase the concentration of Dextromethorphan.

CYP2D6 inhibitors
Dextromethorphan is metabolized by CYP2D6 and has an extensive first-pass metabolism. Concomitant use of potent CYP2D6 enzyme inhibitors can increase the dextromethorphan concentrations in the body to levels multifold higher than normal. This increases the patient's risk for toxic effects of dextromethorphan (agitation, confusion, tremor, insomnia, diarrhoea and respiratory depression) and development of serotonin syndrome. Potent CYP2D6 enzyme inhibitors include fluoxetine, paroxetine, quinidine and terbinafine. In concomitant use with quinidine, plasma concentrations of dextromethorphan have increased up to 20-fold, which has increased the CNS adverse effects of the agent. Amiodarone, flecainide and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol, perphenazine and thioridazine also have similar effects on the metabolism of dextromethorphan. If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dextromethorphan dose may need to be reduced.

Alcohol
Concomitant use of dextromethorphan and alcohol may increase the CNS-depressant effects of both drugs.

4.6 Fertility, pregnancy and lactation

Although Dextromethorphan has been in widespread use for many years without apparent ill effect, the safe use of this product in pregnancy has not been established.

Dextromethorphan is excreted in breast milk in minor quantities. Caution should therefore be exercised by balancing the potential benefit of treatment against any possible hazards. This product should only be taken by breast-feeding mothers when considered essential by the physician.

4.7 Effects on ability to drive and use machines

Patients should not drive or operate machinery if affected by drowsiness or dizziness.

4.8 Undesirable effects

The following adverse events have been observed in clinical trials with dextromethorphan and are likely to represent uncommon adverse reactions to dextromethorphan (i.e., occurring in ≥1/1,000 to <1/100 patients). Adverse reactions are listed below by MedDRA System Organ Class.

Immune system disorders	Hypersensitivity reactions
Nervous system disorders	Drowsiness, dizziness
Gastrointestinal disorders	Gastrointestinal upset, nausea, vomiting, abdominal discomfort

Adverse reactions identified during post-marketing use are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but likely to be rare or very rare (occurring in < 1/1,000 patients).

Skin and subcutaneous disorders	Allergic reactions (e.g. rash, urticaria, angioedema)

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 HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Symptoms and signs:

Dextromethorphan overdose may be associated with nausea, vomiting, dystonia, agitation, confusion, somnolence, stupor, nystagmus, cardiotoxicity (tachycardia, abnormal ECG including QTc prolongation), ataxia, toxic psychosis with visual hallucinations, hyperexcitability.
In the event of massive overdose the following symptoms may be observed: coma, respiratory depression, convulsions.

Management:

- Gastric lavage and supportive measures should be used.
- Activated charcoal can be administered to asymptomatic patients who have ingested overdoses of dextromethorphan within the preceding hour.
- For patients who have ingested dextromethorphan and are sedated or comatose, naloxone, in the usual doses for treatment of opioid overdose, can be considered. Benzodiazepines for seizures and benzodiazepines and external cooling measures for hyperthermia from serotonin syndrome can 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.

ATC code: R05DA09

5.2 Pharmacokinetic properties

Dextromethorphan hydrobromide is well absorbed from the GI tract.

Metabolism
Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Genetically controlled O-demethylation (CYD2D6) is the main determinant of dextromethorphan pharmacokinetics in human volunteers.

It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3- hydroxymorphinan and 3-methoxymorphinan have been identified as conjugated products in the urine.

Dextrorphan, which also has antitussive action, is the main metabolite. In some individuals metabolism proceeds more slowly and unchanged dextromethorphan predominates in the blood and urine.

5.3 Preclinical safety data

Non-clinical safety data on dextromethorphan obtained from the literature and in-house have not revealed findings which are of relevance to the recommended dosage and use of the product.

The results of non-clinical studies have demonstrated a lack of adverse effects on fertility, foetal development and postnatal viability following oral administration of up to 50 mg/ kg/ day dextromethorphan to rats (estimated to be approximately 4 times the daily maximum human equivalent therapeutic dose of 120 mg/ day) and rabbits (estimated to be approximately 8 times the daily maximum human equivalent therapeutic dose of 120 mg/ day) during pregnancy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Carmellose Sodium
Sodium Benzoate (E211)
Disodium Edetate
Maltitol Liquid
Citric Acid Anhydrous

Amaranth (E123)
Caramel (E150d)**
Levomenthol
Cherry / Grenadine Flavour*
Sorbitol, liquid (non-crystallising) (70%) (E420)
Sodium Cyclamate
Acesulfame Potassium
Purified Water
Ethanol (96% v/v)

* contains ethanol (96%), propylene glycol and natural and artificial flavourings
** does not contain sucrose

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

33 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Brown glass bottle, hydrolytic class 3, containing 100 ml or 200ml with child resistant caps.
A transparent polypropylene measuring cup is also included.

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

Haleon Ireland Limited,
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Co. Waterford, X35 Y983,
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8 MARKETING AUTHORISATION NUMBER

PA0678/155/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 18 December 2010

10 DATE OF REVISION OF THE TEXT

July 2025