

# 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
Liquid Maltitol	242 mg
Sorbitol Solution 70%	1.454 mg
Sodium benzoate (E211)	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/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

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

**Children under 12 years:** Do not use

### 4.3 Contraindications

Use in children under 12 years of age.

Use in patients taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or for 2 weeks after stopping the medication. (see section 4.5). 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.

### 4.4 Special warnings and precautions for use

Robitussin Dry 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.

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.

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

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.

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 interactions

#### Anti-depressants

Fluoxetine / Paroxetine: Hallucinations and serotonin syndrome may occur.

#### MAOI or SSRI

Do not give to patients taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or for 2 weeks after stopping the medication. 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-arrhythmics

Quinidine and Amiodarone can increase the concentration of Dextromethorphan.

**Anti-bacterials**

Linezolid: Serotonin like symptoms have occurred when Dextromethorphan has been taken with Linezolid.

**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.

**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.

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. 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**

Dextromethorphan hydrobromide has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

The following side effects may be associated with the use of Dextromethorphan although the frequency is not known (cannot be estimated from available data):

<i>Immune system disorders</i>	Hypersensitivity reactions
<i>Nervous system disorders</i>	Dizziness
<i>Gastrointestinal disorders</i>	Gastrointestinal upset

**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](http://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 and little sedative activity.

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

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol  
Croscarmellose Sodium  
Sodium Benzoate (E211)  
Disodium Edetate  
Maltitol Liquid  
Citric Acid Anhydrous  
Amaranth (E123)  
Caramel (E150d)\*\*  
Levomenthol  
Cherry / Grenadine Flavour\*  
Sorbitol Solution (70%) (E420)  
Sodium Cyclamate  
Acesulfame Potassium Salt  
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

PET Bottles: 33 months.

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

Do not store above 25°C.

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

PET bottles containing 100ml or 250ml with PET-lined PP/HDPE child resistant screw caps.

A clear 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**

GlaxoSmithKline Consumer Healthcare (Ireland) Limited  
12 Riverwalk  
Citywest Business Campus  
Dublin 24  
Ireland

### **8 MARKETING AUTHORISATION NUMBER**

PA0678/155/001

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

Date of first authorisation: 18 December 1985

Date of last renewal: 18 December 2010

### **10 DATE OF REVISION OF THE TEXT**

February 2021