

1 PRODUCT NAME

Robitussin Dry Cough Forte Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL of oral solution contains:

Dextromethorphan hydrobromide monohydrate 30 mg

Excipient(s) with known effect:

- Sodium benzoate
- Sorbitol
- Glucose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Robitussin Dry Cough Forte is a cough suppressant

4.2 Dose and method of administration

Every 6 to 8 hours orally when necessary:

Adults and Children 12 years and over: 10 mL

Children 6 years – under 12 years: 5 mL

Do not exceed 4 doses in 24 hours.

Do not use in children under 6 years of age. Use in children aged 6 to 11 years only on the advice of a doctor, pharmacist or nurse practitioner.

4.3 Contraindications

Robitussin Dry Cough Forte is contraindicated for use in:

- patients with known hypersensitivity or idiosyncratic reaction to Dextromethorphan hydrobromide monohydrate or any of the other ingredients in the product.
- patients taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication. If you are not sure if your prescription medication contains one of these

NEW ZEALAND DATA SHEET
ROBITUSSIN DRY COUGH FORTE



- drugs, ask a doctor or pharmacist before taking this product.
- patients having an acute asthma attack
- patients with impaired hepatic function
- patients with respiratory insufficiency and respiratory depression
- children under 6 years of age

4.4 Special warnings and precautions for use

Robitussin Dry Cough Forte:

a) should be used with caution in patients with:

- with a history of asthma

b) should not be used in patients with:

- a chronic persistent cough accompanying a disease state or for cough associated with excessive secretions
- or at risk of developing respiratory failure, e.g. asthma, chronic obstructive airways disease, and pneumonia.

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 CYP 2D6 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 Forte Oral Solution should be discontinued.

This product should be kept out of reach of children.

Use in children:

Serious adverse events may occur in children in case of overdose including neurological disorders. Caregivers should be advised not to exceed the recommended dose.

The recommended dosage should not be exceeded.

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.

Patients with rare glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

The following interactions with dextromethorphan have been noted:

- should not be used in patients taking a prescription monoamine oxidase inhibitor (MAOI), a selective serotonin reuptake inhibitor (SSRI), or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication. If you are not sure if your prescription medication contains one of these drugs, ask a doctor or pharmacist before taking this product. The use of dextromethorphan with, or within two weeks of taking MAOIs, may increase the risk of serious side effects such as hypertensive crisis, hyperpyrexia and convulsions.
- when used with SSRI's (such as fluoxetine) or tricyclic antidepressants (such as clomipramine and imipramine) may result in a "serotonin syndrome" with changes in mental status, hypertension, restlessness, myoclonus, hyperreflexia, diaphoresis, shivering and tremor.
- the concomitant use of dextromethorphan and inhibitors of cytochrome P450 2D6, such as the antiarrhythmics quinidine and amiodarone, antidepressants such as fluoxetine and paroxetine, or other drugs which inhibit cytochrome P450 2D6 such as haloperidol and thioridazine, may increase serum levels of dextromethorphan.
- concomitant use of dextromethorphan and other CNS depressants (e.g. alcohol, narcotic analgesics and tranquillizers) may increase the CNS depressant effects of these drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category A: The active in Robitussin Dry Cough Forte has been taken by large number of pregnant women or women of childbearing age, without any proven increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Breast-feeding

It is not known whether dextromethorphan is excreted in breast milk or whether it has a harmful effect on the breastfeeding infant. Robitussin Dry Cough Forte it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

It is recommended to consult a healthcare professional before using Robitussin Dry Cough Fort Oral Solution if pregnant, trying to become pregnant or breastfeeding.

Fertility

Not available

4.7 Effects on ability to drive and use machines

Risk of impairment is increased when dextromethorphan is taken concurrently with alcohol or medicines that can impair reaction times.

4.8 Undesirable effects

NEW ZEALAND DATA SHEET

ROBITUSSIN DRY COUGH FORTE



Immune system disorders

Hypersensitivity

Nervous system disorders

Drowsiness, fatigue, dizziness

Gastrointestinal disorders

Nausea or vomiting, stomach discomfort, or constipation

Other disorders

Dystonias

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions

<https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

Gastrointestinal disorders

Nausea, vomiting

Nervous system disorders

Depressed level of consciousness, dizziness, dysarthria, myoclonus, nystagmus, somnolence, tremor, nervousness, irritability, restlessness

Psychiatric disorders

Excitability, confusional state, psychotic disorder

Respiratory, thoracic and mediastinal disorders

Respiratory depression

Other side effects that may occur with high doses (overdosage)

“Serotonin syndrome”

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

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dextromethorphan is a non-opioid cough suppressant. It is the methylated dextrorotatory analogue of levorphanol, a codeine analogue. Dextromethorphan acts centrally on the cough centre in the medulla and nucleus tractus solaris to increase the cough threshold. It does not have classical analgesic, sedative or respiratory depressant effects at usual antitussive doses.

5.2 Pharmacokinetic properties

Dextromethorphan is well absorbed from the gastrointestinal tract after oral administration. It is metabolised in the liver, exhibiting polymorphic metabolism involving the cytochrome P450 isoenzyme (CYP 2D6). It is excreted in the urine as unchanged dextromethorphan and demethylated metabolites, including dextrorphan, which has some cough suppressant activity. The plasma elimination half-life of dextromethorphan is 1.2 to 3.9 hours. However, the rate of metabolism varies between individuals according to phenotype (extensive v poor metabolisers), with half-life being as long as 45 hours in patients who are poor metabolisers.

5.3 Preclinical safety data

Not available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Allura red AC, Cherry flavour (vanilla) 21146 as Cherry Vanilla Flavour 21146, Citric acid, Ethanol, Glucose liquid, Glycerol, High fructose corn syrup, Menthol, Purified water, Saccharin sodium, Sodium benzoate, Vanilla flavour 52089A.

6.2 Incompatibilities

Not available

6.3 Shelf life

3 Years.

6.4 Special precautions for storage

NEW ZEALAND DATA SHEET
ROBITUSSIN DRY COUGH FORTE



Store below 25°C.

6.5 Nature and contents of container

Robitussin Chesty Cough Forte is a dark red coloured syrup, packed in bottles.

Pack sizes:

25 mL (professional sample), 45 mL (professional sample); 100 mL, 200 mL and 250 mL.

6.6 Special precautions for disposal

Not available

7 MEDICINE SCHEDULE

Restricted Medicine

8 SPONSOR

Pfizer New Zealand Limited
P O Box 3998
AUCKLAND 1140
New Zealand
☎ Toll Free 0800 447 400
Web: www.robitussin.co.nz

9 DATE OF FIRST APPROVAL

14 October 1999

10 DATE OF REVISION OF THE TEXT

21 May 2020

SUMMARY TABLE OF CHANGES

Section changed	Section changed
All	New data sheet in SmPC format