ROBITUSSIN COUGH AND CHEST CONGESTION

1 PRODUCT NAME

Robitussin Cough & Chest Congestion Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL of oral solution contains:
Guaifenesin 20 mg, Dextromethorphan hydrobromide monohydrate 3 mg

Excipient(s) with known effect:
- Sodium benzoate
- Sorbitol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Robitussin Cough & Chest Congestion is an expectorant cough suppressant. For the temporary relief of cough and chest congestion due to cold and flu

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 Cough & Chest Congestion is contraindicated for use in:
- patients with known hypersensitivity or idiosyncratic reaction to Guaifenesin, 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 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 Cough & Chest Congestion
a) should be used with caution in patients with:
- porphyria, as guaifenesin is possibly porphyrogenic
- in patients 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 pulmonary disease (COPD), emphysema or smoker's cough or 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 Cough & Chest Congestion should be discontinued.

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.

This product should be kept out of reach of children.

The recommended dosage should not be exceeded.

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.

4.5 Interaction with other medicines and other forms of interaction

There are no reported interactions with other medicines and guaifenesin.

The following interactions with dextromethorphan have been noted:

Dextromethorphan 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.

Dextromethorphan 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.

Serum levels of dextromethorphan may be increased by the concomitant use of 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.

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 ingredients in Robitussin Cough & Chest Congestion have 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 or guaifenesin are excreted in breast milk or whether they have a harmful effect on the breastfeeding infant. Robitussin Cough & Chest Congestion 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 Cough & Chest Congestion 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

Immune system disorders
Hypersensitivity

Nervous system disorders
Drowsiness, fatigue, dizziness, headache

Gastrointestinal disorders
Nausea or vomiting, stomach discomfort, constipation, diarrhoea and stomach pain

Skin disorders
Rash

Other disorders
Dystonia

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

The following signs or symptoms may be associated with an overdose of Robitussin Cough and Chest Congestion:

Gastrointestinal disorders
Nausea or severe nausea, vomiting diarrhoea and stomach pain

Nervous system disorders
Depressed level of consciousness, dizziness, dysarthria, myoclonus, nystagmus, somnolence, tremor, nervousness, irritability, restlessness, headache, drowsiness

Psychiatric disorders
Excitability, confusional state, psychotic disorder

Respiratory, thoracic and mediastinal disorders
Respiratory depression

Skin disorders
Rash

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

Guaifenesin is an expectorant, which clears chest congestion by loosening and reducing the viscosity of phlegm, increasing the volume of phlegm and making coughs more productive.

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

Guaifenesin is well absorbed from the gastrointestinal tract. It is metabolised primarily to Beta-2-methoxyphenoxy-lactic acid and then excreted in the urine. In a study where subjects were given 400 mg of guaifenesin orally, no unchanged drug could be detected in the urine. The plasma half-life of guaifenesin is one hour.

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

Glycerol, Sodium benzoate, Saccharin sodium, Citric acid, Propylene glycol, Sorbitol solution (70%) (crystallizing), Allura red AC, Ethanol, Menthol, Cherry flavour (vanilla) 21146, Vanilla bean flavour 52.089A, Lemon flavour No 462924, Cherry flavour 119062, Sweet artificial flavour 13540488, Purified water.

6.2 Incompatibilities

Not available

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Robitussin Chesty Cough Forte is a clear, red syrup with mentholated cherry flavour, packed in bottles.

Pack sizes:
25 mL (professional sample) and 45 mL (professional sample), 100 mL, 200 mL & 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

9 April 1998

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
6.1	Change excipient name from Lemon flavour wonf S-2522 to Lemon flavour No 462924
6.5	Addition of 250 mL pack size