ROBITUSSIN DRY COUGH LIQUID CAPSULES

1 PRODUCT NAME

Robitussin Dry Cough Liquid Filled Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Liquid Filled Capsule Contains:
Dextromethorphan hydrobromide monohydrate USP 15 mg

Excipient(s) with known effect:
- Sorbitol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Liquid Filled Capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Robitussin Dry Cough Liquid Capsules controls dry coughs for up to 8 hours; relieves a dry, irritating cough; is a cough suppressant.

4.2 Dose and method of administration

Every 6 to 8 hours orally when necessary. Swallow whole with water:
Adults and Children over 12 years: 2 capsules

Do not use in children aged 12 years and under.

Do not exceed 4 doses per 24 hours.

Stop use and consult your doctor if you have a cough that persists for more than 1 week, tends to recur or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

If you forget to take it, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your pharmacist or doctor.

4.3 Contraindications

Robitussin Dry Cough Liquid Capsules 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 drugs, ask a doctor or pharmacist before taking this product.
- patients having an acute asthma attack
- children aged 12 years and under
- patients with impaired hepatic function.
- patients with respiratory insufficiency and respiratory depression

Some of the symptoms of an allergic reaction may include:
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

4.4 Special warnings and precautions for use

Tell your pharmacist or doctor if you have allergies to any medicines, foods, preservatives or dyes.

Robitussin Dry Cough Liquid Capsules:
a) should not be used until a doctor is consulted before use for patients:
- with a history of asthma, chronic obstructive airways disease (COPD), pneumonia, or any other respiratory (breathing) conditions
- with a history of liver problems
- that are pregnant or nursing a baby, or plan to become pregnant
- that are breastfeeding
- that are taking other cough and cold medicines
- who have a chronic or persistent cough such as occurs with smoking, or chronic lung disease such as asthma, chronic bronchitis or emphysema. The product may make your cough worse.
- Who have a cough with excessive phlegm, or a condition that produces large amounts of mucus. The product may make your condition worse.
- taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

b) should not be used in patients with:
- a risk of developing respiratory failure, e.g. asthma, chronic obstructive airways disease, and pneumonia.

Stop use and consult your doctor if you have a cough that persists for more than 1 week, tends to recur or is accompanied by fever, rash or persistent headache. 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 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 Liquid Capsules should be discontinued.

This product should be kept out of reach of children.

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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using dextromethorphan, talk to your doctor or pharmacist.

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 monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days. These include moclobemide, phenelzine and tranylcypromine. 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 selective serotonin reuptake inhibitors (SSRI's - such as fluoxetine) or tricyclic antidepressants (such as clomipramine and imipramine), either taken at present or within 2 weeks after stopping the medication. The use of dextromethorphan with, or within two weeks of taking these medications, 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 medicines 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 medicines.
- Other medications that are for depression, psychiatric, or emotional conditions, or Parkinson's disease, either taken at present or within 2 weeks after stopping the medication.

If you are not sure if your prescription medication contains one of these medicines, ask a doctor or pharmacist before taking this product.

4.6 Fertility, pregnancy and lactation

Pregnancy
If pregnant, ask a healthcare professional before use.

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

Breast-feeding
If lactating, ask a healthcare professional before use.

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

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

Fertility
Not available

4.7 Effects on ability to drive and use machines

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery. Be careful driving or operating machinery until you know how dextromethorphan affects you. Dextromethorphan may cause dizziness in some people. If this happens, do not drive or operate machinery.

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

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

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), or go to your nearest Accident and Emergency Centre, if you think you or anyone else may have taken too much dextromethorphan. Do this even if there are no signs of discomfort or poisoning.

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, Brilliant blue FCF, Gelatin, Macrogol 400, Opacode white NSP-78-18022, Povidone, Propyl gallate, Purified water, Sorbitol special glycerin blend A810.

6.2 Incompatibilities

Not available

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Robitussin Dry Cough Liquid Capsules are clear, red, oval softgels filled with a clear liquid and printed with "R" in white ink on one side.

Robitussin Dry Cough Liquid Capsules is available in bottles of 20 liquid capsules.

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

1 December 2016

10 DATE OF REVISION OF THE TEXT

21 May 2020

SUMMARY TABLE OF CHANGES

Section changed	Summary of changes
All	New data sheet in SmPC format