SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Almus Dry Cough Linctus with Decongestant
Boots Dry Cough & Congestion Relief Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Mg/5ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudoephedrine hydrochloride</td>
<td>30.0</td>
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<tr>
<td>Dextromethorphan hydrobromide</td>
<td>10.0</td>
</tr>
</tbody>
</table>

3 PHARMACEUTICAL FORM

Oral Solution.
A clear, yellow, viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Cough suppressant for the relief of acute non-productive cough associated with upper respiratory tract infection. Decongestant for the relief of catarrh and blocked sinuses associated with nasal congestion and congestion of mucous membranes of the upper respiratory tract associated with the common cold.

4.2 Posology and method of administration

Adults and children over 12 years: two 5ml spoonfuls to be taken three times a day.

Elderly: the normal adult dose is appropriate in the elderly.
Children 6-12 years: one 5ml spoonful to be taken three times a day.

This medicine is contraindicated in children under 6 years of age (see section 4.3).

Children of 6-12 years of age: not to be used for more than 5 days without the advice of a doctor. Parents and carers should seek medical attention if the child's condition deteriorates during treatment.

Warning: Do not exceed the stated dose.

Keep out of the sight and reach of children.

4.3 Contraindications

Hypersensitivity to the active substances or any of the excipients.
Severe renal impairment
Cardiovascular disease including hypertension and peripheral vascular disease
Diabetes mellitus
Phaeochromocytoma
Hyperthyroidism
Closed angle glaucoma
Prostatic enlargement
Patients with chronic or persistent cough such as occurs with asthma, if you are suffering from an acute asthma attack, or where cough is accompanied by excessive secretions.
Dextromethorphan should not be given to subjects in, or at risk of developing respiratory failure.
Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment (see section 4.5).
Patients taking selective serotonin reuptake inhibitors (SSRIs, see section 4.5).
Beta-blockers – (see section 4.5).
Concomitant use of other sympathomimetic decongestants.
Not to be used in children under the age of 6 years.

4.4. Special warnings and precautions for use

Dextromethorphan
Should be used with caution in patients with liver disease.

Should be used with caution in atopic children due to histamine release.

Do not take with any other cough and cold medicines.

Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.
Cases of dextromethorphan abuse 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 metabolisers of CYP2D6 or use CYP2D6 inhibitors (see also section 4.5).

**Pseudoephedrine**

If any of the following occur, this medicine should be stopped
- Hallucinations
- Restlessness
- Sleep disturbances

Caution in moderate to severe renal impairment.

If symptoms persist consult your doctor.

### 4.5. Interaction with other medicinal products and other forms of interaction

**Dextromethorphan**

Not to be used in patients taking monoamine oxidase inhibitors or within 14 days of stopping treatment as there is a risk of serotonin syndrome (pyrexia, hypertension, arrhythmias) when MAOIs are taken in combination with dextromethorphan.

Dextromethorphan might exhibit additive CNS depressant effects when co-administered with alcohol, antihistamines, psychotropics, and other CNS depressant drugs.

**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, flecanide 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.

Pseudoephedrine

**MAOIs and/or RIMAs:** should not be given to patients treated with MAOIs or within 14 days of stopping treatment: increased risk of hypertensive crisis.

**Moclobemide:** risk of hypertensive crisis.

**Antihypertensives** (including adrenergic neurone blockers & beta-blockers): this medicine may block the hypotensive effects.

**Cardiac glycosides:** increased risk of dysrhythmias.

**Ergot alkaloids** (ergotamine & methysergide): increased risk of ergotism.

**Appetite suppressants and amphetamine-like psychostimulants:** risk of hypertension.

**Oxytocin** – risk of hypertension.

Enhances the effects of **anticholinergic drugs** (such as TCAs).

There is an increased risk of arrhythmias if given to patients receiving anticholinergic drugs such as tricyclic antidepressants.

Concomitant use with sympathomimetic agents such as decongestants, tricyclic antidepressants, may occasionally cause a rise in blood pressure.

4.6. **Pregnancy and Lactation**

In view of a possible association of foetal abnormalities with first trimester exposure to pseudoephedrine, the use of the product during pregnancy should be avoided. Although amounts of pseudoephedrine secreted into breast milk are considered to be too small to be harmful, there is no data on the secretion of dextromethorphan into breast milk and therefore use of this product during lactation should be avoided.

4.7 **Effects on ability to drive and use machines**

This medicine can impair cognitive function and can affect a patient’s ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine
- However, you would not be committing an offence (called a ‘statutory defence’) if:

  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
  - It was not affecting your ability to drive safely
4.8 Undesirable effects

Dextromethorphan
The following side effects may be associated with the use of dextromethorphan:
Gastrointestinal disorders: vomiting, gastrointestinal disturbances (nausea and diarrhoea).
Nervous system disorders: drowsiness (occasional), dizziness, convulsions.
Psychiatric disorders: excitation, mental confusion.
Respiratory, thoracic and mediastinal disorders: respiratory depression.
Skin and subcutaneous tissue disorders: skin reactions including rash.

Pseudoephedrine
Cardiovascular disorders: tachycardia, palpitations, other cardiac dysrhythmias.
Gastrointestinal disorders: nausea and/or vomiting.
General disorders and administration site conditions: irritability.
Immune system disorders: hypersensitivity reactions, including cross-sensitivity that may occur with other sympathomimetics.
Nervous system disorders: headache, tremor, anxiety, restlessness, excitability, insomnia, hallucinations (particularly in children) and paranoid delusions.
Psychiatric disorders: sleep disturbance.
Renal and urinary disorders: difficulty in micturition including urinary retention.
Skin and subcutaneous tissue disorders: skin reactions including rash.
Vascular disorders: hypertension.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9 Overdose

Dextromethorphan
It is thought to be of low toxicity, but the effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms: These include nausea and vomiting, CNS depression, dizziness, dysarthria (slurred speech), nystagmus, somnolence (drowsiness), excitation, mental confusion, psychotic disorder (psychosis), and respiratory depression, convulsions.

Management: Treatment of overdose should be symptomatic and supportive. Gastric lavage may be of use. Convulsions should be controlled with
intravenous diazepam. The specific narcotic antagonist naloxone can be used to reverse the effects of dextromethorphan.

**Information for children**
Naloxone has been used successfully to reverse central or peripheral opioid effects of dextromethorphan in children (0.01mg/kg body weight).

**Pseudoephedrine**
Symptoms: Symptoms of overdosage include abdominal discomfort, excitation, confusion, hallucinations, ataxia, irritability, restlessness, palpitations, hypertension, difficulty in micturition and thirst.

Management: In severe overdosage gastric lavage and aspiration should be performed. Symptomatic and supportive measures should be undertaken, particularly with regard to the cardiovascular and respiratory systems. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta-blocker may be required to control cardiac arrhythmias.

5. **PHARMACOLOGICAL PROPERTIES**

5.1. **Pharmacodynamic Properties**

Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion.

Dextromethorphan is a cough suppressant.

5.2. **Pharmacokinetic properties**

Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract and is largely excreted in the urine unchanged. It has an elimination half-life of 5 to 8 hours but its urinary elimination and hence half-life is pH dependent. Pseudoephedrine is rapidly distributed throughout the body, its volume of distribution being 2 to 3 L/kg bodyweight.

Dextromethorphan is well absorbed from the gastrointestinal tract, metabolised in the liver and excreted as both unchanged drug and demethylated metabolites.

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 predominated in the blood and urine.

5.3. Pre-clinical Safety Data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium saccharin
- Liquid sugar
- Hydroxyethylcellulose
- Glycerin
- Alcohol 96%
- Levomenthol
- Domiphen bromide
- Pear drop flavour C1353
- Peach flavour 17403109
- Quinoline yellow 14031
- Sodium citrate
- Citric acid monohydrate
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

2 years.
6.4. Special Precautions for Storage

None.

6.5 Nature and contents of container

An amber PET bottle with a child resistant plastic cap containing a low density polyethylene wad.
Pack size: 120ml

6.6. Instructions for Use/Handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA

Trading as: BCM

8. MARKETING AUTHORISATION NUMBER(S)

PL 0014/0501

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

01 July 1996
DATE OF REVISION OF THE TEXT

22/11/2016