1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

BRONKESE COMPOUND (linctus)

COMPOSITION

Each 5 ml of BRONKESE COMPOUND contains:

Bromhexine hydrochloride	4,00 mg
Orciprenaline sulphate	5,00 mg

Excipients:

Caramel flavour, disodium edetate, ethanol 96 %, propyl hydroxybenzoate, purified water, sodium methyl hydroxybenzoate, sorbitol solution

Preservatives:

Propyl hydroxybenzoate	0,015 % *m/v*
Sodium methyl hydroxybenzoate	0,050 % *m/v*

Contains sugar: Sorbitol solution	2,5 ml

CATEGORY AND CLASS

A 10.1: Antitussives and Expectorants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Bromhexine with orciprenaline has mucolytic and bronchodilatory properties.

INDICATIONS

BRONKESE COMPOUND is indicated for cough associated with bronchospasm (wheeziness) and tenacious phlegm (sputum).

CONTRAINDICATIONS

Acute coronary disease and cardiac asthma. Caution should be observed in patients suffering from hyperthyroidism and/or peptic ulceration. Not to be administered concurrently with α-and β-blocking medicines.

WARNINGS AND SPECIAL PRECAUTIONS

BRONKESE COMPOUND should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as it may induce ventricular fibrillation. An increased risk of arrhythmias may also occur if given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

Many sympathomimetics interact with monoamine oxidase inhibitors, and should not be given to patients receiving such treatment or within 14 days of its termination.

KEEP OUT OF THE REACH OF CHILDREN.

Since bromhexine may disrupt the gastric mucosal barrier, it should be given with caution to patients with gastric ulceration.

BRONKESE COMPOUND should be used with caution in patients who may be hyper susceptible to the effects of sympathomimetic medicines, particularly those with hyperthyroidism. Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease; arrhythmia or tachycardia; occlusive vascular disorders, including arteriosclerosis; hypertension; or aneurysms. Anginal pain may be precipitated in patients with angina pectoris. Care is also required when given to patients with diabetes mellitus or closed-angle glaucoma.

Sympathomimetics may increase blood pressure and therefore special care is advisable in patients receiving antihypertensive therapy.

In the case of acute, rapidly worsening dyspnoea, a doctor should be consulted immediately. If bronchial obstruction deteriorates it is inappropriate and possibly hazardous to simply increase the use of *β*-agonists such as is contained in the form of orciprenaline in BRONKESE COMPOUND beyond the recommended dose over extended periods of time. The use of high amounts of *β*-agonists on a regular basis to control bronchial obstruction may suggest declining disease control.

In this situation, the patient's therapy plan and in particular the adequacy of anti-

inflammatory therapy should be reviewed to prevent potentially life-threatening deterioration of disease control.

Excipients

BRONKESE COMPOUND contains sorbitol and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take BRONKESE COMPOUND.

INTERACTIONS

Interactions of sympathomimetics with *α*- and *β*-blocking medicines may be complex.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years: 10 ml to 20 ml three times a day.

Children younger than 12 years: 5 ml to 10 ml three times a day.

Infants: 2,5 ml to 5 ml three times a day.

SIDE EFFECTS

Gastrointestinal side effects may occur occasionally with bromhexine and a transient rise in serum aminotransferase value has been reported.

Orciprenaline sulphate, a sympathomimetic, may produce a wide range of adverse effects. Central effects include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, and psychotic states. Appetite may be reduced, and nausea and vomiting may occur. Cardiac effects include vasoconstriction which may be sufficiently severe to cause gangrene or a rise in blood pressure which may produce cerebral haemorrhage and pulmonary oedema, reflex bradycardia. Stimulation of β_1-adrenergic receptors of the heart may produce tachycardia, cardiac arrhythmias, anginal pain, palpitations, and cardiac arrest; hypotension with dizziness and fainting, and flushing may occur.

Other effects that may occur include difficulty in micturition and urinary retention, dyspnoea, altered metabolism including disturbances of glucose metabolism, sweating and hypersalivation. Headache is also common.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

The symptoms are tremor, palpitations and rise in blood pressure which tend to subside within 3 hours. Cardiac arrhythmias and ventricular fibrillation may occur. Symptoms usually subside rapidly when treatment is stopped.

Treatment

A β-blocker may be administered to counteract the effects of excessive doses, but it must be given with caution to asthmatics because of the risk of increasing broncho-constriction.

IDENTIFICATION

A clear, bright, colourless liquid.

PRESENTATION

100 ml and 200 ml are packed into a round, amber glass bottle and sealed with a white low density polyethylene concap.

500 ml are packed into a round, amber glass bottle and sealed with a white polypropylene screw-cap closure fitted with a expanded polyethylene liner.

2,5 litres are packed into a round, amber glass bottle and sealed with a red high density polyethylene screw cap fitted with an expanded polyethylene liner.

100 ml and 200 ml are packed into a round, amber polyvinylchloride bottle and sealed with a white unlined linear low density polyethylene pilfer proof snap-on cap.

2,5 litres are packed into a rectangular brown high density polyethylene bottle with carry handle with a white polypropylene ribbed screw cap with latex liner.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep container tightly closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/10.1/387

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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