

IRISH MEDICINES BOARD ACT 1995
MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998
(S.I. No.142 of 1998)

PA0979/013/002
Case No: 2032524

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Reckitt Benckiser Ireland Ltd

7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Lemsip Pharmacy Blackcurrant with Phenylephrine Powder for Oral Solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **06/02/2007** until **23/09/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Pharmacy Blackcurrant with Phenylephrine Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	mg/Sachet
Paracetamol	650
Phenylephrine hydrochloride	10
Ascorbic acid 650	50

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

Pale lilac coloured powder with an odour and taste of blackcurrant.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of the symptoms associated with the common cold or influenza.

4.2 Posology and method of administration

Oral.

Adults and children over 12 years only: The usual dose is the contents of one sachet. The dose may be repeated in 4 hours with a maximum of four doses in a 24 hour period.

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.

Use in patients who are currently receiving other sympathomimetic drugs.

Use in patients who are receiving or who have received within 14 days, monoamine oxidase inhibitors.

4.4 Special warnings and precautions for use

Prolonged use except under medical supervision can be harmful. If symptoms persist, the physician

should be consulted.

If you are taking any other medications or are under the care of a doctor you should consult the physician before using.

Use with caution in patients with diabetes. Each sachet contains approximately 3.2 g of carbohydrate.

Contains aspartame.

The physician or pharmacist should reassure himself that sympathomimetic containing preparations are not simultaneously administered by several routes, e.g. oral and topically.

4.5 Interaction with other medicinal products and other forms of interaction

Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta-blockers. Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdose.

4.6 Pregnancy and lactation

This product should not be used during pregnancy or lactation unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

4.9 Overdose

Overdosage with paracetamol should be treated promptly by gastric lavage followed by N-acetylcysteine infusion or oral methionine since liver damage following overdose does not become apparent for one to six days after ingestion. Initial mild symptoms consist of nausea, vomiting and pallor. Measurement of the blood paracetamol level and the time elapsed since ingestion is important in order to determine whether further therapy with N-acetylcysteine is necessary.

Features of severe overdose of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression. Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an IV α -receptor blocking agent.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol

Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis within the central nervous system.

Phenylephrine

Phenylephrine is a postsynaptic alpha-receptor agonist with low cardioselective beta-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

5.2 Pharmacokinetic properties

Paracetamol

Paracetamol is absorbed rapidly and completely mainly from the small intestine producing peak plasma levels after 15-20 minutes following oral dosing. The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a T_{1/2} of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (>80%) which are excreted in urine.

Phenylephrine

Phenylephrine is absorbed from the gastrointestinal tract, but has reduced bioavailability by the oral route due to first-pass metabolism. It retains activity as a nasal decongestant when given orally, the drug distributing through the systemic circulation to the vascular bed of the nasal mucosa. When taken by mouth as a nasal decongestant phenylephrine is usually given at intervals of 4 to 6 hours.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caster sugar
Pulverised sucrose
Citric acid anhydrous granular
Sodium citrate
Blackcurrant whole dried
Blackcurrant flavour Witham
Aspartame (E951)
Saccharin sodium
Enocyanin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The finished product is heat sealed into a paper/polythene/foil/polythene laminate and packed into cardboard outer, containing five sachets per carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Oral administration, after dissolution in hot water.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/13/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 September 1984

Date of last renewal: 24 September 2004

10 DATE OF REVISION OF THE TEXT

February 2007