SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF MEDICINAL PRODUCT

Lemsip Cold & Flu Blackcurrant.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	mg/Sachet	Specification
Paracetamol	650	Ph Eur
Phenylephrine hydrochloride	*10	BP
Ascorbic acid	50	Ph Eur

*Equivalent to phenylephrine base 8.21 mg.

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For relief of the symptoms of colds and influenza, including relief of aches and pains and nasal congestion, and lowering of temperature.

4.2. Posology and method of administration

Oral, after dissolution in water.

Adults and children over 12: Contents of one sachet dissolved by stirring in hot water and sweetened to taste. The dose may be repeated after 4 hours. No more than four doses should be taken in 24 hours.

There is no indication that dosage need be modified for the elderly.

Not to be given to children under 12.

4.3. Contraindications

Severe coronary heart disease, hypertension, hypersensitivity to paracetamol, phenylephrine or any other ingredient.

4.4. Special warnings and special precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Patients should be advised not to take other paracetamol-containing products concurrently.

Use with caution in patients with Raynaud's phenomenon or diabetes. Each sachet contains approximately 3.2 g of carbohydrate. Due to its aspartame content this product should not be given to patients with phenylketonuria.

Label warnings: Do not exceed the stated dose. Keep out of the reach of children. Contains paracetamol (panel). If symptoms persist consult your doctor. If you are pregnant or being prescribed medicine by your doctor, seek his advice before taking this product. Total sugars 3.2 g. Contains aspartame.

Do not take with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Leaflet: Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4.5. Interaction with other medicaments 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, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Not recommended for patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6. Pregnancy and lactation

Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Paracetamol is excreted in breast milk, but not in a clinically significant amount. Available published data do not contraindicate breastfeeding.

4.7. Effect 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.

Phenylephrine hydrochloride: High blood pressure with headache and vomiting, probably only in overdosage. Rarely palpitations. Also, rare reports of allergic reactions.

4.9. Overdose

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12-48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10 g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention, and any patient who has ingested around 7.5 g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetyl cysteine, which may have a beneficial effect up to at least 48 hours after the overdosage, may be required. General supportive measures must be available.

Features of severe overdosage 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 i.v. alpha-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 post-synaptic 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 T½ 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 nasal mucosa. When taken by mouth as a nasal decongestant, phenylephrine is usually given at intervals of 4-6 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, sodium citrate, enocyanin, blackcurrant whole dried, blackcurrant flavour Witham, aspartame and saccharin sodium.

6.2. Incompatibilities

None known.

6.3. Shelf-life

Three years.

6.4. Special precautions for storage

Store below 25°C in a dry place.

6.5. Nature and contents of container

Heat sealed laminate sachet of 41 gsm paper/10-12 gsm LD polyethylene/8-9 micron aluminium foil/18 gsm polyethylene in a cardboard outer carton.

Pack size: 5's, 10's and 16's.

6.6. Instructions for use/handling

Oral administration, after dissolution in hot water.

7. MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited,
Dansom Lane,
Hull,
HU8 7DS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

MA096/00406

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

24th April 2006

10. DATE OF (PARTIAL) REVISION OF THE TEXT