SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Lemsip Max Flu Lemon

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>mg/Sachet</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>1000.00</td>
<td>Ph Eur</td>
</tr>
<tr>
<td>Pseudoephedrine hydrochloride*</td>
<td>60.00</td>
<td>Ph Eur</td>
</tr>
</tbody>
</table>

*Equivalent to pseudoephedrine (base) 49.1 mg.

Excipient(s) with known effect:
Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Oral powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For relief of the symptoms of heavy colds and influenza, including the relief of aches and pains, headache and sore throat, nasal congestion or a runny nose, pain and congestion of sinusitis, and lowering of temperature.

4.2 Posology and method of administration
Oral administration after dissolution in water.

Adults and children over 12: One sachet dissolved by stirring in hot water and sweetened to taste.
The dose may be repeated in four to six hours.

No more than four doses should be taken in 24 hours.

Not to be given to children under 12.

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

4.3 Contraindications

Hypersensitivity to paracetamol, pseudoephedrine or any other ingredient

Severe coronary heart disease and cardiovascular disorders

Severe hypertension

Patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors

4.4 Special warnings and precautions for use

Use with caution in patients with hypertension, heart disease, diabetes, hyperthyroidism, hyperexcitability, phaeochromocytoma, prostatic enlargement or close angle glaucoma. Each sachet contains approximately 2.1 g of carbohydrate. Care is advised in the administration of paracetamol to patients with severe renal or severe 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.

Label warnings: Warning - Do not exceed the stated dose (panel). Keep out of the reach of children. Contains paracetamol (panel). If symptoms persist, consult your doctor. If you are pregnant or are being prescribed medicine by your doctor, seek his advice before taking this product. Total sugars 2.1 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.
This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

Pseudoephedrine: Pseudoephedrine may adversely interact with antihypertensive agents or tricyclic antidepressants or other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants, to cause a rise in blood pressure. Pseudoephedrine may partially reverse the hypotensive action of drugs which interfere with sympathetic activity, such as bethanidine or methyldopa.

Paracetamol: 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.

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

Paracetamol

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 breast feeding.

Pseudoephedrine

Defective closure of the abdominal wall (gastroschisis) reported very rarely in newborns after first trimester exposure. The product should not be used in pregnancy unless considered essential by the physician. Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. It has been estimated that 0.5–0.7% of a single dose of pseudoephedrine ingested by a mother will be excreted in the breast milk over 24 hours.

4.7 Effects on ability to drive and use machines

None known.
4.8 Undesirable effects

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

Acute pancreatitis after ingestion of above normal amounts.

Pseudoephedrine
Adverse reactions due to pseudoephedrine are uncommon, but dry mouth, anorexia, urinary retention in men, skin rashes and symptoms of CNS excitation such as tension, restlessness, sleep disturbance or hallucinations may rarely occur.

4.9 Overdose
Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g of more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors
If the patient:

(a) Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

(b) Regularly consumes ethanol in excess of recommended amounts.

Or

(c) Is likely to be glutathione deplete, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with
acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

**Management**

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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines. See BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the NPIS or a liver unit.

Caffeine: Symptoms - emesis and convulsions may occur. No specific antidote. However, treatment is usually fluid therapy. Fatal poisoning is rare. If symptoms become apparent or overdose is suspected, consult a doctor immediately.

Phenylephrine hydrochloride: 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.

Pseudoephedrine: Pseudoephedrine is an adrenergic agonist acting at both alpha- and beta- adrenoceptors. It is reported to have less tachycardia and pressor activity and central nervous system effects that ephedrine. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

The active ingredients are not known to cause sedation.
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.

Pseudoephedrine: Pseudoephedrine is rapidly and completely absorbed after oral administration, up to about 90% of a dose is excreted unchanged in the urine within 24 hours of dosing. The half life is between 5 and 8 hours but may be increased when the urine is alkaline and reduced when it is acid. Onset of nasal decongestant action occurs approximately 30 minutes after an oral dose of 60 mg and continues for at least 4 hours.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6.1 List of excipients

Caster sugar, pulverised sucrose, citric acid, lemon flavour, saccharin sodium, aspartame, sodium citrate, ascorbic acid granular and curcumin (curcumin (E100), Lactose, Polysorbate 80 (E433) and Silica (E551)).

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 25°C.
6.5 Nature and contents of container

Heat-sealed laminate sachet of Paper, PE, Aluminium foil and Ionomer

Pack sizes: 5, 7, 9 and 10 sachets.

6.6 Special precautions for disposal

Oral administration after dissolution in water.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0040

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/04/1995 / 13/03/2009

10 DATE OF REVISION OF THE TEXT

19/07/2016