SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Max Flu Lemon

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	*mg/Sachet*	*Specification*
Paracetamol	1000.00	Ph Eur
Pseudoephedrine hydrochloride*	60.00	Ph Eur

*Equivalent to pseudoephedrine (base) 49.1 mg.

Excipient(s) with known effect:
Lactose
Aspartame
Sodium
Sucrose

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

Duration of treatment should be limited to a maximum of 5 days. Patients should consult a doctor or pharmacist if symptoms persist for more than 5 days, or worsen.

Posology
Adults, the elderly and children aged 16 years and over: Content of one sachet dissolved by stirring in hot water and sweetened to taste.

Dose may be repeated every 4-6 hours as required.

Do not take more than 4 sachets in 24 hours.

Do not give to children under 16 years of age.

Elderly Population: No dosage adjustment is considered necessary in the elderly.
However, in frail, immobile, elderly subjects or in elderly patients with renal or hepatic impairment, a reduction in the amount or frequency of dosing may be appropriate.

Method of Administration
Oral administration after dissolution in water.

4.3 Contraindications

- Hypersensitivity to paracetamol, pseudoephedrine or any of the excipients listed in section 6.1.
- Patients with severe coronary heart disease and cardiovascular disorders.
- Patients with severe hypertension or uncontrolled hypertension.
- Patients with hyperthyroidism.
- Patients with severe acute or chronic kidney disease/renal failure.
- Patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (MAOIs).
- Patients with prostatic enlargement.
- Patients with phaeochromocytoma.
- Patients with diabetes mellitus.
- Patients with closed-angle glaucoma.
- To be used with caution in combination with antihypertensives including adrenergic neurone blockers and beta-blockers (see section 4.5). The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.
- To be used with caution in combination with other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine-like psycho-stimulants (see section 4.5).

4.4 Special warnings and precautions for use

Use with caution in patients with hyperexcitability.

If hallucinations, restlessness, or sleep disturbances are experienced whilst taking the product, use of the product should be discontinued.

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.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Ischaemic optic neuropathy
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
Cases of PRES and RCVS have been reported with the use of pseudoephedrine containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3). Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as, severe renal impairment and sepsis, or malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as an underlying cause of HAGMA in patients with multiple risk factors.

Risks of abuse
Pseudoephedrine carries the risk of abuse. Increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 4.2).

Excipients:

This medicine contains 62.5mg aspartame in each sachet. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine. Neither non-clinical or clinical data are available to assess aspartame use in infants below 12 weeks of age.

This medicinal product contains 121.9 mg sodium per dose, equivalent to 6.1 % of the WHO recommended maximum daily intake for sodium.
The maximum daily dose of this product is equivalent to 24.4 % of the WHO recommended maximum daily intake for sodium.
Lemsip Max Flu Lemon is considered high in sodium. This should be particularly taken into account for those on a low salt diet."

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Keep out of the sight and reach of children.

Do not exceed the stated dose.

If symptoms persist, consult your doctor.

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.

Monoamine Oxidase Inhibitors (MAOIs) and Reversible Inhibitors of monoamine oxidase A (RIMAs): Increased risk of hypertensive crisis (see section 4.3).

Cardiac glycosides: Increased risk of dysrhythmias.

Oxytocin: Risk of hypertension.

Ergot alkaloids (ergotamine and methysergide): Increased risk of ergotism.

Paracetamol: Liver enzyme-inducing drugs: Potentially hepatotoxic drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, phenytoin, carbemazapine, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage.

Antiemetics: The speed of absorption of paracetamol may be increased by metoclopramide or domperidone.

Cholestyramine: Paracetamol absorption may be reduced by cholestyramine.

Anticoagulants: 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.

Flucloxacillin: Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4).

Isoniazid: The toxicity of paracetamol may be increased by isoniazid.

Linezolid: Pseudoephedrine may cause elevated blood pressure in patients taking linezolid.

4.6 Pregnancy and lactation

Pregnancy

Paracetamol

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy, however, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Pseudoephedrine

There are no or limited amount of data from the use of pseudoephedrine in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). 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.

Breast-feeding

Both paracetamol and pseudoephedrine are excreted in breast milk. The product should be avoided during lactation unless recommended by a healthcare professional.

Fertility

No data on human fertility are available.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse events which have been associated with paracetamol and pseudoephedrine are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

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: http:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Not known	Haemopoietic disorders[1]
Immune System Disorders	Not known	Hypersensitivity
Metabolism and Nutrition Disorders	Not known	High anion gap metabolic acidosis[2]
Psychiatric Disorders	Not known	Anorexia nervosa, insomnia, agitation, hallucination, anxiety, restlessness
Nervous System Disorders	Not known	Headache, tremor, Posterior reversible encephalopathy syndrome (PRES)[3], reversible cerebral vasoconstriction syndrome (RCVS)[3], Haemorrhagic stroke, Ischaemic stroke, Transient ischaemic attack (TIA)
Eye Disorders	Not known	Ischaemic optic neuropathy
Cardiac Disorders	Not known	Tachycardia, arrhythmia, palpitations, myocardial infarction
Vascular Disorders	Not known	Hypertension
Gastrointestinal Disorders	Not known	Nausea, vomiting, dry mouth, ischaemic colitis, pancreatitis acute
Skin and Subcutaneous Tissue Disorders	Very rare Not known	Cases of serious skin reactions have been reported Skin rash, hyperhidorosis
Renal and Urinary Disorders	Not known	Urinary retention[4]
General and Administration Site Conditions	Not known	Irritability

Description of selected adverse reactions

[1] 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.

[2] High anion gap metabolic acidosis: Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see

section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

[3] See section 4.4 for additional information.

[4] Especially in males.

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4.9 Overdose

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or 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.

Or

(d) Is taking isoniazid.

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. Overdose may result in disseminated intravascular coagulation.

As with other sympathomimetics, pseudoephedrine overdose may cause symptoms of central nervous system and cardiovascular stimulation, including hypertension, tachycardia, irritability, restlessness, tremor, palpitations, and cardiac arrhythmias. Convulsions, urinary retention, nausea and vomiting have also 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.

Management of pseudoephedrine overdose generally involves supportive and symptomatic therapy. Elimination can be accelerated by acid diuresis or by dialysis. Hypertensive effects may be treated with an IV alpha- receptor blocking agent. Cardiac effects may require the use of a beta-adrenergic blocking agent after alpha-adrenergic blockade.

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-adrenoreceptors. It is reported to have less tachycardia and pressor activity and central nervous system effects than 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

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

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

Two years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Heat-sealed laminate sachet of 40 gsm paper, 12 gsm PE extrusion, 8 micron aluminium foil and ethylene/methacrylic acid copolymer. In a cardboard outer carton.

Pack size: 5, **6,** 7, **8, 9,** 10, **12, 14,** and 16 sachets.

Not all pack sizes may be marketed.

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

09/04/2026