Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Max Cough & Cold Powder for Oral Solution Paracetamol 1000 mg Guaifenesin 200 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	mg/sachet
Paracetamol	1000.00
Guaifenesin	200.00

Excipients with known effect:
Aspartame 61.5 mg/sachet
Sodium 128.71 mg (5.6 mmol) / sachet
Sucrose 1.99 g/sachet
Lactose: 9.72 mg per sachet (present in curcumin powder)

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Pale yellow powder for oral solution with the odour and taste of lemons.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, chesty coughs and lowering of temperature.

4.2 Posology and method of administration

Paracetamol should be used at the lowest effective dose for the shortest possible time. The maximum daily dose must not be exceeded.

Posology:

Adults, the elderly and adolescents 16 years and over: One sachet dissolved by stirring in hot water and sweetened to taste.

Dose may be repeated in 4-6 hours. No more than four doses should be taken in 24 hours.

In all patients over 16 years of age, the maximum daily dose of paracetamol should not exceed 60 mg/kg/day (up to a maximum of 2 g per day) in the following situations, unless directed by a physician: (see section 4.4)

- Weight less than 50kg
- Dehydration
- Malnutrition
- Chronic alcoholism

Renal impairment
Paracetamol should be used with caution in patients with renal impairment as a reduced dose and/or prolonged dosing interval may be necessary (see section 4.4).

Hepatic impairment
Paracetamol should be used with caution in patients with hepatic impairment as a reduced dose or prolonged dosing interval may be necessary (see section 4.4).

The elderly
Experience has indicated that normal adult dosage of paracetamol is usually appropriate. 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 (see section 4.4).

Paediatric population under 16 years:
Do not give to children under 16 years of age.
For children under 16 years, other formulations and dosage strengths are available which may be more appropriate.

Method of Administration:

For oral administration after dissolution in hot water.

4.3 Contraindications

Hypersensitivity to paracetamol, guaifenesin or any of the excipients listed in Section 6.1

Do not take if suffering from porphyria.

4.4 Special warnings and precautions for use

Serious skin reactions, including Stevens-Johnson Syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis have been reported very rarely in association with paracetamol. These severe hypersensitivity reactions are potentially life threatening. The product should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Patients with hepatitis, non-cirrhotic alcohol liver disease, hepatic insufficiency or renal insufficiency **are at an increased risk of adverse reactions** associated with paracetamol use. These patients should seek the advice of a doctor before taking this product.

Should not be taken with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed, serious liver damage (see section 4.9).

This medicine contains 61.5 mg aspartame in each sachet. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine.

This medicinal product contains 128.71 mg sodium per dose, equivalent to 6.4 % of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 25.7 % of the WHO recommended maximum daily intake for sodium.

Lemsip Max Cough & Cold is considered high in sodium. This should be particularly taken into account for those on a low salt diet

This medicinal product contains 1.99 g of sucrose per sachet. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. The sucrose content should be taken into account in patients with diabetes mellitus.

This medicine contains 9.72 mg of lactose per sachet. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption syndrome should not take this medicine.

Do not take if you pregnant or breast feeding unless recommended by a healthcare professional (see section 4.6).

Keep out of the sight and reach of children.

Do not exceed the stated dose.

If symptoms persist consult your doctor.

Paracetamol should be administered with caution under the following circumstances (see section 4.2 where relevant):

- Glucose-6-phosphate dehydrogenase deficiency
- Haemolytic anaemia
- Glutathione deficiency
- Dehydration
- Elderly

Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range. These cases were reported in patients with one or more risk factors for hepatotoxicity including low body weight (<50 kg), renal and hepatic impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs, and in acute and chronic malnutrition (low reserves of hepatic glutathione). Paracetamol should be administered with caution to patients with these risk factors. Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency (see sections 4.2 and 4.9). Doses of paracetamol should be reviewed at clinically appropriate intervals and patients should be monitored for emergence of new risk factors for hepatotoxicity which may warrant dosage adjustment.

In general, medicinal products containing paracetamol should be taken for only a few days without the advice of a physician or dentist and not at high doses.

If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.

Prolonged or frequent use is discouraged. Patients should be advised not to take other paracetamol containing products concurrently. Taking multiple daily doses in one administration can severely damage the liver; in such case medical assistance should be sought immediately.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulants: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.
Guaifenesin may increase the rate of absorption of paracetamol.

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

Cholestyramine: The speed of absorption of paracetamol may be reduced by cholestyramine.

Laboratory Interference: If urine is collected within 24 hours of a dose of the medicinal product, a metabolite of Guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Concurrent use of paracetamol and flucloxacillin is associated with an increased risk of metabolic acidosis, especially in patients with severe renal impairment, hepatic impairment, sepsis, malnutrition and chronic alcoholism

4.6 Fertility, pregnancy and lactation

Pregnancy

This product should not be used during pregnancy unless recommended by a healthcare professional.

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.

There are limited data on the use of guaifenesin in pregnant women.

Breast-feeding

Available published data does not contraindicate breast-feeding, however the product should be avoided during lactation unless recommended by a healthcare professional.
There is no information on the use of guaifenesin in lactation.
Paracetamol is excreted in breast milk, but not in a clinically significant amount.

Fertility

No known effects.

4.7 Effects on ability to drive and use machines

The product has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

Adverse effects of paracetamol are rare.
Adverse events which have been associated rarely with paracetamol and guaifenesin 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.

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Not known	Thrombocytopenia [a] Agranulocytosis [a1] Leukopenia [a1]
Immune System Disorder	Not known	Hypersensitivity [ab2]
Gastrointestinal Disorders	Not known	Abdominal discomfort [b] Nausea [b] Vomiting [b] Diarrhoea
Skin and Subcutaneous Tissue Disorders	Not known	*Steven-Johnson Syndrome [a2] *Toxic Epidermal Necrolysis [a2] *Acute generalised exanthematous pustulosis [a2] Skin rash [a]

Description of Selected Adverse Reactions
[1] There have been occasional reports of blood dyscrasias, including thrombocytopenia and agranulocytosis
[2] Serious hypertensivity very rare cases of serious skin reactions have been reported (see Section 4.4)
*Severe Cutaneous Adverse Reactions (SCARs) including the 3 hypersensitivity skin disorders: Steven-Johnson Syndrome, Toxic Epidermal Necrolysis and Acute generalized exanthematous pustulosis.

Active Ingredients
[a] Paracetamol
[b] Guaifenesin

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Immediate medical advice should be sought in the event of an overdose, even if you feel well. The main cause for concern in overdosage with this product is paracetamol intake.

Symptoms:
Symptoms of paracetamol overdose 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 also been reported.

Guaifenesin overdose may also cause nausea and vomiting.

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.

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 efficacy of the antidote declines progressively 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 seek medical advice from a poisoning specialist.

Additional information on special populations:

An increased risk of liver damage from paracetamol overdosing has been associated with:

- Patient on long term treatment with enzyme -inducing drugs (such as carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin and St John's Wort);
- Patients who consume ethanol in excess of recommended amounts
- Patients likely to be glutathione depelete (example those with eating disorders, cystic fibrosis, HIV infection, starvation, and cachexia)

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, Anilides
ATC Code: N02BE51

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.

Guaifenesin: Guaifenesin is an expectorant which increases the volume of mucous that can be expelled by mucocilliary action due to a reduction in the adhesiveness and viscosity of tenacious sputum.

5.2 Pharmacokinetic properties

Paracetamol: Paracetamol is absorbed rapidly and completely 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.

Guaifenesin: Guaifenesin is absorbed from the gastrointestinal tract after oral administration and rapidly metabolized by oxidation to beta-(2-methoxyphenoxy)-lactic acid. Within 3 hours, approximately 40% of a single dose is excreted in the urine as this metabolite. The half-life in plasma is approximately 1 hour. Guaifenesin may increase the rate of absorption of paracetamol.

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

Ascorbic acid
Sucrose
Citric acid anhydrous
Sodium citrate
Lemon flavour no. 1
Aspartame (E951)
Saccharin sodium
Curcumin WD powder (contains lactose)

Polysorbate 80
Silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Heat-sealed sachet of paper/polyethylene/aluminium foil/ethylene/methacrylic acid copolymer laminate in an outer cardboard carton.
Packs: 5 sachets.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24

Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd June 2007

Date of last renewal: 22nd June 2012

10 DATE OF REVISION OF THE TEXT

January 2024