SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	mg/sachet
Paracetamol	1000.0
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 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.

Renal impairment

It is recommended when giving paracetamol to patients with renal impairment, to reduce the dose and to increase the minimum interval between each administration to at least 6 hours unless directed otherwise by a physician. See table below:

Adults:

Glomerular filtration rate	**Dose**
10-50 ml/min	500 mg every 6 hours
<10 ml/min	500 mg every 8 hours

This product is not suitable for patients with renal insufficiency when a reduced dose is required. More appropriate forms are available for that circumstance.

Hepatic impairment

In patients with hepatic impairment or Gilbert's syndrome, the dose should be reduced or the dosing interval prolonged. The daily dose should not exceed 2 g/day unless directed by a physician.

Elderly population

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).

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:

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

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 special 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).

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

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 in patients with malnutrition or 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 underlying cause of HAGMA in patients with multiple risk factors.

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.

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.

4.5. Interactions with other medicinal 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.

CYP Inducers: Drugs inducing hepatic cytochrome P-450 isoenzyme 2E1 (CYP2E1) may increase the hepatotoxic potential of paracetamol, whilst also reducing plasma paracetamol levels. For example, anticonvulsants including phenytoin, barbiturates, carbamazepine and alcohol.

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

Guaifenesin: May increase the rate of absorption of paracetamol

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 risk factors (see section 4.4.)

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).

4.6. Use in 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 know effects.

4.7. Effect on ability to drive and to 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	Not known	Thrombocytopenia [a]

System Disorders		Agranulocytosis [a1] Leukopenia [a1]
Immune System Disorder	Not known	Hypersensitivity [ab2]
Gastrointestinal Disorders	Not known	Abdominal discomfort [b] Nausea b Vomiting [b] Diarrhoea
Metabolism and Nutrition Disorders	Not known	High anion gap metabolic acidosis[3]
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 hypersensitivity and 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.

[3] 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.

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, hemorrhage, hypoglycemia, 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.

In severe poisoning, CNS stimulation & delirium may occur initially followed by CNS

depression, stupor, hypothermia, rapid shallow breathing, hypotension and circulatory failure. Shock may also develop as well as seizures and coma.

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)
- Patients taking isoniazid.

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

None known.

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/ polyethylene laminate in an outer cardboard carton.

Packs: 5 sachets.

6.6. Instructions for use/handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PA 979/28/1.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 22/06/2007
Date of last renewal: 22/06/2012

10. DATE OF PREPARATION OF THE TEXT

February 2025