# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lemsip Cold & Flu Headcold 500 mg Powder for Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**ActiveIngredient mg/Sachet**
Paracetamol Ph Eur 500.0

Excipients with known effects: Aspartame - 22.5 mg/sachet
Sodium – 93.77 mg (4 mmol) / sachet
Sucrose - 2.99 g/sachet
Lactose - 9.72 mg per sachet

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for oral solution.

Pale cream coloured homogenous powder with an odour of lemon and menthol and a taste of lemon and menthol intended for dissolution in water and oral administration to human beings.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

As an analgesic and antipyretic for the relief of the symptoms associated with the common cold and influenza.

### 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 aged 16 years and over: 1 sachet every 4 hours as required. Do not take more than 6 sachets in 24 hours.

**Paediatric population under 16 years:**
Children (12-15 years): 1 sachet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.
**Children under 12 years of age**: Do not use.

**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 |

**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 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 50 kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

**Method of administration**

For oral administration after dissolution in water.

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

**4.3 Contraindications**

Hypersensitivity to paracetamol or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

Serious skin reactions, including Stevens-Johnson Syndrome, toxic epidermal necrolysis, and acute generalised 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 alcoholic 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 or other drugs that affect the liver.

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 (see section 4.9).

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 recommended 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 sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This sucrose content should be taken into account in patients with diabetes mellitus. This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. This medicinal product contains 93.77 mg sodium per sachet, equivalent to 4.7 % of the WHO recommended maximum daily intake of 2g sodium for an adult." This medicine contains 22.5mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

**4.5 Interaction with other medicinal products and other forms of interaction**

Paracetamol may falsely elevate continuous blood glucose monitor (CGM) readings compared to finger stick (BG meter) readings.

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

**Anticoagulants:**Large doses or prolonged regular daily use of paracetamol may potentiate anticoagulant the effects of warfarin and other coumarin anticoagulants with increased risk of bleeding.

The hepatotoxicity of paracetamol may be potentiated by other drugs that affect the liver.

**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 with 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).

**4.6 Fertility, pregnancy and lactation**

**Pregnancy**
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 if clinically needed however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

**Breast-feeding**
Paracetamol is excreted in breast milk, but not in a clinically significant amount. Product use is compatible with breast-feeding.

**Fertility**
No known effects.

**4.7 Effects on ability to drive and use machines**

None.

**4.8 Undesirable effects**

Side-effects are rare when the product is used correctly.
Skin rashes and other allergic reactions occur occasionally with paracetamol.

Adverse events which have been associated with paracetamol 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.

| **SystemOrganClass** | **Frequency** | **AdverseEvents** |
|---|---|---|
| Blood and Lymphatic System Disorders | Not known | Thrombocytopenia, agranulocytosis |
| Metabolism and nutrition disorders | Not known | High anion gap metabolic acidosis[2] |
| Skin and Subcutaneous Tissue Disorders | Not known | Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis1<br><br>Skin rash |

**Descriptionof SelectedAdverseReactions**
1 Very rare cases of serious skin reactions have been reported (see section 4.4)
[2] 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.

**Reportingof SuspectedAdverseReactions**
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

**4.9 Overdose**

Paracetamol overdose can result in liver damage which may be fatal.

Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.

Overdose of paracetamol cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration.

Liver damage is likely in patients who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Some patients may be at increased risk of liver damage from paracetamol toxicity.
Risk Factors include:

- Patients with liver disease
- Elderly patients
- Young children
- Patients receiving long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

- Patients who regularly consume ethanol in excess of recommended amounts
- Patients with glutathione depletion e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia
- Patients taking isoniazid.

Acute renal failure with acute tubular necrosis may also develop.

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.

Emergency Procedure: Immediate transfer to hospital
Blood sampling to determine initial paracetamol plasma concentration
In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.
Administration of activated charcoal should be considered if the overdose of paracetamol has been ingested within the previous hour.

The antidote N-acetylcysteine, should be administered as soon as possible in accordance with national treatment guidelines.

Symptomatic treatment should be implemented.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic Group:** Analgesics, Anilides;
**ATC Code:** N02BE01

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.

### 5.2 Pharmacokinetic properties

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 a T½ of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (>80%) which is excreted in urine.

### 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
Menthol flavour
Aspartame (E951)
Curcumin WD (containing curcumin, lactose, polysorbate and silica)

Saccharin sodium

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

Two years.

**6.4 Special precautions for storage**

Do not store above 25ºC.

**6.5 Nature and contents of container**

A heat-sealed sachet of paper/polyethylene/aluminium foil/polyethylene laminate in an outer cardboard carton.
Pack sizes: 5 or 10 sachets

Not all pack sizes may be marketed.

**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**

The contents of each sachet are to be dissolved in hot water before administration.

**7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA0979/014/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 9th November 1994

Date of last renewal: 9th November 2009

**10 DATE OF REVISION OF THE TEXT**

February 2025