Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Cold & Flu 500 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of paracetamol.

Excipients:

Each tablet contains 38 mg of aspartame.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Convex pale yellow oval shaped tablet with lemon odour and flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Adults (16 years and over): Two tablets every 4-6 hours to a maximum of four doses in any 24 hours.

Do not exceed eight tablets in any 24 hours.

Children 12-15 years: One tablet every 4-6 hours to a maximum of four doses in any 24 hours.

Do not exceed four tablets in any 24 hours.

Swallow whole with water. Do not chew.

OR

Oral administration after dissolution in water.

Adults 16 years and over: Two tablets dissolved by stirring in half a mug of hot, not boiling water and sweetened to taste.

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

Children 12 – 15 years: One tablet dissolved by stirring in half a mug of hot, not boiling water and sweetened to taste.

Dose may be repeated in 4-6 hours to a maximum of four doses in any 24 hours. Do not exceed four doses (four tablets)

Once prepared the drink should be taken as soon as possible and should not be stored.

Not recommended for children under 12 years of age.

4.3 Contraindications

Paracetamol : Hypersensitivity to paracetamol or any other constituents

4.4 Special warnings and precautions for use

Use with caution in patients with Raynaud's phenomenon or diabetes mellitus.

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.

Label: 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.

Do no exceed the stated dose. Keep out of the reach and sight of children. Contains paracetamol (panel). If symptoms persist consult your doctor. If you are pregnant or are being prescribed medicine by your doctor, seek their advice before taking this product. Do not take with any other paracetamol-containing products.

Due to its aspartame content this medicinal product should not be given to patients with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

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 Fertility, pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

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

4.9 Overdose

Paracetamol: 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, primadone, 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 depleted, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Sumptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12-48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10 g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

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 or 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 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code N02BE51 – paracetamol, combinations excluding psycholeptics

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.

5.2 Pharmacokinetic properties

Paracetamol: Paracetamol is absorbed readily after taking the product and is detected in the plasma within 5 minutes or oral dosing. The pharmacokinetic model shows faster absorption seen over the first 30 minutes for the product compared to a standard does of two paracetamol tablets, however, the overall extent of absorption of both products remains the same. Actual mean plasma levels at each time point show the time to achieve a level of 5 µg/ml is less than 14 minutes, compared to 22 minutes for standard paracetamol tablets; the speed to achieve 10 µg/ml being 19 minutes versus 30 minutes.

The median time to maximum plasma concentration (t_{max}) was 35 minutes which was the same as a standard dose of two tablets of 500 mg paracetamol.

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.

5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose

Crospovidone

Citric acid

Aspartame

Quinoline yellow

Lemon flavour

Magnesium stearate

Povidone

Pre-gelatinised maize starch

6.2 Incompatibilities

None known

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Tablets are packed in blister trays of cold-form aluminium base and peelable paper/aluminium laminate lidding.

Pack sizes: 6 tablets and 12 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 979/51/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st July 2010

10 DATE OF REVISION OF THE TEXT