Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Max Sinus & Flu Hot Lemon Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains Paracetamol 1000mg.
Pseudoephedrine hydrochloride 60mg.

Excipient(s) with known effect:
Aspartame: 62.5mg/sachet

Sodium: 121.91 mg (5.3 mmol)/sachet

Sucrose: 2.19 mg/sachet

Lactose*: 9.72mg per sachet (present in curcumin powder)

For thefull list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
A pale yellow powder with a lemon odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms of sinusitis, common cold and influenza, such as headache and nasal and sinus congestion.

4.2 Posology and method of administration

Oral.
Adults only: The usual dose is one sachet up to three times daily. A maximum dose of three sachets per 24 hours should not be exceeded.
Paracetamol should be used at the lowest effective dose for the shortest possible time. The maximum daily dose must not be exceeded.
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).

4.3 Contraindications

1. Use in patients hypersensitive to the active ingredient.

2. Use in patients who are receiving monoamine oxidase inhibitors or who have received these within the previous fourteen days.

3. Use in patients with severe hypertension or severe coronary artery disease.

4.4 Special warnings and precautions for use

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.

The product should be used only with caution in patients with thyrotoxicosis, glaucoma or urinary retention.

Use with caution in diabetic patients as the product may cause an increase in blood sugar level.

Special labelling requirements:
If you are taking other medication consult your doctor or pharmacist.
If symptoms persist, consult your doctor.
Do not exceed the stated dose.
Do not use for more than three days without consulting a doctor.

Severe Skin reactions: Severe skin reactions such as acute generalised exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. The acute pustular eruption may occur within the first 2 days of treatment, with fever,

and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localised on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema or many small pustules are observed, administration of Lemsip Max Sinus and Flu Hot Lemon should be discontinued and appropriate measures taken if needed.

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.

This medicinal product contains 121.9 mg sodium per sachet, equivalent to 6.1 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. This medicine is considered high in sodium. This should be taken into account for those on a low salt diet
This medicine contains 62.5mg 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.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase- isomaltase insufficiency should not take this medicine. Use with caution in diabetic patients as the product may cause an increase in blood sugar level

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

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants, or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.
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

The product should not be used in pregnancy unless considered essential by the physician.

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.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side-effects include symptoms of central nervous system excitation such as restlessness. Tachycardia, sleep disturbance and more rarely hallucinations, skin rash and urinary retention, have also been reported.
Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP).

Gastrointestinal disorders: Ischaemic colitis. Frequency unknown

Eye disorders: Ischaemic optic neuropathy. Frequency unknown

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of a medicinal product is important. It allows continued monitoring of the benefits/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

Features of severe overdosage of pseudoephedrine may include irritability, palpitations, hypertension, convulsions, tremor, hyperactivity, hyperpyrexia, dryness of the skin and mucous membranes, and the possible effects given in "Undesirable effects". Treatment includes early gastric lavage and symptomatic and supportive measures. Elimination can be accelerated by acid diuresis or by dialysis. Hypertensive effects may be treated with an i.v. alpha-receptor blocking agent. Convulsions may be treated with an anticonvulsant.

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 can 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 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

Acute renal failure with acute tubular necrosis may also develop.

Cardiac arrhythmias and pancreatitis have also been reported.

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

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 α- and β-adrenoreceptors. It is reported to have less tachycardic 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.

5.2 Pharmacokinetic properties

N/A.

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
Sodium citrate
Citric acid anhydrous
Curcumin (contains lactose)
Lactose
Polysorbate 80
Silica
Lemon flavour
Aspartame (E951)
Sucrose
Saccharin sodium

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two 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.

Pack size : 10 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

Oral administration after dissolution in water.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 09 May 2006

10 DATE OF REVISION OF THE TEXT

January 2024