Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Decongestant & Flu Lemon Tablets Paracetamol 500 mg Phenylephrine Hydrochloride 6.1 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of paracetamol and 6.10 mg of phenylephrine hydrochloride.

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.

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, nasal congestion 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

- Hypersensitivity to any of the active substances or any other ingredient.
- Severe coronary heart disease and cardiovascular disorders.
- Hypertension.
- Hyperthyroidism.
- Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (see section 4.5).

4.4 Special warnings and precautions for use

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

Patients with prostatic hypertrophy may have increased difficulty with micturition.

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.

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

The stated dose must not be exceeded. To be kept out of the reach and sight of children. Contains paracetamol. If symptoms persist a doctor should be consulted. If the patient is pregnant or being prescribed a medicine, medical advice needs to be sought before taking this product. Must not be taken with any other paracetamol-containing products. The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes, i.e. orally and topically (nasal, aural and eye preparations).

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

Phenylephrine should be used with care in patients with closed angle glaucoma and prostatic enlargement.

4.5 Interaction with other medicinal products and other forms of interactions

Paracetamol

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.

Medicinal products which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxity of paracetamol, particularly after overdose

Phenylephrine hydrochloride

Monoamine oxidase inhibitors (including moclobemide): hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see section 4.3).

Sympathomimetic amines: concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.

Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa): phenylephrine may reduce the efficacy of beta-blockers and antihypertensives. The risk of hypertension and other cardiovascular side effects may be increased.

Tricyclic antidepressants (e.g. amitriptyline): may increase the risk of cardiovascular side effects with phenylephrine.

Digoxin and cardiac glycosides: concomitant use of phenylephrine may increase the risk of irregular heartbeat or heart attack.

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 breastmilk, but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Due to the vasoconstrictive properties of phenylephrine the product should not be used in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion. There is no information on use in lactation. The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Paracetamol

Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been a few reports of blood dyscrasias including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Acute pancreatitis after ingestion of above normal amounts.

Phenylephrine hydrochloride

High blood pressure with headache and vomiting, probably only in overdosage. Rarely palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie ; E-mail: medsafety@hpra.ie

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, primidone, 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 deplete, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms of paracetamol overdosage 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 been reported.

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. See BNF overdose section.

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.

Phenylephrine Hydrochloride
Features of severe overdose of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression. Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an i.v. alpha-receptor blocking agent.

Phenylephrine overdose is likely to result in: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, Mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy). Additional symptoms may include hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than that required to cause paracetamol-related liver toxicity.

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking medicinal products such as phentolamine.

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.

Phenylephrine: phenylephrine is a post-synaptic alpha-receptor agonist with low cardioselective beta-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

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.

Phenylephrine: Phenylephrine is absorbed from the gastro-intestinal tract, but has reduced bioavailability by the oral route due to first-pass metabolism. It retains activity as a nasal decongestant when given orally, the drug distributing through the systemic circulation to the vascular bed of nasal mucosa. When taken by mouth as a nasal decongestant, phenylephrine is usually given at intervals of 4-6 hours.

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

PA0979/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th August 2010
Date of last renewal: 21st April 2015

10 DATE OF REVISION OF THE TEXT

December 2018