Essential Information

Lemsip Max All in One Cold & Flu Capsules.

Active Ingredients: Each capsule contains paracetamol 500mg, phenylephrine hydrochloride 6.1mg and guaifenesin 100mg. **Indications:** For the relief of symptoms of cold and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion, lowering of temperature and chesty coughs. **Dosage & administration:** Patients should consult a doctor or pharmacist if symptoms persist for more than 3 days, or worsen. Posology: Adults, the elderly and children aged 16 years and over: Two capsules every 4-6 hours, as required. Do not take more than 8 capsules (4 doses) in 24 hours. **Do not give to children under 16 years of age.** Elderly Population: No dosage adjustment is considered necessary in the elderly. Method of Administration: For oral administration. Swallow whole with water. Do not chew. **Contraindications:** • Hypersensitivity to any of the active substances or any of the excipients listed in section 6.1. • 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 (MAOI). • Concomitant use of other sympathomimetic decongestants. • Avoid in patients with prostatic enlargement. • Contraindicated in patients with phaeochromocytoma. **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. Do not take with any other paracetamol-containing products. Phenylephrine should be used with care in patients with closed angle glaucoma. This medicine contains less than 1 mmol sodium (23mg) per capsule, essentially “sodium free”. **Interaction with other medicinal products and other forms of interaction**: Paracetamol: The rate of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption may be reduced by cholestyramine. Medicinal product which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdose. 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. 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 (see section 4.3). Tricyclic antidepressants (e.g. amitriptyline): may increase the risk of cardiovascular side effects with phenylephrine (see section 4.3). Digoxin and cardiac glycosides: concomitant use of phenylephrine may increase the risk of irregular heartbeat or heart attack. Guaifenesin: Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxyindoleactic acid or vanillylmandelic acid. 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). **Fertility, pregnancy and lactation: • Pregnancy**: The product should not be used during pregnancy unless recommended by a healthcare professional. 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. In addition, because phenylephrine may reduce placental perfusion, the product should not be used in patients with a history of preeclampsia. Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage. There are limited data on the use of guaifenesin in pregnant women. Guaifenesin has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy. •**Breast-feeding:** The product should be avoided during lactation unless recommended by a healthcare professional. There are limited data on the use of phenylephrine in lactation. Paracetamol is excreted in breast milk, but not in a clinically significant amount. Available published data do not contraindicate breast feeding. There is no information on the use of guaifenesin in lactation. •**Fertility**: There are no available data regarding the effects of the active ingredients on fertility. **Effects on ability to drive and use machines:** Lemsip Max All in One Cold and Flu Capsules.has no or negligible influence on ability to drive or use machinery.**Undesirable effects:** Paracetamol: Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia, leucopenia, pancytopenia, nutropenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Phenylephrine hydrochloride: High blood pressure with headache, vomiting, Rarely, palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males. Guaifenesin: Guaifenesin has occasionally been reported to cause gastro-intestinal discomfort, nausea and vomiting, particularly in very high doses. Also, hypersensitivity reactions may occur. **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 depleted, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia. 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, 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 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, 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. Guaifenesin: Very large doses may cause nausea and vomiting. The active substance is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically. **Legal Classification:** GSL. **Licence Holder:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS. **Licence Number:** PL 00063/0551. **MRRP:** £5.49. **Last Revised:** 01/09/2021.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0333 200 5345