SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lemsip Max All In One Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	mg/20ml
Paracetamol	1000
Guaifenesin	200
Phenylephrine hydrochloride	12.18
Cetylpyridinium Chloride	3.0

Excipient(s) with known effect:

- Ethanol	3000 mg/20ml
- Maltitol liquid (E965)	2000 mg/20ml
- Propylene glycol (E1520)	4300 mg/20ml
- Sodium	19 mg/20ml
- Sorbitol (E420)	3000 mg/20ml
- Potassium	23.32 mg/20ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short term symptomatic relief of the symptoms of colds and influenza, including aches and pains, headache, nasal congestion, tickly sore throat and chesty coughs.

4.2 Posology and method of administration

For short term use only. Duration of treatment should be limited to a maximum of 5 days. Patients should consult a doctor or pharmacist if symptoms persist for more than 5 days, or worsen.

Posology

Adults (16 years and over): Fill the measure cup with 10 - 20ml for each dose. Take one dose up to 4 times per day.

Leave at least 4 hours between doses, and do not take more than 4 doses in any 24 hours.

Wipe the neck of the bottle clean and replace the cap securely, without over-tightening it. Rinse the measure cup after use.

Do not exceed the stated dose. Do not give to children under 16 years of age.

Elderly Population: Experience has indicated that normal adult dosage 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.

Method of administration
For oral administration. It is important to shake the bottle for at least 10 seconds before use.

4.3 Contraindications

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

Due to the presence of phenylephrine, use of the product is contraindicated in:

- Patients with severe coronary heart disease or cardiovascular disorders.
- Patients with hypertension.
- Patients with hyperthyroidism.
- Patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (MAOIs).
- Patients using other sympathomimetic decongestants concomitantly.
- Patients with prostatic enlargement.
- Patients with phaeochromocytoma.
- Patients with closed-angle glaucoma.
- Patients with diabetes mellitus.

4.4 Special warnings and precautions for use

Use with caution in patients with Raynaud's phenomenon.

Respiratory: this product should not be used for persistent or chronic cough, such as that occurring with smoking, asthma, chronic bronchitis or emphysema, or for cough associated with excessive phlegm. A persistent cough may be indicative of a serious condition. If cough persists for more than 10 days, is recurrent, or is accompanied by fever, rash, or persistent headache, a physician should be consulted.

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.

Patients should be advised not to take other paracetamol-containing products concurrently.
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 (see section 4.9).

Use with caution in patients with porphyria.

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 malnutrition and 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 an underlying cause of HAGMA in patients with multiple risk factors.

The product should not be used during pregnancy unless recommended by a healthcare professional (see section 4.6).

Use during breastfeeding should be avoided, unless recommended by a healthcare professional (see section 4.6).

Excipients:
This medicine contains 2g Liquid Maltitol in each 20ml dose. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicine contains 3g sorbitol in each 20ml dose.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concurrently.

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, patients with hereditary fructose intolerance should not take this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This product contains 19% (v/v) ethanol. Each 20ml dose contains up to 3g of ethanol (alcohol) equivalent to 32ml of wine or 76ml of beer. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast feeding women, children and high-risk groups such as patients with liver disease, epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines. The amount of alcohol in this medicinal product may impair the ability to drive or use machines.

A dose of 80 ml of this medicine administered to an adult weighing 70kg would result in exposure to C 45 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 7.5 mg/100ml. For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml. Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

This medicine contains 4300 mg propylene glycol in each 20 ml dose.
While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the fetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case by case basis.
Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

Do not take this medicine If pregnant or breast-feeding, unless recommended by a doctor. Doctor may carry out extra checks while patients are taking this medicine.

Patients suffering from a liver or kidney disease, should not take this medicine unless recommended by a doctor. Doctors may carry out extra checks while patients are taking this medicine.

This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

Not recommended for concomitant use with a cough suppressant.

Keep out of the sight and reach of children.

Do not exceed the stated dose.

If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol
Antiemetics: the rate of absorption of paracetamol may be increased by metoclopramide or domperidone.

Cholestyramine: Paracetamol absorption may be reduced by cholestyramine.

Anticoagulants: 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.

Liver-enzyme inducing drugs: drugs which induce or regulate liver microsomal enzymes, such as, anticonvulsants (including phenytoin, barbiturates, carbamazepine) and alcohol, may increase the hepatotoxic potential of paracetamol.

Flucloxacillin: caution should be taken when 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 risks factors (see section 4.4).

Isoniazid: the toxicity of paracetamol may be increased by isoniazid.

Phenylephrine Hydrochloride
Monoamine oxidase inhibitors (including moclobemide): do not use in patients taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days. Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see section 4.3).

Oxytocic agents: the vasopressor effect of sympathomimetics, such as, phenylephrine, may be potentiated when used in conjunction with oxytocic drugs, such as, oxytocin and ergot alkaloids, which can cause an increased risk of haemorrhagic stroke.

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 increase the rate of absorption of paracetamol. Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxyindoleactic acid or vanillylmandelic acid.

Laboratory tests: 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-H HIAA) and vanillylmandelic acid (VMA).

4.6 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 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 pre-eclampsia.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage.

Guaifenesin 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.

In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding.

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.

4.7 Effects on ability to drive and use machines

Lemsip Max All In One Liquid may influence on ability to drive or use machinery due to the amount of alcohol in this medicinal product.

4.8 Undesirable effects

Adverse events which have been associated rarely with paracetamol, phenylephrine, guaifenesin and cetylpyridinium chloride 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.

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Not known	Thrombocytopenia, leukopenia, pancytopenia, neutropenia and agranulocytosis[1]♦
Immune System Disorders	Not known	Hypersensitivity♦■♦
Metabolism and Nutrition Disorders	Not known	High anion gap metabolic acidosis[2]
Nervous System Disorders	Not known	Headache♦
Cardiac Disorders	Not known	Palpitations♦
Vascular Disorders	Not known	Hypertension♦
Gastrointestinal Disorders	Not known	Abdominal discomfort■, nausea■, vomiting■, diarrhoea■
Skin and Subcutaneous Tissue Disorders	Very rare Not known	Cases of serious skin reactions have been reported♦ Skin rash♦
Renal and Urinary Disorders	Not known	Urinary retention[3]♦

Description of Selected Adverse Reactions

[1] There have been reports of blood dyscrasias including thrombocytopenia, leukopenia, pancytopenia, neutropenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

[2] High anion gap metabolic acidosis: 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.

[3] Especially in males.

•Paracetamol; ▪Guaifenesin; ♦Phenylephrine Hydrochloride

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Paracetamol:

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Immediate medical advice should be sought in the event of an overdose, even if you feel well. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors

An increased risk of liver damage from paracetamol overdosing has been associated with:

(a) Patients on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

(b) Patients who regularly consume ethanol in excess of recommended amounts.

Or

(c) Patients likely to be glutathione depleted, e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Or

(d) Patients taking isoniazid.

Symptoms:

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. Overdose may also result in disseminated intravascular coagulation.

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 overdosage 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.

Guaifenesin:

Very large doses may cause nausea and vomiting. The drug is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

Cetylpyridinium Chloride:

Ingestion of cetylpyridinium chloride in large doses may cause gastric upset and central nervous system depression. However, such symptoms are highly unlikely as these are only observed in doses much greater than the concentrations of cetylpyridinium chloride found in this product. Treatment for cetylpyridinium chloride overdose should be symptomatic and supportive.

Management:

Treatment for guaifenesin and cetylpyridinium chloride overdose should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, Anilides, paracetamol, combinations excl. psycholeptics.

ATC Code: N02BE51

Paracetamol has analgesic and antipyretic actions probably due to the inhibition of prostaglandin biosynthesis. It is effective against pain of mild to moderate severity, but is less successful against chronic pain.

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effect on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. It may be given orally to relieve nasal congestion.

Guaifenesin is an expectorant which reduces the viscosity of tenacious sputum.

Cetylpyridinium Chloride is a cationic disinfectant with properties and uses similar to other cationic surfactants. These surfactants have bactericidal activity against Gram-positive and, at higher concentration against some Gram-negative organisms. Cetylpyridinium Chloride may be used in a variety of preparations for the local treatment of minor infections.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract and peak plasma concentrations usually occur 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and largely excreted in the urine as sulphate and glucuronide conjugates. Less than 5% is excreted unchanged. The elimination half-life varies from about 1 to 4 hours.

Phenylephrine hydrochloride is irregularly absorbed after oral administration and undergoes first-pass metabolism by monoamine oxidase in the gut and liver, resulting in reduced bioavailability. Peak plasma concentrations are achieved in 1 to 2 hours. It is excreted in the urine mainly as the sulphate conjugate, with less than 20% as unchanged drug.

Guaifenesin is rapidly absorbed from the gastrointestinal tract. It is rapidly metabolised by oxidation to β-(2 methoxy-phenoxy) lactic acid. Within 3 hours, approximately 40% of a single dose is excreted in the urine as this metabolite. The half-life in plasma is approximately 1 hour. Guaifenesin may increase the rate of absorption of paracetamol, however the clinical relevance of this is unknown.

Cetylpyridinium Chloride has only a local effect.

5.3 Preclinical safety data

There are no preclinical safety data on these active ingredients in the literature of relevance to the prescriber or to the recommended dosage and use of the

product which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Maltitol (E965)
Sorbitol (E420)
Ethanol
Propylene Glycol (E1520)
Glycerol (E422)
Saccharin Sodium (E954)
Sodium Cyclamate (E952)
Acesulfame Potassium (E950)
Sodium Citrate (E331)
Anhydrous Citric Acid (E330)
Xanthan Gum (E415)
Levomenthol
Eucalyptus Oil
Quinoline Yellow (E104)
Patent Blue V (E131)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC.

Keep the container in the outer carton.

Keep the container tightly closed.

6.5 Nature and contents of container

Clear type III glass bottle and polypropylene child resistant closure with aluminium foil film liner containing 160ml.

Clear PET bottle and polypropylene child resistant closure with aluminium foil film liner containing 160ml.

Graduated polypropylene measuring cup.

6.6 Special precautions for disposal

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited
Dansom Lane
Hull
HU8 7DS

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0625

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/10/2024

10 DATE OF REVISION OF THE TEXT

30/01/2026