1 NAME OF THE MEDICINAL PRODUCT

Lemsip Max All In One Breathe Easy Powder for Oral Solution
Lemsip Cough Max for Chesty Cough & Cold Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	**mg/Sachet**
Paracetamol	1000.00
Guaifenesin	200.00
Phenylephrine hydrochloride	12.20

Excipient(s) with known effect:

- Sucrose
- Sodium
- Aspartame
- Lactose
- Sulphite

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution
Pale yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Patients should consult a doctor or pharmacist if symptoms persist for more than 5

days, or worsen.

Posology:
Adults and children 16 years and over:
Content of one sachet dissolved by stirring in hot water and sweetened to taste.
Dose may be repeated in 4-6 hours as required.
Do not take more than 4 sachets 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:
Oral administration after dissolution in water.

4.3 Contraindications

Hypersensitivity to any of the active substances or 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 and cardiovascular disorders
- Patients with hypertension
- Patients with hyperthyroidism
- Patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors (MAOIs)
- Concomitant use of other sympathomimetic decongestants
- Patients with prostatic enlargement
- Patients with phaeochromocytoma
- Patients with diabetes mellitus
- Patients with closed-angle glaucoma

4.4 Special warnings and precautions for use

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.

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.

Patients should be advised not to take other paracetamol -containing products concurrently.

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 5 days, is recurrent, or is accompanied by fever, rash, or persistent headache, a physician should be consulted.

Use with caution in patients suffering from porphyria.

Not recommended for concomitant use with a cough suppressant

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).

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).

Use with care in patients with Raynaud’s Phenomenon.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This product contains 1973.3mg sucrose per dose (total sugars 2g). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This product contains 129.0mg (5.6mmol) sodium per dose - to be taken into consideration for patients on a controlled sodium diet.

Contains a source of phenylalanine. May be harmful for people with phenylketonuria.

Contains sulphite; may rarely cause severe hypersensitivity reactions and bronchospasm.

If you are pregnant or are being prescribed medicine by your doctor, seek his advice before taking this product.

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
The rate of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption may be reduced by cholestyramine.
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.

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.

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.

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).

Sympathomimetic agents: Concomitant use of phenylephrine hydrochloride with other sympathomimetic agents can increase the risk of hypertension and other cardiovascular side effects.

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 increase risk of haemorrhagic stroke.

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
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).

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 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.

4.7 Effects on ability to drive and use machines

This medicine has no or negligible influence on ability to drive or use machinery.

4.8 Undesirable effects

Adverse events which have been associated with paracetamol, guaifenesin and phenylephrine 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, leucopenia, pancytopenia, neutropenia, agranulocytosis[1]
Immune System Disorders	Not known	Hypersensitivity
Metabolism and Nutrition Disorders	Not known	High anion gap metabolic acidosis[2]
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, leucopenia, 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.

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

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 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. 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 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, and allergic dermatitis), dysuria, and 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.

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Analgesics, Anilides**;**

ATC Code: N02B E51. Paracetamol, combinations excl. 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 hydrochloride: Phenylephrine is sympathomimetic post-synaptic α1–adrenergic receptor agonist with low cardioselective beta receptor affinity and minimal central nervous stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

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

The active ingredients are not known to cause sedation.

5.2 Pharmacokinetic properties

Paracetamol: Paracetamol is absorbed rapidly and completely from the small intestine, producing peak plasma levels after 15-20 minutes following oral dosing. 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 hydrochloride: Phenylephrine is absorbed from the gastrointestinal 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 the nasal mucosa. When taken by mouth as a nasal decongestant phenylephrine is usually given at intervals of 4-6 hours.
Guaifenesin: Guaifenesin is absorbed from the gastrointestinal tract. It is rapidly metabolised by oxidation to í-(2 methoxy-phenoxy) lactic acid; which is excreted in the urine. 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6.1 List of excipients

Ascorbic acid
Sucrose
Citric acid
Sodium citrate
Lemon flavour no. 1
Menthol flavour (contains sulphite)
Aspartame (E951)
Saccharin sodium
Curcumin WD (curcumin (E100), Lactose, Polysorbate 80 (E433) and Silica (E551)).

6.2 Incompatibilities

None known.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Heat-sealed laminate sachet of 40 gsm paper, 12 gsm PE extrusion, 8 micron aluminium foil and ethylene/methacrylic acid copolymer. In a cardboard outer carton.

Pack size: 5, **6,** 7, **8, 9,** 10, **12, 14,** and 16 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, East Yorkshire, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0538

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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