

PACKAGE LEAFLET: INFORMATION FOR THE USER
LEMSIP MAX COUGH & COLD
Powder for Oral Solution
Paracetamol 1000mg
Guaifenesin 200mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

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1. What Lemsip MAX Cough & Cold is and what it is used for

Each sachet of Lemsip Max Cough & Cold Powder for Oral Solution contains 1000mg paracetamol and 200mg Guaifenesin. Paracetamol has pain killing (analgesic) and fever reducing (antipyretic) properties. Guaifenesin is an expectorant which reduces the viscosity of tenacious sputum and helps the coughing up of mucus and phlegm. Lemsip Max Cough & Cold can be used to relieve the symptoms of common cold or influenza such as headache, sore throat, body aches and pains, chesty coughs and lowering of temperature.

2. What you need to know before you take Lemsip Max Cough & Cold

As with all medication, Lemsip Max Cough & Cold may not be suitable for some people

Do not take Lemsip Max Cough & Cold

- if you are allergic (hypersensitive) to paracetamol, guaifenesin or any of the other ingredients listed in section 6
- if you are suffering from porphyria.

Do not take Lemsip Max Cough & Cold with any other paracetamol-containing products, decongestants or cold and flu medicines.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Lemsip Max Cough & Cold

- if you have been told by your doctor that you have an intolerance to some sugars,
- if you are on a controlled sodium diet, this product contains 129mg sodium per dose
- if you have phenylketonuria, this product contains a source of phenylalanine
- if you have impaired liver or kidney function
- if you are taking other drugs that affect the liver
- if you have a poor diet

Prolonged use, except under medical supervision can be harmful. If symptoms persist contact your doctor or pharmacist. Only take when necessary. Do not exceed the stated dose.

Other medicines and Lemsip Max Cough & Cold

Tell your doctor or pharmacist or nurse if you are taking, have recently taken or might take any other medicines such as:

- Drugs to stop you feeling sick or vomiting, such as metoclopramide or domperidone: may increase absorption of paracetamol
- Cholesterol drugs such as cholestyramine: may reduce absorption of paracetamol

- Anticoagulants such as warfarin: their effect may be enhanced by long term use of paracetamol
- Guaifenesin may increase the rate of absorption of paracetamol
- Flucloxacillin. There is an increased risk of metabolic acidosis, especially in patients with kidney and liver impairment, sepsis, malnutrition and alcoholism.

Please tell your doctor or pharmacist if you are taking or have recently have taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Do not take if you are pregnant or breast feeding unless recommended by a health professional.'

If necessary, Lemsip Max Cough and Cold can be used during pregnancy. It should be used at the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.

Lemsip Max Cough & Cold with food, drink and alcohol

Alcohol may increase the adverse effects of paracetamol.

Lemsip Max Cough & Cold contains

- 128.71 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6.4 % of the recommended maximum daily dietary intake of sodium for an adult. This product is considered high in salt and should be taken in to account if on a low salt diet.
- 1.99 g of sucrose per sachet. This should be taken into account in patients with diabetes mellitus.
- 9.72 mg of lactose per sachet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 61.5mg of aspartame per dose. 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.

3. How to take Lemsip Max Cough & Cold

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. For oral administration. Dilute the contents of one sachet in a mug of hot water, do not boil the water. Stir until dissolved. If preferred, sweeten to taste with sugar, honey or usual sweetener. Do not take for more than 3 days unless told to do so by your doctor.

Adults, the elderly and adolescents aged 16 years and over: The usual dose is 1 sachet up to 4 times daily. The dose may be repeated in 4 hours with a maximum of four doses in a 24 hour period.

Do not give to children under 16 years of age.

For children under 16 years, other formulations and dosage strengths are available which may be more appropriate.

If you take more Lemsip Max Cough & Cold than you should

Immediate medical advice should be sought in the event of overdosage because of the risk of irreversible liver damage. Symptoms of overdosage may present as nausea, vomiting, loss of appetite and abdominal pain.

If you forget to take Lemsip Max Cough & Cold

Take the next dose as soon as you remember, if needed. Do not double the dose. This product should only be taken when necessary. If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

Like all medicines, Lemsip Max Cough & Cold can cause side effects, although not everybody gets them. Side effects may include changes in the number of blood cells, such as thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily), agranulocytosis (reduction in white blood cells which make infection more likely) or leukopenia (reduction in white blood cells which make fever and infections more likely), hypersensitivity reactions such as skin rashes. If skin rash occurs discontinue use immediately. Guaifenesin can occasionally cause discomfort, nausea, vomiting and diarrhoea, particularly in high doses.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lemsip Max Cough & Cold

Keep out of the sight and reach of children.

Do not use Lemsip Max Cough & Cold after the expiry date (EXP Day/Month/Year) which is stated on the carton and sachet. The expiry date refers to the last day of that month. Do not store above 25°C. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information**What Lemsip Max Cough & Cold contains**

Each sachet contains 1000mg paracetamol and 200mg guaifenesin as active ingredients. The other ingredients are ascorbic acid, sucrose, citric acid anhydrous, sodium citrate, lemon flavour no.1, aspartame (E951), saccharin sodium and curcumin WD.

What Lemsip Max Cough & Cold looks like and contents of the pack

Powder for oral solution, pale yellow powder with an odour and taste of lemons. Each pack contains 5 sachets containing 4.8g of product.

Marketing Authorisation Holder and Manufacturers

MA Holder: RB Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, IE.

Manufacturers: RB Healthcare. (UK) Ltd., Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

For product queries please call: 01 6305429

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