

**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

1. What Lemsip Max Cough & Cold is and what it is used for
2. What you need to know before you take Lemsip Max Cough & Cold
3. How to take Lemsip Max Cough & Cold
4. Possible side effects
5. How to store Lemsip Max Cough & Cold
6. Contents of the pack and other information

**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 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
- if you are underweight (less than 50 kg)
- if you suffer from severe dehydration
- if you are elderly
- if you have glutathione deficiency (a metabolic disorder which may lead to difficulty in breakdown of paracetamol)
- if you have an enzyme deficiency called Glucose-6-phosphate dehydrogenase deficiency
- if you have haemolytic anaemia (abnormal breakdown of red blood cells)

During treatment with Lemsip Max Cough & Cold, tell your doctor straight away if:

- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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. Please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment.

Please tell your doctor or pharmacist if you are taking or have recently 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.<sup>1</sup>

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 into 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.

Do not take more than 2 sachets a day (2 g paracetamol/day) in the following situations, unless directed by your doctor:

- Weight less than 50 kg
- Use of large quantities of alcohol regularly (alcoholism)
- Dehydration
- Malnutrition

Use in kidney or liver impairment:

If you have been diagnosed with kidney or liver problems, please consult your doctor or pharmacist. You may need to take a lower dose or increase the length of time between doses.

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

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage. Symptoms of overdose 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.

Frequency “Very rare”:

- Very rare cases of serious skin reactions have been reported.

Frequency “Not known” (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

### **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](http://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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