

PACKAGE LEAFLET: INFORMATION FOR THE USER

LEMSIP COUGH AND COLD CAPSULES with CAFFEINE Paracetamol 500mg, guaifenesin 100mg, caffeine 25mg

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

- Always take this medicine exactly as described in this leaflet or as our doctor or pharmacist or nurse has 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 or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after three days

What is in this leaflet

1. What Lemsip Cough & Cold Capsules with Caffeine is and what it is used for
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1. WHAT LEMSIP COUGH & COLD CAPSULES WITH CAFFEINE IS AND WHAT IT IS USED FOR?

Each capsule contains the ingredients paracetamol 500mg, guaifenesin 100mg and caffeine 25mg. Paracetamol has pain killing (analgesic) and fever reduction (antipyretic) properties. Guaifenesin is an expectorant which loosens phlegm making it easier to clear from the lungs. Caffeine is a stimulant for relief of fatigue and drowsiness. This product is particularly appropriate for day-time use due to the presence of caffeine. Lemsip Cough & Cold Capsules with Caffeine is used to treat different symptoms of chesty coughs, colds and flu in adults and children over 12 years and over.

You must talk to a doctor if you do not feel better or if you feel worse after three days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEMSIP COUGH & COLD CAPSULES WITH CAFFEINE

Do not take this Lemsip Cough & Cold Capsules with Caffeine

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

Do not take with any other paracetamol-containing products.

Warnings & precautions

Talk to your doctor or pharmacist or nurse before taking Lemsip Cough & Cold Capsules with Caffeine

- If you are pregnant or breast feeding
- If you have problems with your liver or kidney
- If you have or ever had a peptic ulcer
- If you have a poor diet
- 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 Cough & Cold Capsules with Caffeine, 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).

Other medicines and Lemsip Cough & Cold Capsules with Caffeine

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

- Drugs which may affect the absorption of paracetamol, including those used to treat blood cholesterol (cholestyramine) and nausea and vomiting (metoclopramide and domperidone). The effects of blood thinning drugs (warfarin and other coumarins) may be increased by 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.

Lemsip Cough & Cold Capsules with Caffeine with food, drink and alcohol

It is recommended not to take this medicine with alcohol.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

The product contains caffeine, which may have a minor influence on the ability to drive and use machines. Dizziness and agitation have been reported with caffeine use, affected patients should not drive or use machinery.

Lemsip Cough & Cold Capsules with Caffeine contains:

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

3. HOW TO TAKE LEMSIP COUGH & COLD CAPS WITH CAFFEINE

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Adults, the elderly and children aged 16 years and over: 2 capsules every 4-6 hours as required. Do not take more than 8 capsules (4 doses) in 24 hours.

Children: Ages 12 to 15 years: 1 capsule every 4-6 hours when necessary to a maximum of 4 capsules in 24 hours
Do not give to children under 12 years of age.

In patients over 16 years of age, do not take more than 4 capsules a day (2g 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.

For oral administration. The capsule should be swallowed whole with water. Do not chew.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

If the symptoms of your chesty cough, cold or flu persist for more than three days, or worsen, consult your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects are rare;

- Allergic reactions, hypersensitivity (such as skin rashes)
- Changes in the number of blood cells, such as thrombocytopenia (reduction in blood platelets which might mean that you bleed, bruise more easily) or agranulocytosis (reduction in white blood cells which makes infections more likely) or leukopenia (reduction in white blood cells which make fever and infections more likely)
- Stomach discomfort
- Nausea
- Vomiting
- Insomnia
- Restlessness
- Anxiety
- Agitation
- Dizziness

If skin rash occurs discontinue use immediately.

Frequency 'Very rare'

- Very rare cases of 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEMSIP COUGH & COLD CAPSULES WITH CAFFEINE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton (EXP Month/Year). The expiry date refers to the last day of that month.

Do not store above 25°C. do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Lemsip Cough & Cold Capsules with Caffeine contains the active substances Paracetamol (500mg), Guaifenesin (100mg) & Caffeine (25mg).

The other ingredients are maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, talc, gelatin, titanium dioxide (E171), quinoline yellow (E104), patent blue V (E131), erythrosine (E127), shellac and aluminium hydroxide.

Lemsip cough and cold capsules are red and green hard gelatine capsules with “Lemsip C&C” printed in white ink. Each pack contains a blister tray containing 6, 8 or 12 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser Ireland Ltd., Citywest Business Campus, Dublin 24.

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

This leaflet was last revised in upon approval