

## **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
2. What you need to know before you take Lemsip Cough & Cold Capsules with Caffeine
3. How to take Lemsip Cough & Cold Capsules with Caffeine
4. Possible side effects
5. How to store Lemsip Cough & Cold Capsules with Caffeine
6. Contents of the pack and other information

#### **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

## **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 cholesterols (cholestyramine) and nausea and vomiting (metoclopramide and domperidone). The effects of blood thinning drugs (warfarin and other coumarins) may be increased by paracetamol
- Flucloxacillin. There is an increased risk of metabolic acidosis, especially in patients with kidney and liver impairment, sepsis, malnutrition and alcoholism.

## **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. If you have renal or hepatic impairment consult your doctor before taking this product

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.

### **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 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.

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