

PACKAGE LEAFLET: INFORMATION FOR THE USER

LEMSIP COLD & FLU Capsules with Caffeine Paracetamol 500mg, Caffeine 65mg

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 your doctor, pharmacist or nurse 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 or nurse. 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 Cold & Flu Capsules with Caffeine is and what it is used for
2. What you need to know before you take Lemsip Cold & Flu Capsules with Caffeine
3. How to take Lemsip Cold & Flu Capsules with Caffeine
4. Possible side effects
5. How to store Lemsip Cold & Flu Capsules with Caffeine
6. Contents of the pack and other information

1. WHAT LEMSIP COLD & FLU CAPSULES WITH CAFFEINE ARE AND WHAT ARE THEY USED FOR?

Each Lemsip Cold & Flu Capsule with Caffeine contains 500mg paracetamol and 65mg caffeine. Paracetamol has pain killing (analgesic) and fever reduction (antipyretic) properties. Caffeine is a stimulant for relief of fatigue and drowsiness. Lemsip Cold & Flu Capsules with Caffeine can be used to relieve the symptoms of common cold or influenza such as headache, sore throat, body aches and pains, fatigue and drowsiness and lowering of temperature.

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

Do not take this Lemsip Cold & Flu Capsules with Caffeine

- If you are allergic (hypersensitive) to paracetamol, caffeine or any of the other ingredients listed in section 6.
- If you are taking any other paracetamol containing products
- If you have a history of peptic ulcer
- If you are less than 12 years of age

Take special care with Lemsip Cold & Flu Capsules with Caffeine

- If you have impaired liver or kidney function
- If you are taking other drugs that affect the liver

Prolonged use, except under medical supervision can be harmful. If symptoms persist contact your doctor or pharmacist. Only take when necessary. Do not take for any longer than 3 days.

Do not exceed the stated dose.

Taking other medicines

Care should be taken while taking this product if you are currently taking:

- Drugs that prevent nausea and vomiting such as metoclopramide or domperidone: may increase absorption of paracetamol
- Cholesterol drugs such as cholestyramine: may reduce absorption of paracetamol
- Drugs that prevent the clotting of blood such as warfarin: their effect may be enhanced by long term use of paracetamol
- Drugs that affect the liver such as monoamine oxidase inhibitors and antidepressants: may increase the hepatotoxicity (liver toxicity) of paracetamol
- Factors known to alter the activity of this enzyme system may influence caffeine clearance. For example, caffeine elimination is inhibited by cimetidine, disulfiram and oral contraceptive pills

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

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

Alcohol may increase the adverse effects of paracetamol. Excessive intake of caffeine (e.g. coffee, tea and some soft drinks) should be avoided while taking this product.

Pregnancy, breast-feeding and fertility:

It is generally accepted that Paracetamol is safe for use during pregnancy and breastfeeding. Caffeine is not recommended for use during pregnancy due to increased risks associated with caffeine consumption. Caffeine is secreted into breast milk at very low levels and infant irritability and poor sleeping patterns have been reported.

Therefore, this product is not recommended during pregnancy and breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

The product contains caffeine, a central nervous stimulant which help counteract drowsiness and restore alertness. These effects are usually considered to have a positive influence on the ability to drive or operate machinery. However, dizziness and agitation have been reported with caffeine use (see section 4): affected patients should not drive or use machinery.

Important information about some of the ingredients of Lemsip Cold & Flu Capsules with Caffeine

Contains tartrazine, may cause allergic reactions.

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

For oral administration. Swallow whole with water. Do not chew.

Adults, the elderly and children aged 16 years and over: Two capsules every 4-6 hours, with a maximum of 4 doses in 24 hours. Do not exceed 8 capsules 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.

Hepatic Impairment: Patients with hepatic impairment should seek the advice of a doctor before taking this product.

Renal Impairment: Patients with renal impairment should seek the advice of a doctor before taking this product.

Do not take for any longer than 3 days. If your symptoms persist consult your doctor.

If you take more Lemsip Cold & Flu Capsules with caffeine than you should

There is a risk of poisoning and liver damage with taking excess paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdose may present as nausea, vomiting, loss of appetite and abdominal pain.

If you forget to take Lemsip Cold & Flu Capsules with caffeine

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 Cold & flu Capsules with Caffeine can cause side effects, although not everybody gets them. Side effects may include dizziness, insomnia, restlessness, anxiety, agitation, gastric ulcer, nausea, vomiting, changes in the number of blood cells such as thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily) or agranulocytosis (reduction in white blood cells which make infection more likely), hypersensitivity reactions such as skin rashes. 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.

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

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

Keep out of the sight and reach of children.

Do not use Lemsip Cold & Flu Capsules with Caffeine after the expiry date (EXP Day/Month/Year) which is stated on the carton and blister foil.

Do not store above 25°C. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lemsip Cold & Flu Capsules with Caffeine contains

Each capsule contains 500mg paracetamol and 65mg caffeine as active ingredients. The other ingredients are maize starch, croscarmellose sodium, magnesium stearate, sodium laurilsulfate, gelatin, titanium dioxide, quinoline yellow, erythrosine, patent blue V, shellac, tartrazine E102) and aluminium hydroxide.

What Lemsip Cold & Flu Capsules with Caffeine look like and contents of the pack

Red and yellow hard gelatin capsules with “Lemsip” printed. Each pack contains a blister tray containing 12 capsules.

Marketing Authorisation Holder and Manufacturer

MA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Wrafton Laboratories Ltd., Braunton Devon EX33 2DL UK.

For product queries please call: 01 6305429

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