

PACKAGE LEAFLET: INFORMATION FOR THE USER

LEMSIP DECONGESTANT & FLU CAPSULES WITH CAFFEINE

Paracetamol 500mg
Phenylephrine Hydrochloride 6.1mg
Caffeine 25mg

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

1. What Lemsip Decongestant & Flu Capsules with Caffeine is and what it is used for

Paracetamol has pain killing (analgesic) and fever reducing (antipyretic) properties. Caffeine is a stimulant to relieve fatigues and phenylephrine hydrochloride is a decongestant to relieve blocked or runny nose.

Lemsip Decongestant & Flu capsule with caffeine can be used to relieve symptoms of sinusitis, common cold and influenza, such as headaches, body aches & pains, nasal & sinus congestion and lowers temperatures in adults & children (over 12 years).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Lemsip Decongestant & flu Capsules with Caffeine

Do not take Lemsip Decongestant & Flu capsule with Caffeine:

- with any other paracetamol products
- if you allergic to paracetamol, phenylephrine hydrochloride, caffeine or any of the other ingredients of this medicine (listed in section 6)
- if you are between 12-15 years taking any other cough and cold medicines
- if you are taking monoamine oxidase inhibitors (MAOIs) or have done so in the past 14 days
- if you are currently receiving other sympathomimetic medicines, such as decongestants or some medicines to treat asthma or high blood pressure.
- if you have glaucoma or urinary retention
- if you suffer from high blood pressure, severe coronary artery disease or any other heart problems
- if you have an overactive thyroid (hyperthyroidism)
- if you are less than 12 years of age

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Lemsip Decongestant & Flu Capsules with Caffeine

- if you are taking other drugs that effect the liver
- if you have Reynaud's syndrome, diabetes or kidney or liver problems
- if you suffer from prostate problems or if you are to receive anaesthetic
- if you are pregnant or being prescribed any other medication
- if you have alcoholic liver disease as the risk of overdose is greater
- if you are underweight (less than 50 kg) or are malnourished
- if you use large quantities of alcohol regularly (alcoholism)
- 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)
- if you have a history of peptic ulcer

During treatment with Lemsip Decongestant & Flu 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).

If any of the above applies to you, you may need to reduce the amount of paracetamol that you take or avoid taking this medicinal product altogether.

Prolonged use, except under medical supervision can be harmful. If you have a high fever or symptoms get worse or persist for longer than 3 days, contact your doctor or pharmacist. Only take when necessary. Do not exceed the stated dose.

Other medicines and Lemsip Decongestant & Flu Capsules with caffeine

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

- Medicines to prevent nausea such as metoclopramide or domperidone: may increase absorption of paracetamol
- Cholesterol medicines such as cholestyramine: may reduce absorption of paracetamol
- Anticoagulants such as warfarin: their effect may be enhanced by long term use of paracetamol
- Medicines that effect the liver such as monoamine oxidase inhibitors and antidepressants: may increase the hepatotoxicity (liver toxicity) of paracetamol
- Sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants
- Monoamine oxidase inhibitors may occasionally cause a rise in blood pressure
- Vasodilators or beta-blockers (medicine used to treat high blood pressure)
- Barbiturates (medicines used to treat anxiety or to help you sleep)
- digoxin to treat heart fibrillation or flutters
- Anaesthetic agents.
- 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 Decongestant & Flu Capsules with Caffeine with food and drink and alcohol

Alcohol may increase the adverse effects of paracetamol

Pregnancy and 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.

Lemsip Decongestant & Flu Capsules with Caffeine is not recommended in pregnancy and breastfeeding, particular care is required in patients with a history of pre-eclampsia.

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

3. How to take Lemsip Decongestant & Flu Capsules 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.

This medicine contains paracetamol. Always use the lowest effective dose for the shortest time necessary to relieve your symptoms.

The recommended dose is:

Adults and children over 16 years: Two capsules to be taken every 4 hours.

Do not exceed 8 capsules in 24 hours.

Do not take more than four capsules in 24 hours (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.

Children 12-15 years: 1 capsule every 4-6 hours. Do not exceed 4 capsules in 24 hours. Do not take for more than 3 days.

Do not give to children under 12 years of age.

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

If you take more Lemsip Decongestant & Flu Capsules with Caffeine than you should

Immediately 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 palpitations or hypertension.

If you forget to take Lemsip Decongestant & Flu Capsules with Caffeine

Take the next dose as soon as you remember, if needed. Do not take a double dose to make up for a forgotten 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 Decongestant & Flu Capsules with Caffeine can cause side effects, although not everybody gets them.

Side effects are rare but may include:

- hypersensitivity reactions such as skin rashes.
- 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).
- possible side effect of phenylephrine includes high blood pressure with headache, vomiting and rarely palpitations may occur.
- this product may act as a cerebral stimulant giving rise to insomnia (disturbed sleep), nervousness, high temperatures, tremors of convulsions.

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 or 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 Decongestant & Flu 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 after (EXP Day/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

What Lemsip Decongestant & Flu Capsules with Caffeine contains

Each capsule contains 500mg paracetamol, 6.1mg phenylephrine hydrochloride, and 25mg caffeine as active ingredients. The other ingredients are (capsules contents) maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate and talc, (Capsule body) gelatine and indigo carmine (E132), (Capsule Cap) gelatine, titanium dioxide (E171), quinoline yellow (E104), Patent blue V (E132) and erythrosine (E127), (Printing Ink) shellac, and aluminium hydroxide.

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

Red and Blue hard capsules with 'Lemsip' printed on them. Each carton contains 16 capsules.

Marketing Authorisation Holder and Manufacturer

MA Holder:

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

Manufacturer:

Reckitt Benckiser Healthcare (UK) Ltd.,
Dansom lane,
Hull,
HU 7DS,
UK.

For product queries please call: 01 6305429

This leaflet was last revised in upon approval