

Patient Information Leaflet

Lemsip Multi Relief Capsules

Paracetamol 500mg
Phenylephrine Hydrochloride 6.1mg
Guaifenesin 100mg

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

This medicine is available without prescription. However, you still need to take Lemsip Multi-Relief Cold & Flu Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Lemsip Multi-Relief Capsules are and what they are used for
2. What you need to know before you take Lemsip Multi Relief Capsules
3. How to take Lemsip Multi Relief Capsules
4. Possible side effects
5. How to store Lemsip Multi Relief Capsules
6. Contents of the pack and other information

1. WHAT LEMSIP MULTI RELIEF CAPSULES ARE AND WHAT THEY ARE USED FOR

Capsule for oral use.

This medicine is a combination of active ingredients which are effective in relieving the symptoms associated with colds and flu, including relief of aches and pains, sore throats, headache, nasal congestion, lowering of temperature and chesty cough.

Paracetamol is a well-known painkiller (analgesic). It is effective against aches and pains, including headache and can also reduce a fever (antipyretic). Guaifenesin (expectorant) allows you to cough up phlegm when suffering from a chesty cough. Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing pressure which may cause a headache.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEMSIP MULTI RELIEF CAPSULES

Do not take Lemsip Multi Relief Capsules if:

- You are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride or any of the other ingredients listed in Section 6.
- You have a serious heart condition, or an overactive thyroid.
- You have a high blood pressure (hypertension).
- You are taking or have taken within the last 14 days a medicine called a monoamine oxidase inhibitor (MAOI), usually used to treat depression.
- You are taking other decongestant medications.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lemsip Multi Relief Capsules if:

- You suffer from liver or kidney problems, heart disease.
- You suffer from Raynaud's syndrome (poor blood circulation which makes the fingers or toes pale and numb) or diabetes mellitus.
- You have non-cirrhotic (liver disease that is not associated with changes to the structure of the liver) liver disease.
- You have glaucoma or enlarged prostate.

- You are suffering from porphyria (a rare blood disease).
- You have pheochromocytoma
- You are taking medicines that affect your liver

During treatment with Lemsip Cold & Flu Hot Lemon, 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).

Check with your doctor before use if you have liver or kidney problems, are underweight (<50kg), become malnourished or regularly drink alcohol as this may increase your risk of liver damage. You may need to reduce the amount of paracetamol that you take or avoid using this product altogether.

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

Other medicines and Lemsip Multi Relief Capsules:

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

- Do not take with any other paracetamol-containing products.
- Do not take with any other products used for relief of colds, flu or congestion.

If you are taking any of the following medicines, talk to your doctor or pharmacist before taking Lemsip Multi-Relief Capsules:

- Beta-blockers for high blood pressure, or vasodilators (drugs used to treat high blood pressure, leg pain due to vascular problems or Raynaud’s syndrome).
- Tricyclic anti-depressants (a specific class of drugs used to treat depression), other decongestant or barbiturates (used to treat sleep problems or epilepsy).
- You are taking other medicines as some drugs may affect the way paracetamol works, including those used to treat blood cholesterol (cholestyramine) and nausea and vomiting (metoclopramide and domperidone). Some drugs may affect the way in which phenylephrine works (digoxin and cardiac glycosides)
- The effect of blood thinning drugs (warfarin and other coumarins) may be increased by paracetamol.
- Oxytocin and ergot alkaloids may increase the effects of phenylephrine
- Guaifenesin may increase the rate of absorption of paracetamol
- Isoniazid may increase the toxicity of paracetamol
- Anticonvulsants (phenytoin, barbiturates and carbamazepine) may increase the potential of paracetamol to cause liver toxicity
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Lemsip Multi Relief Capsules with food, drink and alcohol:

- Do not take with large quantities of alcohol.

Pregnancy and breast-feeding

- This product should not be used in women with a history of pre-eclampsia. 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:

There are no known effects on driving or using machinery

3. HOW TO TAKE LEMSIP MULTI RELIEF CAPSULES

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

It is important to drink plenty of liquid when suffering from colds and flu.

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

Do not take more than 4 capsules in 24 hours (2g paracetamol / day) in the following situations, unless directed by your doctor:

- Weight less than 50g
- 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.

Do not exceed the stated dose.

Do not give to children under 16 years of age.

If symptoms persist for more than three days, or worsen, consult your doctor.

If you take more Lemsip Multi Relief Capsules than you should:

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. You may experience symptoms of dizziness, palpitations (irregular or forceful heartbeat), stomach pain or high blood pressure with headaches if you take too much of this medicine.

If you forget to take Lemsip Multi Relief Capsules:

This product should only be used when necessary. Do not take a double dosage to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines this product can cause side effects, although not everyone gets them.

- Allergic reactions (such as skin rashes)
- Very rare cases of serious skin reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.
- Blood disorders, such as thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily), leucopenia, pancytopenia (reduction in white and red blood cells), neutropenia and agranulocytosis (reduction in white blood cells which make infections more likely).
- Nausea, vomiting and diarrhoea
- Abdominal discomfort
- Difficulty in passing urine (especially in males)
- Headache
- Palpitations
- High blood pressure
- 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 MULTI RELIEF CAPSULES

Do not store about 25°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.

The expiry date refers to the last day of that month.

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 Multi Relief Capsules contain:

- The active ingredient per capsule are: paracetamol 500mg, phenylephrine hydrochloride 6.1mg and guaifenesin 100mg.
- The other ingredients are: maize starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, talc, gelatin, titanium dioxide (E171), yellow and red iron oxide (E172), brilliant blue – FD&C blue 1 (E133) and shellac (E904).

What Lemsip Multi Relief Capsules look like and the contents of the pack:

The product is a hard gelatine capsule with a green body and a red cap with Lemsip printed on the cap

Ireland: This product is available in cartons of 16 capsules.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

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

Manufacturer: RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL

PA 979/53/1

For product queries please call (01) 630 5429.

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