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Package Leaflet: Information for the User

Lemsip Cold & Flu Breathe Easy

(paracetamol and phenylephrine hydrochloride)

Please read this leaflet carefully before you take this medicine.
If you are unsure of anything, ask your pharmacist or doctor.

1. What this medicine is and what it is used for?

Lemsip Cold & Flu Breathe Easy contains a combination of ingredients which are effective in relieving the symptoms associated with colds and flu, including relief of aches and pains, sore throats, headache, nasal congestion and lowering of temperature.

Paracetamol is a well-known painkiller (analgesic). It is effective against aches and pains, including a headache, and can also reduce a fever (antipyretic). Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing the pressure which may cause a headache.

2. What you need to know before you take this medicine

As with all medicines Lemsip Cold & Flu Breathe Easy may not be suitable for some people.

Do not take this medicine if:

- You are allergic to paracetamol, phenylephrine hydrochloride or to any of the other ingredients listed in section 6.
- You have a serious heart condition or high blood pressure (hypertension).
- You have an overactive thyroid.
- 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 sympathomimetic decongestants.
- You have an enlarged prostate; phaeochromocytoma; diabetes mellitus; or closed-angle glaucoma.

Warnings and precautions: Talk to a doctor or pharmacist before taking this medicine if:

- You have a problem with your liver or kidneys.
- You have Raynaud's syndrome (poor blood circulation making the fingers or toes pale or numb).
- You have a non-cirrhotic liver disease (liver disease that is not associated with changes in the structure of the liver).
- You have phenylketonuria.

During treatment with this medicine, tell your doctor straight away 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 Cold & Flu Breathe Easy

- Do not take with other paracetamol-containing products

Talk to your doctor or pharmacist if you are taking:

- Beta-blockers for high blood pressure, other antihypertensives 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 decongestants or barbiturates (used to treat sleep problems or epilepsy).
- Other medicines. Some drugs may affect the way in which paracetamol works, including those used to treat blood cholesterol (cholestyramine) and nausea and vomiting (metoclopramide and domperidone). The effect of blood thinning drugs (warfarin and other coumarins) may be increased by paracetamol. Some drugs may affect the way in which phenylephrine works (MAOIs, other sympathomimetic amines, antihypertensives, tricyclic antidepressants, digoxin and cardiac glycosides).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see section 2).
- Medicines used to treat epilepsy (phenytoin and carbamazepine), medicines used to treat sleeping problems (barbiturates such as pentobarbital, phenobarbital), as they may increase side effects on liver.
- Isoniazid (medicine used to treat tuberculosis), it may increase side effects of paracetamol.
- Oxytocin (medicine used to help contractions during childbirth) and ergot alkaloids (medicines used to treat migraine such as ergotamine, methylsergide), they may increase the risk of brain stroke (stroke caused by bleeding inside the brain).

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

Pregnancy and breast-feeding This product should not be used in women with a history of pre-eclampsia. Ask your doctor or pharmacist for advice before taking this product if you are pregnant or breast-feeding.

This medicine contains:

- Aspartame, 45mg in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- This medicine contains 120.74mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6% of the recommended maximum daily dietary intake of sodium for an adult. The maximum recommended daily dose of this medicinal product contains 482.96mg sodium (found in table salt). This is equivalent to 24.1% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need this medicine on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.
- Sucrose (2.57g of sucrose per sachet dose). This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take this medicine

To be made into a hot drink. Dissolve one sachet in a mug of hot, but not boiling, water. Stir until dissolved. If preferred, sweeten to taste with sugar, honey or your usual sweetener.
It is important to drink plenty of fluids when suffering from colds and flu.

Adults, the elderly and children aged 16 years and over: One sachet every 4 to 6 hours as required. Do not take more than 4 sachets in 24 hours.

Do not give to children under 16 years.

If the symptoms of your cold or flu persist for **more than five days**, or worsen, consult your pharmacist.

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If you take more Lemsip Cold and Flu Breathe Easy 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, high blood pressure with headache, unhealthy pale appearance (pallor), feeling sick (nausea) or vomiting if you take too much of this medicine. Severe poisoning can cause problems with the blood's ability to clot.

If you forget to take this medicine: Do not take a double dose to make up for a forgotten dose.
If you forget a dose, take it as soon as you remember it and then take the next dose at least 4 hours later.

4. Possible side effects

Like all medicines this product can cause side effects, although not everybody gets them. These include:

Very rare (fewer than 1 in 10,000 patients treated)

- Cases of serious skin reactions have been reported.

Frequency not known

- Allergic reactions (such as skin rashes).
- Blood disorders, such as, thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily), pancytopenia (reduction in white and red blood cells), agranulocytosis, leucopenia or neutropenia (reduction in white blood cells which makes infections more likely).
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).
- Headaches, high blood pressure or palpitations.
- Stomach and gut disorder, such as, feeling sick, being sick or abdominal discomfort.
- Difficulty in passing urine (especially in males).

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 the Yellow Card Scheme at:
http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep all medicines out of the sight and reach of children. Do not store above 25°C (77°F).
Store in the original package. Do not use after the end of the month of the expiry date (EXP month/year) shown on the pack.

6. Contents of the pack and other information

What this medicine contains:

- The active substances per sachet are: paracetamol 650mg and phenylephrine hydrochloride 10mg.
- The other ingredients are: ascorbic acid (Vitamin C), citric acid, sucrose, aspartame, sodium citrate, saccharin sodium, curcumin WD, caster sugar, lemon and menthol flavour.

Contents of the pack

This product is available in cartons of 5 and 10 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer:
Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS, UK. (PL 00063/0041)

Manufacturer:
RB NL Brands B.V. WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH Schiphol, Netherlands.
Leaflet last revised January 2026.
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CUSTOMER INFO
Minimum Point Size =9.00pt