

Package Leaflet: Information for the User

Lemsip Max Daytime Cold & Flu Relief

(paracetamol, caffeine and phenylephrine hydrochloride)

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 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. 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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine

6. Contents of the pack and other information

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

Lemsip Max Daytime Cold & Flu Relief contain 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). Caffeine (a mild stimulant), helps relieve fatigue and drowsiness through the day. 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 Max Daytime Cold & Flu Relief may not be suitable for some people.

Do not take this medicine if:

- You are allergic to paracetamol, caffeine or phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- You have a serious heart condition
- You have high blood pressure (hypertension) or 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
- You have phaeochromocytoma

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if:

- You have Raynaud's syndrome (poor blood circulation which makes the fingers or toes pale and numb), or diabetes mellitus
- You have a problem with your liver or kidneys or a history of stomach ulcer
- You have non-cirrhotic liver disease (liver disease that is not associated with changes in the structure of the liver)
- You have closed angle glaucoma

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).

Children and adolescents:

Do not give this medicine to children under 16 years of age.

Other medicines and Lemsip Max Daytime Cold & Flu Relief

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

- Do not take with other paracetamol-containing products
- Do not take if you are taking or have taken within the last 14 days a medicine called a monoamine oxidase inhibitor (MAOI), a medicine used to treat depression.
- Concomitant use of other cough and cold medicines could lead to overdose and should therefore be avoided.

Talk to your doctor or pharmacist if you are taking:

- 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 antidepressants (a specific class of drugs used to treat depression), other decongestants, or barbiturates (used to treat sleep problems or epilepsy)

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- 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 (digoxin and cardiac glycosides). The speed at which caffeine is disposed of by the body can be slowed down by cimetidine (used to reduce stomach acid), disulfiram (used to treat alcoholism) or oral contraceptives

- 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).

Pregnancy and breast-feeding:

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.

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

Driving and using machines:

This medicine can cause difficulty in sleeping, restlessness, nervousness or mental confusion. Do not drive or use machines if you are affected by any of these symptoms.

This medicine contains: Sodium (less than 23 mg per dose), that is to say essentially 'sodium-free'.

3. How to take this medicine

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

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

Adults, the elderly and children aged 16 years and over : Take two capsules every 4-6 hours as required to a maximum of four doses in any 24 hours, or up to a maximum of three doses in any 24 hours if a night-time paracetamol-containing product is taken before bedtime. Do not take more than 8 capsules (4 doses) in any 24 hours.

Do not give to children under 16 years of age.

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

If you take more 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, high blood pressure with headache, unhealthy pale appearance (pallor), feeling sick (nausea), vomiting or loss of appetite if you take too much of this medicine.

4. Possible side-effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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)
- Stomach and gut disorder, such as feeling sick, being sick or abdominal discomfort
- Difficulty in sleeping, restlessness, nervousness or mental confusion. If you are affected by any of these symptoms, do not drive or use machines
- Caffeine, if taken close to bedtime, may interfere with sleep
- Difficulty in passing urine (especially in men)

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: 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 use after the end of the month of the expiry date (EXP month/year) shown on the pack. Do not store above 25°C (77°F). Store in the original package. 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 this medicine contains:

- The active ingredients are: paracetamol 500mg, caffeine 25mg and phenylephrine hydrochloride 6.1mg.
- The other ingredients are starch, croscarmellose sodium, sodium lauril sulfate, magnesium stearate, sterilised talc, gelatin, titanium dioxide (E171), patent blue V (E131), erythrosine (E127) shellac and quinoline yellow (E104).

What this medicine looks like and contents of the pack: The product are red/yellow hard gelatine capsules. The product is available in cartons of 4, 6, 8 and 16 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer:

Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS, UK. PL 00063/0148

Manufacturer:

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