

Package Leaflet: Information for the User
Lemsip Max Apple & Cinnamon Flavour Powder for Oral Solution
(paracetamol and phenylephrine hydrochloride)

Please read this leaflet carefully before you take this medicine. If you are not sure of anything, ask your pharmacist or doctor.

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

Lemsip Max Apple & Cinnamon Flavour Powder for Oral Solution 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 Max Apple & Cinnamon Flavour Powder for Oral Solution may not be suitable for some people.

Do not take this medicine if:

- You are allergic to any ingredient (see Section 6 for further information).
- 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; pheochromocytoma; diabetes mellitus; or closed-angle glaucoma.

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).
- You have a problem with your liver or kidneys.
- You have 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 Max Apple & Cinnamon Flavour Powder for Oral Solution

- Do not take with other paracetamol-containing products.
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).
- Taking tricyclic antidepressants (a specific class of drugs used to treat depression), other decongestants, or barbiturates (used to treat sleep problems or epilepsy).
- Taking 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).
- Taking 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).
- Taking isoniazid (medicine used to treat tuberculosis), it may increase side effects of paracetamol.
- Taking oxytocin (medicine used to help contractions during childbirth) and ergot alkaloids (medicines used to treat migraine such as ergotamine, methysergide), they may increase the risk of brain stroke (stroke caused by bleeding inside the brain).
- Taking 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.

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, a source of phenylalanine. This medicine contains 61.5mg aspartame in each sachet. 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.
- Sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sulphites, may rarely cause severe hypersensitivity reactions and bronchospasm.
- Sodium (129.0mg per sachet), main component of cooking/table salt. This is equivalent to 6.45% of the recommended maximum daily dietary intake of sodium for an adult. The maximum recommended daily dose of this medicinal product contains 514.84mg sodium (found in table salt). This is equivalent to 25.7% 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.

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 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.

If you take more Lemsip Max Apple & Cinnamon Flavour Powder for Oral Solution 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 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).
- Headaches, high blood pressure or palpitations.
- Stomach and gut disorder, such as feeling 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: 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. Store in the original package.

6. Contents of the pack and other information What this medicine contains:

- The active substances per sachet are: paracetamol 1000mg and phenylephrine hydrochloride 12.2mg.
- The other ingredients are: ascorbic acid, caster sugar, pulverised sucrose, citric acid anhydrous, sodium citrate, apple and cinnamon flavour, aspartame (E951), saccharin sodium and caramel (E150).

Contents of the pack This product is available in cartons of 5, 7, 9 and 10 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd, Hull, HU8 7DS. (PL 00063/0163)

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