

Package Leaflet: Information for the User
Lemsip Max Flu Lemon
(paracetamol and pseudoephedrine 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.

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 Flu Lemon contains a combination of ingredients which are effective in relieving the symptoms associated with heavy colds and flu, including effect of aches and pains: — headache, sore throat, nasal congestion or runny nose, pain and congestion of sinuses 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 fever (antipyretic).

Pseudoephedrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing the pressure which can cause headache.

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

As with all medicines, Lemsip Max Flu Lemon may not be suitable for some people.

One of the active ingredients in Lemsip Max Flu Lemon, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Lemsip Max Flu Lemon than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

Do not take Lemsip Max Flu Lemon if:

- you are allergic to any ingredients (see section 6 for further information), or
- you have serious heart condition, or
- you have high blood pressure (hypertension), or hypertension not controlled by your medication, or
- you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure; or
- you are taking or have taken within the last 14 days a medicine called monoamine oxidase inhibitor (MAOI), usually used to treat depression, or
- you are a child under 16

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

- you have overactive thyroid or enlarged prostate,
- you are breast feeding, or
- you have diabetes, or
- you have hyperexcitability (restlessness), or
- you have problem with your liver, kidneys including pheochromocytoma (tumour),
- you have a glaucoma

Sudden abdominal pain or rectal bleeding may occur with Lemsip Max Flu Lemon, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Lemsip Max Flu Lemon and contact your doctor or seek medical attention immediately. See section 4.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Lemsip Max Flu Lemon immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS. See section 4.

Other medicines and Lemsip Max Flu Lemon

- 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).
 - 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, such as appetite suppressants, bethamide or methyllopa (both for high blood pressure).
- Some drugs may affect the way in which paracetamol works, including those used to treat blood cholesterol (cholesterol-lowering drugs (warfarin and other coumarins) may be increased by paracetamol.

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

Lemsip Max Flu Lemon with 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.

Ask your doctor or pharmacist for advice before taking this product if you are pregnant or breast-feeding.

This medicine contains:

- Aspartame, 62.5mg in each sachet. Aspartame

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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.

- Sodium (main component of cooking/table salt), 121.9 mg in each sachet. This is equivalent to 6.1 % of the recommended maximum daily dietary intake of sodium for an adult. The maximum recommended daily dose of this medicinal product contains 487.64 mg sodium (found in table salt). This is equivalent to 24.4 % of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Lemsip Max Flu Lemon on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

- Lactose. Saccharose 2.19g per sachet. This should be taken into account in patient with diabetes.

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 the content of one sachet by stirring into a mug of hot, but not boiling, water and sweetener to taste. Stir until dissolved.

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 4-6 hours as required. Do not take more than 4 sachets in 24 hours.

Do not give to children under-16 years of age:
If the symptoms persist for more than 3 days, or worsen, consult your pharmacist.

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, unhealthily pale appearance (pallor), feeling sick (nausea) or vomiting if you take too much of this medicine.

If you forget to take this medicine:
Do not take a double dose to make up for forgotten individual doses. 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, Lemsip Max Flu Lemon can cause side effects, although not everybody gets them:

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) (frequency not known). Stop using Lemsip Max Flu Lemon immediately and seek urgent medical attention if you develop symptoms, that may be signs of PRES or RCVS. These include: severe headache with sudden onset, feeling sick, vomiting, confusion, seizures, changes in vision.
- 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) —

- Loss of appetite, dry mouth, difficulty in passing urine (in men only), tension, restlessness, sleep disturbance or hallucinations may rarely occur.
- Acute pancreatitis (after ingestion of above normal amounts).
- Inflammation of the colon due to insufficient blood supply (ischemic colitis) (frequency not known).
- Reduced blood flow to the optic nerve (ischemic optic neuropathy) (frequency not known).

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 out of the sight and reach of children.
Do not use Lemsip Max Flu Lemon after the expiry date (EXP month/year) which is stated on the pack. The expiry date refers to the last day of that month.

Store below 25°C (77°F).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lemsip Max Flu Lemon contains:
Each sachet of Lemsip Max Flu Lemon (powder) contains the active ingredients paracetamol 100mg and pseudoephedrine hydrochloride 60mg. The other ingredients are caster sugar, sucrose, citric acid, lemon flavour, saccharin sodium, aspartame, sodium citrate, ascorbic acid (Vitamin C) and curcumin (contains curcumin E100, lactose, polysorbate 80 E433 and silica E551). Each sachet contains approximately 2.1 g of sugar.

What Lemsip Max Flu Lemon looks like:
It is a pale yellow, off-white to cream powder available in cartons of 5 and 10 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer:
Reckitt Benckiser Healthcare (UK) Limited, Hall, H18 7DS, UK. (PL.00063/0040)

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