

Package leaflet: Information for the user

LEMSIP MAX SINUS & FLU

Hot Lemon

Powder for Oral Solution

Paracetamol 1000mg

Pseudoephedrine Hydrochloride 60mg

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has 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 or nurse. 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

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2. What you need to know before you take Lemsip Sinus & Flu Hot Lemon
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1. What Lemsip Max Sinus & Flu Hot Lemon is and what it is used for?

Each sachet of Lemsip Max Sinus & Flu Hot Lemon Powder for Oral Solution contains 1000mg paracetamol and 60mg pseudoephedrine hydrochloride. Paracetamol has pain killing (analgesic) and fever reducing (antipyretic) properties. Pseudoephedrine Hydrochloride is a decongestant to relieve blocked or runny nose. Lemsip Max Sinus & Flu Hot Lemon can be used to relieve the symptoms of sinusitis and common cold & flu, such as headache and congestion in the nose and sinuses.

2. What you need to know before you take Lemsip Max Sinus & Flu Hot Lemon

Do not take Lemsip Max Sinus & Flu Hot Lemon

- if you are allergic (hypersensitive) to paracetamol or any of the other ingredients listed in Section 6.
- if you are taking any other paracetamol containing products
- if you are taking monoamine oxidase inhibitors (MAOIs) or have done so in the past 14 days
- if you suffer from hypertension or severe coronary artery disease
- if you are less than 18 years of age

Warnings & precautions:

Take special care with Lemsip Max Sinus & Flu Hot Lemon

- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product
- if you are on a controlled sodium diet, this product contains 122mg sodium per dose
- if you have phenylketonuria, this product contains a source of phenylalanine
- if you have impaired liver or kidney function
- if you are taking other drugs that affect the liver
- if you suffer from thyrotoxicosis, glaucoma or urinary retention
- if you develop a feverish generalised erythema associated with pustules, stop taking Lemsip Max Sinus & Flu Hot Lemon and contact your doctor or seek medical attention immediately. See Section 4.
- Sudden abdominal pain or rectal bleeding may occur with Lemsip Max Sinus & Flu Hot Lemon due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.

Prolonged use, except under medical supervision can be harmful. If symptoms persist contact your doctor or pharmacist. Only take when necessary.
Do not exceed the stated dose.

Reduction of blood flow to your optic nerve may occur with Lemsip Max Sinus & Flu Hot Lemon. If you develop sudden loss of vision, stop taking Lemsip Max Sinus & Flu Hot Lemon and contact your doctor or seek medical attention immediately. See section 4.

Other medicines and Lemsip Max Sinus & Flu Hot Lemon Care should be taken while taking this product if you are currently taking:

- anti-emetic drugs such as metoclopramide or domperidone; may increase absorption of paracetamol
- cholesterol drugs such as cholestyramine; may reduce absorption of paracetamol
- anticoagulants such as warfarin; their effect may be enhanced by long term use of paracetamol
- drugs that affect the liver such as monoamine oxidase inhibitors and antidepressants; may increase the hepatotoxicity (liver toxicity) of paracetamol
- sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants
- monoamine oxidase inhibitors may occasionally cause a rise in blood pressure
- flucloxacillin. There is an increased risk of metabolic acidosis, especially in patients with kidney and liver impairment, sepsis, malnutrition and alcoholism.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Lemsip Max Sinus & Flu Hot Lemon with food, drink and alcohol

Alcohol may increase the adverse effects of paracetamol.

Pregnancy, breastfeeding and fertility

This product should not be used in pregnancy unless considered essential by your doctor.

If necessary, Lemsip Max Sinus & Flu Hot Lemon can be used during pregnancy. It should be used at the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.

Important information about some of the ingredients of Lemsip Max Sinus & Flu Hot Lemon

- this medicine contains 2.19g of sucrose per sachet. 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.
- this medicine contains 121.9 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6.1 % of the recommended maximum daily dietary intake of sodium for an adult. This product is considered high in salt and should be taken into account if on a low salt diet.
- this medicine contains 62.5mg aspartame 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 9.72mg of lactose per sachet. 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 Lemsip Max Sinus & Flu Hot Lemon

Oral use. Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Dilute the contents of one sachet in a mug of hot water, to not boil the water. Stir until dissolved. If preferred, sweeten to taste with sugar, honey or usual sweetener.

Adults: the usual dose is one sachet up to 3 times a day. Do not exceed 3 doses in 24 hours.

If you take more Lemsip Max Sinus & Flu Hot Lemon than you should

Immediate medical advice should be sought in the event of overdosage because of the risk of irreversible liver damage. Symptoms of overdosage may present as nausea, vomiting, loss of appetite and abdominal pain, palpitations or hypertension.

If you forget to take Lemsip Max Sinus & Flu Hot Lemon

Take the next dose as soon as you remember, if needed. Do not double dose. This product should only be taken when necessary. If you have any further questions on the use of this product, ask your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lemsip Max Sinus & Flu Hot Lemon can cause side effects although not everybody gets them. Side effects may include hypersensitivity reactions such as skin rashes and inflammation of the colon due to insufficient blood supply (ischemic colitis; frequency "not known"). There have also been reports of blood disorders, but these were not necessarily caused by paracetamol.

Possible side effects of pseudoephedrine include central nervous system excitation such as restlessness, tachycardia, sleep disturbances and more rarely hallucinations, skin rash and urinary retention. Frequency "not known": sudden onset of fever, reddening of the skin or many small pustules (possible symptoms of Acute Generalised Exanthematous Pustulosis (AGEP) may occur within the first 2 days of treatment with Lemsip Max Sinus & Flu Hot Lemon, a reduced blood flow to the optic nerve (Ischaemic optic neuropathy). See section 2. Stop using this medicine if you develop these symptoms and contact your doctor or seek medical attention immediately. 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.

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 Max Sinus & Flu Hot Lemon

Keep this medicine out of the sight and reach of children.

Do not use Lemsip Max Sinus & Flu Hot Lemon after the expiry date (EXP Day/Month/Year) which is stated on the carton and sachet.

Do not store above 25°C.

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 Max Sinus & Flu Hot Lemon contains

Each sachet contains 1000mg paracetamol and 60mg pseudoephedrine hydrochloride as active ingredients.

The other ingredients are sucrose, citric acid anhydrous, lemon flavour, saccharin sodium, aspartame (E951), sodium citrate, ascorbic acid, silica, polysorbate 80, lactose and curcumin (contains lactose).

What Lemsip Max Sinus & Flu Hot Lemon look like and contents of the pack

Pale yellow coloured homogenous powder for oral solution with a taste and odour of lemon. Each carton contains 10 sachets, each containing 4.8g of product.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer:

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For product queries please call: 01 63005429

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