

PACKAGE LEAFLET: INFORMATION FOR THE USER

LEMSIP COLD & FLU
Headcold 500mg
Powder for Oral solution
Paracetamol

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

This medicine is available without prescription. However, you still need to take Lemsip Cold & Flu Headcold carefully to get the best results from it.

1. WHAT LEMSIP COLD & FLU HEADCOLD IS AND WHAT IT IS USED FOR?

Each sachet of Lemsip Cold & Flu Headcold 500mg Powder for Oral Solution contains 500mg paracetamol. Paracetamol has pain killing (analgesic) and fever reduction (antipyretic) properties. Lemsip Cold & Flu Headcold can be used to relieve the symptoms of common cold or influenza such as headache, sore throat, fever, body aches and pains.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEMSIP COLD & FLU HEADCOLD

Do not take Lemsip Cold & Flu Headcold

- 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 less than 12 years of age

Take special care with Lemsip Cold & Flu Headcold

- If you have impaired liver or kidney function
- If you are underweight (less than 50 kg) or are malnourished
- If you use large quantities of alcohol regularly (alcoholism)
- If you suffer from severe dehydration
- If you are taking other drugs that affect the liver (see Taking other medicines)
- If you are elderly
- If you have glutathione deficiency (a metabolic disorder which may lead to difficulty in breakdown of paracetamol)
- If you have an enzyme deficiency called Glucose-6-phosphate dehydrogenase deficiency
- If you have haemolytic anaemia (abnormal breakdown of red blood cells)

If any of the above applies to you, you may need to reduce the amount of paracetamol that you take or avoid taking this medicinal product altogether.

During treatment with Lemsip Cold & Flu Headcold, tell your doctor straight away if:

- 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).

If you are diabetic, paracetamol contained in this medicine may falsely elevate continuous blood glucose monitor readings compared to finger prick readings. This is not the case with all continuous blood glucose monitors. Please refer to the information provided by the manufacturer of your monitor. Contact your doctor, pharmacist or nurse if you are unsure or should you require further advice.

Prolonged use, except under medical supervision can be harmful. If you have a high fever, or if symptoms get worse or persist for longer than 3 days, consult your doctor.

Other medicines and Lemsip Cold & Flu Headcold

Care should be taken while taking this product if you are currently taking:

- Drugs to stop you feeling or being sick 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.

- Flucloxacillin. Please inform your doctor or pharmacist if you are taking flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment.

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

Taking Lemsip Cold & Flu Headcold with food, drink and alcohol

Alcohol may increase the adverse effects of paracetamol.

Pregnancy, breast-feeding and fertility:

Lemsip Cold & Flu Headcold can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Paracetamol is excreted in breast milk, but not in a clinically significant amount. You can take this product whilst breastfeeding.

Important information about some of the ingredients of Lemsip Cold & Flu Headcold

- This medicine contains 22.5mg 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 93.77 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 4.7 % of the recommended maximum daily dietary intake of sodium for an adult.
- This product contains 2.99g 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 product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE LEMSIP COLD & FLU HEADCOLD

Always use the lowest effective dose for the shortest time necessary to relieve your symptoms. Do not exceed the stated dose.

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

Adults, the elderly and children aged 16 years and over: 1 sachet every 4 hours as required. Do not take more than 6 sachets in 24 hours.

Children aged 12-15 years: 1 sachet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Do not give to children under 12 years of age.

In all patients over 16 years of age, do not take more than 4 sachets a day (2g/day) in the following situations, unless directed by your doctor:

- Weight less than 50 kg
- Use of large quantities of alcohol regularly (alcoholism)
- Dehydration
- Malnutrition

Use in kidney or liver impairment:

If you have been diagnosed with kidney or liver problems, please consult your doctor or pharmacist. You may need to take a lower dose or increase the length of time between doses.

If you take more Lemsip Cold & Flu Headcold than you should:

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage. Symptoms of overdose may present as pallor, nausea, vomiting, loss of appetite and abdominal pain. There is an increased risk of liver damage from paracetamol overdosing associated patients who consume alcohol in excess of recommended amounts, patients on long-term treatment with enzyme-inducing drugs and patients likely to be lacking glutathione e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

If you forget to take Lemsip Cold & Flu Headcold

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 Cold & Flu Headcold can cause side effects although not everybody gets them. Side effects may include hypersensitivity reactions such as skin rashes, skin and tissue disorders such as shedding of your skin, blisters on your skin and mucous membranes, facial swelling, tongue swelling. If skin rash occurs discontinue use immediately. There have also been reports of blood disorders.

Frequency "Very rare":

- Very rare cases of serious skin reactions have been reported.

Frequency "Not known" (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 COLD & FLU HEADCOLD

Keep out of the sight and reach of children.

Do not use Lemsip Cold & Flu Headcold 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 Cold & Flu Headcold contains

Each sachet contains 500mg of paracetamol as the active ingredient. The other ingredients are sucrose, citric acid anhydrous, lemon flavour no. 1, menthol flavour, saccharin sodium, aspartame (E951), sodium citrate, ascorbic acid and curcumin WD (constituents of curcumin WD include; curcumin, lactose, polysorbate and silica).

What Lemsip Cold & Flu Headcold looks like and contents of the pack

Pale cream coloured homogenous powder for oral solution with a taste and odour of lemon and menthol. Each carton contains 5 or 10 sachets, each containing 4.8g of product.

Marketing Authorisation Holder and Manufacturer

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturers: Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

For product queries please call: 01 6305429

Date of revision of text: upon approval