PACKAGE LEAFLET: INFORMATION FOR THE USER

Lemsip Decongestant & Flu Blackcurrant Tablets

Paracetamol 500mg

Phenylephrine hydrochloride 6.1mg

Read all of this leaflet carefully because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve after 3 days.
- 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.

In this leaflet:

1. What this medicine is and what it is used for.
2. Before you take this medicine.
3. How to take this medicine.
4. Possible side effects.
5. How to store this medicine.
6. Further information.

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR.

This product contains a combination of two active ingredients, Paracetamol and phenylephrine 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 mild to moderate aches and pains, including headache. It can also reduce raised temperatures or fever (antipyretic). Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing pressure which may cause a headache.

2. BEFORE YOU TAKE THIS MEDICINE

Do not take this medicine if:

- You are allergic to paracetamol, phenylephrine hydrochloride or any of the other ingredients listed in Section 6,
- You have a serious heart condition,
- You have an overactive thyroid,
- You have high blood pressure (hypertension),
- 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 have taken another medicine for the treatment of cold and flu

Take special care with this medicine if:

- You suffer from liver or kidney problems,
- You have non-cirrhotic liver disease (liver disease that is not associated with changes to the structure of the liver),
- You suffer from Raynaud's syndrome (poor blood circulation which makes the fingers or toes pale and numb), or diabetes mellitus,
- You have glaucoma or enlarged prostate.

Taking other medicines:

Do not take any other paracetamol containing products.
Do not take with MAOI (see section "Do not take this medicine if you").

Taking Lemsip Decongestant & Flu Blackcurrant Tablets with other medicines can change how they work or how this medicines works. Tell your doctor or pharmacist if you are taking any of the following:

- Cholestyramine (to treat blood cholesterol) , metoclopramide and domperidone (to treat nausea and vomiting),
- Warfarin and other coumarins (to thin the blood),
- Tricyclic antidepressants (used to treat depression), babiturates (sleeping pills), or alcohol,
- Other decongestants or sympathomimetic amines (for blocked nose),
- Beta-blockers and other antihypertensives (to treat high blood pressure) including debrisoquine, guanethidine, reserpine and methyldopa,
- Digoxin and cardiac glycosides (to treat heart failure and irregular heart beats).

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

Taking this medicine with food and drink:

- Do not consume large quantities of alcohol while taking this medicine

Pregnancy or 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.

Important information about some of the ingredients in your medicine:

- This product contains aspartame, a source of phenylalanine, which may be harmful for people with phenylketonuria (an inherited genetic disorder).

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3. HOW TO TAKE THIS MEDICINE

Do not exceed the stated dose.

Tear along the perforations and peel back to reveal the tablet. Follow the instructions on the blister. Replace unopened blisters back into carton.

There are two possible ways to take this medicine.

Either

Swallow whole with water. Do not chew.

Or

Make into a hot drink. Dissolve in half a mug of hot (not boiling) water. Stir until dissolved. If preferred sweeten to taste using sugar, honey or your usual sweetener. Once prepared the drink should be taken as soon as possible and should not be stored.

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

Age	Dose and how often to take
Adults and children 16 years and over	Take two tablets every 4-6 hours. Do not take more than eight tablets in a total of 24 hours
Children aged 12 to 15 years old	Take one tablet every 4-6 hours. Do not take more than four tablets in a total of 24 hours.
Do not give to children under 12 years of age	

If the symptoms persist for more than three days, or worsen, consult your doctor.

If you take more of this medicine than you should:

Immediate medical advice should be sought in the event of an overdose, even if you feel well because the risk of delayed, serious liver damage.

If you forget to take this medicine:

This product should only be used when necessary. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

- Allergic reactions (such as skin rashes),
- Changes in the number of blood cells, such as thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily), leucopoenia, pancytopenia, neutropenia and agranulocytosis (reduction in white blood cells which make infections more likely).
- High blood pressure with headache,
- Nausea and vomiting,
- Irregular or fast heartbeats.
- Difficulty in passing urine (in men only).
- Severe pain in the abdomen and back due to inflammation of the pancreas especially after ingestion of amounts of products above normal.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie E-mail: medsafety@hpra.ie
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 reach and sight of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last date of that month.

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 protect the environment.

6. FURTHER INFORMATION

What this medicine contains:

- The active ingredients per tablet are: paracetamol 500mg and phenylephrine hydrochloride 6.1mg.
- The other ingredients are: crospovidone, citric acid (E330), aspartame (E951), microcrystalline cellulose, magnesium stearate (E470b), enocyanine (E163), blackcurrant flavour, pre-gelatinized starch, povidone (E1201).

What the medicine looks like and the contents of the pack:

The product is a convex pale yellow oval shaped tablet with blackcurrant odour.

The product is available in cartons of 6 and 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24 (PA 979/50/1).

Manufacturer: Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Lemsip Max Blackcurrant Flavour Tablets

Ireland: Lemsip Decongestant & Flu Blackcurrant Tablets Paracetamol 500mg Phenylephrine hydrochloride 6.1mg

Alternative format patient information for the visually impaired is available on request from the marketing authorisation holder.

For product queries please call 01-6305429.

Leaflet last revised February 2015.

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CUSTOMER INFO:
Minimum Point Size = 9.00pt

RB Artwork and Print Specification

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Segment:	Tablets Blackcurrant
Pack Size:	N/Aunit
Market/Country:	EIRE
Date:	16/02/15
RBH Contact:	Laura OToole

Artwork Type: Submission

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BARCODE INFO

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Truncated By:	N/A
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Bar Height (Smallest Bar):	N/A
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Encoded Data:	N/A

Reckitt Benckiser

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