#### PACKAGING LEAFLET: INFORMATION FOR THE USER

#### Lemsip Max All in One Cold & Flu Capsules

Paracetamol, Guaifenesin and Phenylephrine Hydrochloride

#### 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 this medicine 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,

# 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

Capsules for oral use.

This Medicine is a combination of active ingredients which are effective in relieving the symptoms associated with colds and flu, including relief of aches and pains, sore throats, headache, nasal congestion, lowering of temperature and chesty cough.

Paracetamol is a well known painkiller (analgesic). It is effective against aches and pains including headache and can also reduce a fever (antipyretic). Guaifenesin (expectorant) allows you to cough up phlegm when suffering from a chesty cough. Phenylephrine hydrochloride (nasal decongestant) phlegm when suffering from a chesty cough. Phenylephrine hydrochloride (nasal decongestant) phlegm when suffering from a chesty cough. Phenylephrine hydrochloride (nasal decongestant) phlegm when suffering from a chesty cough. Phenylephrine hydrochloride (nasal decongestant) and reducing pressure which may cause a headache.

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

#### Do not take this medicine if:

- You are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride or any of the other ingredients listed in section 6.
- You have a serious heart condition, or an overactive thyroid.
- You have a high blood pressure (hypertension).
- --- You are taking or have taken within the last-14 days a medicine called a monoamine oxidase ---inhibitor (MAOI), usually to treat depression.
- You have an enlarged prostate
- You are taking other decongestant medications.
- You have phaeochromocytoma

### Warnings and precautions

# -Talk-to-your doctor-or-pharmacist-before taking Lemsip Max All-in-One Cold & Flu Capsules if: -

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

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 flueloxaeillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially "sodium free".

# Other Medicines and Lemsip Max All in One Cold & Flu Capsules:

- Do not take with any other paracetamol containing products.
- Do not take with any other product used for relief of cold, flu or congestion.

If you are taking any of the following medicines, talk to your doctor or pharmacist before taking Lemsip Max All in One Cold & Flu Capsules:

- 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).
- You are taking other medicines some drugs may affect the way paracetamol works, including those used to treat blood cholesterol (cholestyramine) and nausea and vomiting metoclopramide and domperidone). Some drugs may affect the way in which phenylephrine works (digoxin and cardiac  $-00000000^{\dagger}$

- The effect of blood thinning drugs (warfarin and other coumarins) may be increased by paracetamol.
- 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 this medicine with food and drink:

• 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. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### 3. How to take this Medicine

The capsule should be swallowed whole with-water. Do not-chew.

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

Adults, the elderly and children 16 years and over: Take two capsules every 4-6 hours as required. Do not take more than 8 capsules (4 doses) in 24 hours.

#### Do not give to children under 16 years of age.

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

#### If you take more of this medicine 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 or high blood pressure with headache if you take too much of this medicine

## If you forget to take this medicine:

This product should only be used when necessary.

Do not take a double dosage 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

- Blood disorders, such as thrombocytopenia (reduction in blood platelets which might mean that you bleed or bruise more easily), leucopoenia, pancytopenia(reduction in white and red blood cells), neutropenia and agranulocytosis (reduction in white blood cells which make infection more likely).
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)
- Very rare cases of serious skin reactions have been reported.
- Nausea and Vomiting.
- 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 MHRAYellow 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

Do not store above 25°C.

Keep out of the sight and reach of children.

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 day 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 environment.

# 6. Contents of the pack and other information

#### What this medicine contains:

- The active ingredients per capsule are: paracetamol 500mg, guaifenesin 100mg and phenylephrine hydrochloride 6.1mg.
- The other ingredients are: maize, starch, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, talc, gelatin, titanium dioxide (E171), yellow and red oxide (E172), brilliant blue – FD&C blue I (E133) and shellac (E904).

# What the medicine looks like and the content of the pack:

The product is a hard gelatin capsule with a green body and a red cap with Lemsip printed on the cap. UK: The product is available in carton of 8 and 16 capsules.

NZ: The product is available in carton of 16 capsules

#### Marketing Authorisation Holder/Manufacturer:

Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS, UK. (PL 00063/0551)

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