

**Package Leaflet: Information for the User**  
**Lemsip Max Day & Night Cold & Flu Relief Capsules**  
(paracetamol, caffeine and phenylephrine 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.

**What is 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 Day & Night Cold & Flu Relief Capsules contain a combination of ingredients 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 aches and pains, including a headache, and can also reduce a fever (antipyretic). Caffeine (a mild stimulant), helps relieve fatigue and drowsiness through the day (it is only used in the Day capsule). Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing the pressure which may cause a headache.

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

As with all medicines Lemsip Max Day & Night Cold & Flu Relief Capsules may not be suitable for some people:

**Do not take this medicine if:**

- You are allergic to paracetamol, caffeine or phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- You have a serious heart condition
- You have high blood pressure (hypertension) or an overactive thyroid
- 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 are taking other sympathomimetic decongestants
- You have an enlarged prostate
- You have phaeochromocytoma

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

- You have Raynaud's syndrome (poor blood circulation which makes the fingers or toes pale and numb), or diabetes mellitus
- You have a problem with your liver or kidneys or a history of stomach ulcer
- You have non-cirrhotic liver disease (liver disease that is not associated with changes in the structure of the liver)
- You have closed angle glaucoma

**Children and adolescents:** Do not give this medicine to children under 16 years of age.

**Other medicines and Lemsip Max Day & Night Cold & Flu Relief Capsules:**

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

- Do not take with other paracetamol-containing products
- Do not take if you are taking or have taken within the last 14 days a medicine called a monoamine oxidase inhibitor (MAOI), a medicine used to treat depression.
- Concomitant use of other cough and cold medicines could lead to overdose and should therefore be avoided.

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 antidepressants (a specific class of drugs used to treat depression), other decongestants, or barbiturates (used to treat sleep problems or epilepsy)
- Other medicines. Some drugs may affect the way in which paracetamol works, including those used to treat blood cholesterol (cholestyramine) and nausea and vomiting (metoclopramide and domperidone). The effect of blood thinning drugs (warfarin and other coumarins) may be increased by paracetamol. Some drugs may affect the way in which phenylephrine works (digoxin and cardiac glycosides). The speed at which caffeine is disposed of by the body can be slowed down by cimetidine (used to reduce stomach acid), disulfiram (used to treat alcoholism) or oral contraceptives
- Flucloxacillin (antibiotic). Due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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**Pregnancy and breast-feeding**

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. This product should not be used in women with a history of pre-eclampsia.

**Driving and using machines:** This medicine can cause difficulty in sleeping, restlessness, nervousness or mental confusion. Do not drive or use machines if you are affected by any of these symptoms.

**This medicine contains:** Sodium (less than 23 mg per dose), that is to say essentially 'sodium-free'.

**3. How to take this medicine**

The capsules should be swallowed whole with water. Do not chew.

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

**Adults, the elderly and children aged 16 years and over:**

Daytime	Night time
Take two red and yellow capsules every 4-6 hours during the day to a maximum of 3 doses when necessary. Do not take more than 6 red and yellow capsules in any 24 hours.	Take two blue and red capsules at night if needed.

**Do not take more than 8 capsules (4 doses) in any 24 hours. Do not give to children under 16 years of age.**

If the symptoms of your cold and flu persist for more than 3 days, or worsen consult your pharmacist.

**If you take more capsules 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, high blood pressure with headache, unhealthy pale appearance (pallor), feeling sick (nausea), vomiting or loss of appetite if you take too much of this medicine.**

**4. Possible side-effects**

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

Very rare (fewer than 1 in 10,000 patients treated)

- Cases of serious skin reactions have been reported

Frequency not known

- 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)
- Stomach and gut disorder, such as feeling sick, being sick or abdominal discomfort
- Difficulty in sleeping, restlessness, nervousness or mental confusion. If you are affected by any of these symptoms, do not drive or use machines
- Caffeine, if taken close to bedtime, may interfere with sleep.
- Difficulty in passing urine (especially in men)

**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](http://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 all medicines out of the sight and reach of children.

Do not use after the end of the month of the expiry date (EXP month/year) shown on pack.

Do not store above 25°C (77°F). Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

**6. Contents of the pack and other information**

**What this medicine contains:** Red and yellow Day capsules contain:

- The active ingredients are: paracetamol 500mg, caffeine 25mg and phenylephrine hydrochloride 6.1mg.

The other ingredients are: starch, croscarmellose sodium, sodium lauril sulfate, magnesium stearate, sterilised talc, gelatin, titanium dioxide (E171), patent blue V (E131), erythrosine E127 shellac and quinoline yellow (E104).

Red and blue Night capsules contain:

- The active ingredients are: paracetamol 500mg and phenylephrine hydrochloride 6.1mg.
- The other ingredients are: starch, croscarmellose sodium, sodium lauril sulfate, magnesium stearate, sterilised talc, gelatin, titanium dioxide (E171), patent blue V (E131) and erythrosine E127 shellac.

**What this medicine looks like and contents of the pack:** Day-time capsules are red/yellow hard gelatin capsules, Night-time capsules are red/blue hard gelatin capsules. The product is available in cartons of 8 and 16 capsules. Not all pack sizes may be marketed.

**Marketing Authorisation Holder/Manufacturer:**

Reckitt Benckiser Healthcare (UK)-Limited, Hull; HU8 7DS, UK. PL-00063/0143

**Manufacturer:**

RB NL Brands B.V. WTC Schiphol Airport, Schiphol Boulevard 207, 1118 BH Schiphol, Netherlands  
Leaflet last revised May 2022

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160

160

300

300

Production line		
Manufacturing site		
Pack Tech approver	1 <sup>st</sup> 2 <sup>nd</sup>	
Date		
Check Criteria	Details Et Comments	Checks
Approvals		1 <sup>st</sup> 2 <sup>nd</sup>
Market Approval		
Regulatory Approval		
3rd Party Approval		
Technical Drawing/ Cutter ref no. Et PPI component code		
PPI component code number/s correct on artwork?		
PPI component code number/s in correct position on artwork?		
Correct drawing for the production line?		
Profile shape Et dimensions		
Graphics layout/orientation		
Unwind diagram (PPTD1022/1-20)		
Printable areas/bleed		
Varnish free areas		
Variable coding position Et dimensions		
Varnish and print requirements		
Pre-printed headers (alignment and suitability)		
Embossing, Braille Et Foil Blocking		
Separations on artwork		
Alignment within cutter		
Braille structure		
Verification Code Type; Pharma Code / 2D / OCV		
Bar sequence and/or number correct on artwork		
Bar sequence and/or number in correct position on artwork?		
Size (height, width, spacing, font)		
Direction of read		
Light margins and print free areas		
Colour		
Repeat distance (reeled material)		
Cross check related docs ie BOM		
Bar code Type; EAN, ITF, Code39, etc		
Magnification / width and height		
Colour (e.g. black print on white background)		
Light margins Et indicators		
Bearer bars Et H gauges (if required)		
Symbol grade (Pass = A,B,C; Action = D,F)		
Bar code number (human readable)		
Bar code number (encoded Et hidden data)		
Confirm bar code number from source		
Cross check related docs (JDE/PID)		
Photo-electric cell mark / edge marks		
Present Et per Tech drawing?		
Correct pitch?		
Additional markings		
e-mark, recycle logo etc		
Legend box (RB specification)		
Correct component code		
Correct D spec / has cutter changed?		
Correct printer / has printer changed?		
Correct Substrate		
A/W is set up appropriately for this substrate		
Edge mark details		
Pharmacode details		
Colours Et print process		
Varnish		
Barcode information		
General details are correct		
Pass / Fail comments and Signature		
By approving the artwork referenced within this form I authorise it for release to the print supplier		
Additional Comments		

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## RB Artwork and Print Specification

Trident Reference No: RB520240  
 ZEN Ref: **TR2492700**  
 Action: **B**  
 Brand: Lemsip  
 Category: Max  
 Segment Group: Cold & Flu  
 Segment: Day & Night Capsules  
 Pack Size: 8 16 Pack  
 Market/Country: UK  
 Date: 10/05/2022

RBH Contact: Rachel Beresfordward

### Artwork Type: BW Commercial

Component Code (2D if applicable): **3240611**  
 2<sup>nd</sup> Component Code (if applicable): **N/A**  
 Parent Technical Packaging Specification: D8047730  
 Finished Goods Code: **3138322**  
 Supply Point: RB Hull  
 3rd Party Code: N/A  
 Pharmacode No/NE: 000100 (67)  
 Edgemark Position: N/A

CAD Cam Ref: Lsp-LR-D8047730-160x300mm  
 Printer: Westrock MPS (Tewkesbury, UK)  
 Substrate: Paper White

Technical & Non Printing Items  
 Dieline Dieline 2 (if applicable)  
 Guides Guides 2 (if applicable)

Colours  
 Black



Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

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