FLAT DIMENSION = 130 x 430mm
FOLDED DIMENSION = 130 x 27mm

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Package leaflet: Information for the patient

Lemocalm® Cold and Flu Relief Powder for Oral Solution
(paracetamol 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 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. 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 three 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

Lemocalm® Cold and Flu Relief Powder for Oral Solution contains 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). 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

Do not take this medicine if:
- You are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)
- You have a serious heart condition
- You have pheochromocytoma, a rare tumour of the adrenal gland
- You have high blood pressure (hypertension) or an overactive thyroid
- You have diabetes, closed angle glaucoma
- You are taking beta-blockers (used to treat heart conditions)
- 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 are pregnant or breast feeding, unless your doctor tells you to.

Do not take anything else containing paracetamol while taking this medicine.
Do not take with any other flu, cold or decongestant product.

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you:
- Are suffering from liver problems including liver problems due to excessive alcohol consumption
- Have Gilbert's syndrome (mild jaundice)
- Are suffering from kidney problems
- Are suffering from dehydration and chronic malnutrition
- Suffer from asthma and are sensitive to aspirin
- Are taking any other paracetamol containing medicines
- Have a fever that does not improve after taking this medicine
- Have glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency)
- Have hemolytic anemia (abnormal breakdown of red blood cells)
- Have Raynaud's syndrome (poor blood circulation which makes the fingers or toes pale and numb) or diabetes mellitus
- 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)
- Have closed angle glaucoma or prostatic enlargement.
- You have non-cirrhotic liver disease (liver disease that is not associated with changes in the structure of the liver)
- You have phenylketonuria

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

Other medicines and Lemocalm® Cold and Flu Relief Powder for Oral Solution
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially the following:
- 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 (MAOIs; other sympathomimetic amines (ephedrine, pseudoephedrine); antihypertensives (ramipril, losartan, amlodipine); tricyclic antidepressants; digoxin and cardiac glycosides)
- Probenecid (Medicine used to treat high levels of uric acid in the blood stream (gout))
- Medicine to treat fever or mild pain (Aspirin, Salicylamide)
- Medicines used to treat epilepsy (phenytoin and carbamazepine), medicines used to treat sleeping problems (barbiturates such as pentobarbital, phenobarbital), as they may increase side effects on liver.
- Medicines to treat tuberculosis (Isoniazid), it may increase side effects of paracetamol.
- Tricyclic antidepressants (a specific class of drugs used to treat depression)
- Beta-blockers for high blood pressure, other antihypertensives or vasodilators (drugs used to treat high blood pressure, leg pain due to vascular problems or Raynaud's syndrome, including, ramipril, losartan, amlodipine).
- Other decongestants (used to treat cold and flu)
- Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide) prescribed for depression
- Oxytocin (medicine used to help contractions during childbirth) and ergot alkaloids (medicines used to treat migraine such as ergotamine, methylsergide), they may increase the risk of brain stroke (stroke caused by bleeding inside the brain).
- 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).

Pregnancy, breast-feeding and fertility
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. If necessary, this medicine can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.
Driving and using machines
This product does not have any effect on the ability to drive or use machines.
Effects of paracetamol on laboratory tests
Uric acid and blood sugar tests may be affected.

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Front

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Important information about the ingredients of this medicine
If you have phenylketonuria (an inherited genetic disorder) please note that this product contains aspartame, a source of phenylalanine. This medicine also contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Information on sodium content
The maximum recommended daily dose of this medicinal product contains 553.36 mg sodium (found in table salt). This is equivalent to 27.67% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need this medicine on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How to take this medicine

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

The recommended dose is:
Adults, the elderly and children aged 12 years and above:
Dissolve one sachet in a mug of hot, but not boiling water. Stir until dissolved. If preferred sweeten to taste with sugar, honey or your usual sweetener. It is important to drink plenty of fluids when suffering from colds and flu.
The dose may be repeated in 4-6 hours. Do not take more than four sachets in a total of 24 hours.
Do not give to children under 12 years, except on medical advice.
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, high blood pressure with headache, unhealthy pale appearance (pallor), feeling sick (nausea) or vomiting if you take too much of this medicine.
If you forget to take this medicine
Do not take a double dose to make up for a forgotten dose. If you forget a dose, take it as soon as you remember it and then take the next dose at least 4 hours later.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
You should stop taking this medicine and see your doctor immediately if you experience symptoms like:
- Serious skin disease causing rash, skin peeling and sores.
- Severe blistering and peeling of the skin.
- Accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction),
- Swelling on the face, mouth, hands (angioedema)
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen or aspirin.

Paracetamol:
Rare (may affect up to 1 in 1,000 people):
Oedema (abnormal accumulation of fluid under the skin), abnormal vision, simple skin rash or urticaria (dark red rash on the skin), haemorrhage (bleeding), abdominal pain, diarrhoea, nausea, vomiting, dizziness, fever, reduction of irritability or agitation (sedation), platelet disorders (clotting disorders), stem cell disorders (disorders of the blood forming cell in the bone marrow), abnormal liver function, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching), feeling lousy (malaise)**.**
Very rare (may affect up to 1 in 10,000 people):
Hepatotoxicity (damage caused to the liver), thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding or bruising), leucopenia (frequent infections due to poorly functioning white blood cells or decrease in white blood cells), neutropenia (reduced neutrophil count in blood), agranulocytosis (severe decrease in white blood cells which may lead to severe infections), hemolytic anemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), hypoglycemia (low levels of glucose in the blood), cloudy urine and kidney disorders.
Not known (frequency cannot be estimated from available data):
A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). Anaemia (decrease in red blood cells), problems with the way your kidneys work (kidney alteration), problems with the way your liver works (liver alteration), haematuria (blood in urine), anuresis (inability to urinate), gastro intestinal effects, vertigo. There have been cases of difficulty breathing, wheezing, coughing, and shortness of breath with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen.
Phenylephrine:
- Raised blood pressure, headache, dizziness, difficulty sleeping, nervousness, anxiety, diarrhoea or sickness.
- Visual disturbances. This is rare but is more likely in those with glaucoma. Unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat.
- Difficulty passing water. This is more likely to occur in men with an enlarged prostate gland.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- 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
- The active substances are 650 mg paracetamol and 10 mg phenylephrine hydrochloride.
- The other ingredients are Sucrose, Sodium citrate, Citric acid, Tartaric acid Pregelatinised maize starch, Lemon juice, Ascorbic acid, Aspartame (E951), Natural colour (E100), Lemon flavour.

What are the contents of the pack
- The medicine is available in packs containing 5 or 10 sachets.
  Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Name and address: Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire,
Hp4 1EG, United Kingdom
Telephone: 0044 (0)1442 200922
E-mail: info@bristol-labs.co.uk

Lemocalm® Cold and Flu Relief Powder for Oral Solution; PL 17907/0165

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