

PL & Product Name: 12063/0034 Max Strength Cold & Flu Relief Lemon Flavour Powder For Oral Solution

Reason for change: 2020 Q2 PIL Safety Update

MHRA Approved

Version: c

Date: 19/01/2021



Package Leaflet: Information for the user

Max Strength Cold & Flu Relief Lemon Flavour Powder For Oral Suspension(Paracetamol, Phenylephrine)

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 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

This medicine contains:

- **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- **phenylephrine** which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily

These sachets are used for the relief of the symptoms of colds and flu, including headache, aches and pains, sore throat, nasal congestion (blocked nose) and feverishness (high temperature).

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

X Do not use in children under 16 years of age.X Do not take this medicine if you:

- are **allergic** to paracetamol, phenylephrine or any of the other ingredients (listed in Section 6)
- have a serious heart condition
- have high blood pressure (hypertension)
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's) or have taken them within the last 14 days –these are medicines such as moclobemide, phenelzine and isocarboxazid
- you are taking other decongestants such as ephedrine or xylometazoline
- have an overactive thyroid gland
- have an enlarged prostate or prostate problems
- have pheochromocytoma (rare tumor of the adrenal gland tissue).

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Warnings and precautions

! Talk to your doctor or pharmacist before taking this medicine if you:

- are pregnant or breast-feeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- you have non-cirrhotic liver disease (liver disease that is not associated with changes in the structure of the liver)
- suffer with phenylketonuria, a rare, inherited metabolic disorder
- have diabetes mellitus
- have closed angle glaucoma.

Other medicines and this medicine

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

- antidepressant drugs called monoamine oxidase inhibitors (MAOI's) or have taken them within the last 14 days – these are medicines such as phenelzine and isocarboxazid
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as **colestyramine**.
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins – you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitone
- tricyclic antidepressants such as imipramine, amitriptyline
- medicines to lower blood pressure, treat heart or circulatory problems such as beta blockers (e.g. atenolol), vasodilators (e.g. hydralazine) or cardiac glycosides (e.g. digoxin)
- other decongestant drugs such as ephedrine or xylometazoline

! Contains paracetamol.

Do not take anything else containing paracetamol while taking this medicine.

This medicine with food and alcohol

Do not drink alcohol (beer, wine spirits etc) while taking this product.

Pregnancy, 'breast-feeding' and fertility

If you are pregnant or 'breast-feeding', think you may be pregnant or are planning to have baby, you should not take this product.

This product should not be used in women with a history of pre-eclampsia (high blood pressure during pregnancy which can lead to seizures).

Always ask your doctor or pharmacist for advice before taking this medicine.

This medicine contains sucrose, aspartame (E951) & sodium

Contains 1.9 g sucrose (sugar) per sachet. 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 medicine contains 25 mg 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.

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This medicine contains 118 mg of sodium (the main component of cooking/table salt) in each sachet. This is equivalent to 6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take this medicine

Pour the contents of 1 sachet into a standard mug. Fill the mug to below the brim with approximately 250ml (8 fluid oz) of hot, but not boiling, water. Stir until dissolved and allow to cool to a drinkable temperature.

Adults, the elderly and children 16 years and over: 1 sachet every 4 to 6 hours as required. Do not take more than 4 sachets (4 doses) in any 24 hour period. Leave at least 4 to 6 hours between doses.

Do not give to children under 16 years.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Do not take for longer than 3 days, unless your doctor agrees.

! 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. If you experience any of the following side effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist:

- Serious skin reactions
- Allergic reactions (such as skin rashes).

Other side effects:

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

- 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 vomiting, nausea or 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 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 use this medicine after the expiry date printed on the pack.

Do not store above 25°C.

6. Contents of the pack and other information

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What this medicine contains

The active ingredients are paracetamol and phenylephrine hydrochloride. Each 5 g sachet contains paracetamol 1000 mg and phenylephrine hydrochloride 12.2 mg.

The other ingredients are: sucrose, citric acid, natural lemon flavours, sodium citrate, ascorbic acid (Vitamin C), acesulfame potassium (E950), aspartame (E951) and quinoline yellow (E104).

What this medicine looks like and contents of the pack

Each 5 g sachet contains yellow powder.

This pack contains 5, 8 or 10 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation holder Wrafton Laboratories Limited Braunton Devon EX33 2DL

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Leaflet prepared April 2020

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA