

Package leaflet: Information for the patient

Panadol Max Strength Fever and Congestion Hot Lemon Powder for Oral Solution

Paracetamol 1000mg

Phenylephrine hydrochloride 10mg

Ascorbic Acid 40mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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.

WHAT IS IN THIS LEAFLET

1. What Panadol Max Strength Fever and Congestion Hot Lemon is and what it is used for
2. What you need to know before you take Panadol Max Strength Fever and Congestion Hot Lemon
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6. Contents of the pack and other information

1. WHAT PANADOL MAX STRENGTH FEVER AND CONGESTION HOT LEMON IS AND WHAT IT IS USED FOR

Each sachet contains Paracetamol 1000mg, Phenylephrine hydrochloride 10mg and Ascorbic Acid 40mg as the active ingredients.

Paracetamol is an analgesic (pain killer) and antipyretic (it reduces body temperature when you have a fever). It is provided at the maximum dose. Phenylephrine hydrochloride is a sympathomimetic decongestant, which unblocks your nose and sinuses helping you breathe more easily. Ascorbic acid is a common ingredient of 'flu and cold products. It is included to help replace the vitamin C which may be lost in the initial stages of 'flu and colds.

Panadol Max Strength Fever and Congestion Hot Lemon is a product for the short term relief of the symptoms of influenza ('flu), colds and chills. These symptoms include headache, shivers, aches and pains, congested or blocked nose, painful sinuses and sore throat pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PANADOL MAX STRENGTH FEVER AND CONGESTION HOT LEMON

CHECK BEFORE YOU TAKE THIS MEDICINE

Do not take Panadol Max Strength Fever and Congestion Hot Lemon:

- if you are allergic to paracetamol, ascorbic acid, phenylephrine hydrochloride or any of the other ingredients listed in section 6.
- if you have kidney or liver problems, over active thyroid, diabetes or are under the care of your doctor for high blood pressure or heart disease.
- if you have glaucoma
- if you have urinary retention
- if you are taking drugs or within the last two weeks have taken drugs prescribed by your doctor or hospital for depression (including monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants), or for heart problems (including betablockers, cardiac glycosides, digoxin).
- with any other medicines for the relief of 'flu, colds or congestion or with other paracetamol containing medicines.
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Warnings and precautions

Talk to your doctor or pharmacist before taking Panadol Max Strength Fever and Congestion Hot Lemon if:

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- you have any of the following conditions:
 - phaeochromocytoma
 - Gilbert's syndrome
 - prostatic hypertrophy
 - haemolytic anaemia
 - occlusive vascular disease
- you suffer from severe dehydration
- you are on a low sodium diet as this product contains sodium
- you are allergic to or have problems digesting sugar (sucrose)

During treatment with Panadol Max Strength Fever and Congestion Hot Lemon, 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).

Contact a doctor immediately if you get a combination of these symptoms -

Pregnancy and breastfeeding

As with all medicines you should ask your doctor before using Panadol Max Strength Fever and Congestion Hot Lemon if you are pregnant. You should only use the product at this time if your doctor thinks it is appropriate and necessary, at the lowest effective dose

If you are breastfeeding it is best to ask your doctor before taking Panadol Max Strength Fever and Congestion Hot Lemon. You should only use the product at this time if your doctor thinks it is appropriate and necessary.

Driving and using machines:

This product may cause dizziness. If affected do not drive and operate machinery.

Other medicines and Panadol Max Strength Fever and Congestions

Tell your doctor or pharmacist if you are taking or have recently used any of the following medicines:

- cholestyramine which is used to lower blood cholesterol
- digoxin to treat heart fibrillation or flutters
- ergot alkaloids to treat migraines
- blood thinners e.g warfarin
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

3. HOW TO TAKE PANADOL MAX STRENGTH FEVER AND CONGESTION HOT LEMON

Empty the contents of one sachet into a mug. Half fill with very hot water. Stir well. Add cold water as necessary and sugar if desired.

Adults (including the elderly) and children aged 16 years and over:

The contents of one sachet to be taken every four to six hours as necessary. Do not take more than four sachets in any 24 hours.

Do not give to children under 16 years of age unless your doctor tells you to.

Do not exceed the stated dose.

Contains Paracetamol.

Do not take with any other paracetamol containing products.
This product should be used only when clearly necessary.
Use the lowest amount needed for the shortest duration of treatment to relieve symptoms. If symptoms persist or get worse, consult your doctor.
Prolonged use without medical supervision may be harmful.

What should you do if you take too much?

IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE, BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
You may experience headache, dizziness, nervousness, increased blood pressure, nausea vomiting.

Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if:

- You experience allergic reactions such as skin rash, itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face
- You experience skin peeling, or mouth ulcers
- You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar experience with this product
- You experience unexpected bruising or bleeding
- You experience loss of vision which may be due to abnormally high blood pressure in the eye. This is very rare but is more likely to occur in those with glaucoma
- You experience an unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat
- You experience difficulty in passing water. This is more likely to occur in men with an enlarged prostate gland

A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). The frequency of this side effect is not known (cannot be estimated from the available data).

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 PANADOL MAX STRENGTH FEVER AND CONGESTION HOT LEMON

Do not store above 25°C

Do not use this medicine after the expiry date (EXP) shown on the outer carton and sachet. The expiry date refers to the last day of that month.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Panadol Max Strength Fever and Congestion Hot Lemon contain

Each sachet contains Paracetamol 1000mg, Phenylephrine hydrochloride 10mg and Ascorbic Acid 40mg as the active ingredients. Each sachet also contains sucrose, anhydrous citric acid, sodium

citrate, maize starch, sodium cyclamate, saccharine sodium, anhydrous colloidal silica, lemon flavor and natural curcumin. Sodium content 0.12g per dose. This should be taken into account if you have diabetes.

What is in the pack:

Each pack contains five sachets of powder to oral solution. Each sachet contains 6.4g powder.

Marketing Authorisation Holder and Manufacturer

The product authorisation holder is:

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland and all enquiries should be sent to this address.

They are manufactured by:

SmithKline Beecham S.A. Poligooono Industrial 42A 28806 Alcala De Henares, Madrid, Spain.

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<LOGO> Haleon

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland