

Perrigo Cold & Flu Tablets
Paracetamol 250 mg,
Guaifenesin 100 mg,
Phenylephrine hydrochloride 5 mg

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet as 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 symptoms persist for more than 3 days, get worse or other symptoms occur.

What is in this leaflet:

1. What Perrigo Cold & Flu Tablets is and what it is used for
2. What you need to know before you take Perrigo Cold & Flu Tablets
3. How to take Perrigo Cold & Flu Tablets
4. Possible side effects
5. How to store Perrigo Cold & Flu Tablets
6. Contents of the pack and other information

1. What Perrigo Cold & Flu Tablets is and what is it used for?

Perrigo Cold & Flu Tablets contains the following active substances:

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

These tablets are used for the relief of symptoms of colds and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty coughs.

This medicine can be used by adults, the elderly and adolescents aged 12 years and over.

You must talk to a doctor if symptoms persist for more than 3 days, get worse or other symptoms occur.

2. What you need to know before you take Perrigo Cold & Flu Tablets

Do not take Perrigo Cold & Flu Tablets if you:

- are **allergic** to paracetamol, guaifenesin, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI's) such as moclobemide, phenelzine, isocarboxazid and

- tranylcypromine, or have taken them within the last 14 days.
- have high blood pressure (hypertension)
 - have a serious heart condition or cardiovascular disorder(s)
 - have an overactive thyroid (hyperthyroidism).
 - have diabetes
 - have a rare adrenal gland tumour (phaeochromocytoma)
 - are taking tricyclic antidepressants such as imipramine or amitriptyline
 - are taking beta-blockers or other medicines used to treat high blood pressure.
 - have closed angle glaucoma (high pressure inside the eyes).
 - have liver problems
 - are pregnant
 - have porphyria, which is a type of blood disorder that causes skin or nervous system problems
 - are currently taking other decongestant drugs (e.g. ephedrine and xylometazoline) or stimulants (e.g. dexamfetamine).

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

Warnings and precautions

You should see your doctor if:

- you experience symptoms for more than 3 days.
- your symptoms get worse.
- you develop a high fever or other symptoms

Please see your doctor or pharmacist before taking Perrigo Cold & Flu Tablets if you:

- suffer from alcoholic liver disease or alcohol dependence
- have been told by your doctor you have an intolerance to some sugars
- if you have a circulatory disease such as a condition called Raynaud's Phenomenon,
- are taking medicine which affects liver function.
- have an enzyme deficiency or metabolic disorder (Glucose-6-phosphate dehydrogenase deficiency, glutathione deficiency or familial non-haemolytic jaundice).
- have a disorder which causes red blood cells to be destroyed faster than they are made (haemolytic anaemia)
- if you have Gilbert's Syndrome (familial non-haemolytic jaundice)
- if you are dehydrated
- if you have an enlarged prostate or have difficulty passing urine
- if you have asthma or chronic cough
- if you have heart or circulation disease
- suffer with phenylketonuria, a rare, inherited metabolic disorder.
- if you have frequent or daily headaches

Check with your doctor before use if you have liver or kidney problems, are underweight (<50 kg), are malnourished, or regularly drink alcohol as this may increase your risk of liver damage. You may need to reduce the amount of paracetamol that you take or avoid using this product altogether.

This product contains paracetamol. Do not use this product at the same time as taking other paracetamol-containing products

During treatment with Perrigo Cold & Flu Powder for Oral Solution, 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).

Children and adolescents

Do not give to children under 12 years of age.

Other medicines and this medicine

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

If you are taking any of the following medicines do not take this medicine (see 'Do not take this medicine'):

- Tricyclic antidepressants such as imipramine and amitriptyline.
- Monoamine oxidase inhibitors (MAOI's) such as moclobemide, phenelzine, isocarboxazid and tranylcypromine, used to treat depression.
- Medicines known as beta-blockers, such as metoprolol and atenolol.
- Other products containing sympathomimetic amines such as phenylephrine pseudoephedrine.
- Medicines used to lower blood pressure such as guanethidine, reserpine and methyl dopa.

If you are taking any of the following medicines, talk to your doctor before taking this medicine:

- Probenecid which is sometimes used to treat gout.
- 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.
- The antibiotic chloramphenicol.
- Medicines to treat heart problems, such as digoxin.
- Medicines to treat migraine such as ergotamine and methylsergide.
- Other cough medicines.
 - If you are taking Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
 - phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine)

Talk to your doctor before taking this medicine if you are going to have urine tests because taking this medicine may affect the results.

Other important information:

This medicine with alcohol

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

Pregnancy and breastfeeding

Pregnancy

Do not take this medicine if you are pregnant or think you may be pregnant. If you are planning to have a baby, talk to your doctor or pharmacist before taking this medicine.

Taking phenylephrine hydrochloride during pregnancy can cause deformities at birth.

This medicine should not be used in pregnancy.

Breastfeeding

This medicine should not be taken during breast-feeding without medical advice.

If you **are taking medication**, or **are under medical care**, consult your doctor before using this medicine. Do not take with other flu, cold or decongestant products or cough suppressants.

Long term use of this product is not recommended.

Driving and using machines

This product may cause dizziness. Do not drive or operate machinery if you feel dizzy after taking this medicine.

3. How to take Perrigo Cold & Flu Tablets

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

The recommended dose is:

Adults, the elderly and adolescents aged 12 years and over: Two tablets every 4-6 hours when necessary to a maximum of 4 doses in 24 hours. Do not exceed the stated dose. Do not take more than 8 capsules in any 24-hour period.

Perrigo Cold & Flu Tablets should not be used in adults, the elderly and adolescents aged 12 years and over, who weigh less than 50kg.

Do not take more than 4 capsules a day in the following situations, unless directed by your doctor:

- Chronic alcoholism
- Dehydration
- Malnutrition

Use in elderly patients and those with liver or kidney disease

Speak to your doctor or pharmacist before taking this medicine if you are elderly or have kidney or liver disease because you may need a lower or less frequent dose.

Children under 12 years:

Not to be used unless recommended by a doctor.

Directions for use:

- For oral use.
- Swallow the tablets whole with water. Do not chew.
- Dosage should not be continued for longer than 3 days without consulting a doctor.
- Do not exceed the stated dose

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

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Initial symptoms of overdose may include pale skin, nausea, vomiting and abdominal pain. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

If you forget to take this medicine and what to do

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Most people do not have any side effects while taking this medicine. However, 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 which may be severe such as skin rash, peeling of the skin, itching, swollen red areas of the skin, sometimes with shortness of breath or swelling of the mouth, lips, tongue, throat or face.
- Changes in your blood which may make you more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers
- Problems or pain passing urine
- Increased pressure inside the eye (acute angle glaucoma)
- Dilated pupils
- Breathing problems, which are more likely if you have experienced them before when taking other painkillers such as acetylsalicylic acid or ibuprofen.
- Raised blood pressure
- A faster, slower or irregular resting heartbeat
- Liver problems

The above side effects are rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people). The frequency of pain and problems passing

urine is unknown.

Other side effects for this medicine are presented below according to how frequently they are reported to occur.

The frequency of the following side effects is unknown:

- Difficulty sleeping (insomnia)
- Nervousness
- Headache
- Dizziness
- Tingling or cool skin
- 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 the following side effects is rare (may affect up to 1 in 1,000 people):

- Stomach pain or discomfort
- Diarrhoea (upset stomach)
- Nausea (feeling sick)
- Vomiting (being sick)

The frequency of the following side effects is very rare (may affect up to 1 in 10,000 people):

- Cloudy urine (due to increased white blood cells in urine)

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. Website: www.hpra.ie; By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Perrigo Cold & Flu Tablets

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 foil. The expiry date refers to the last day of the month.

Do not store above 25°C.

6. Contents of the pack and other information

Each white, capsule-shaped tablet contains the active ingredients: paracetamol 250 mg, guaifenesin 100 mg and phenylephrine hydrochloride 5 mg.

The other ingredients are: microcrystalline cellulose, stearic acid, povidone, hypromellose and polyethylene glycol.

This product is available in pack sizes of 8, 10, 12, 16, 20 or 24 tablets, although not all pack sizes may be marketed.

Marketing Authorisation Holder

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

Manufacturer(s)

Omega Pharma International NV
Venecoweg 26
Nazareth, 9810
Belgium

Perrigo Supply Chain International DAC,
The Sharp Building,
10-12 Hogan Place,
Dublin 2,
Ireland

Perrigo is a registered trademark.

Text revised: January 2025

PA 1186/021/001