

Package Leaflet: Information for the user

Perrigo Cold & Flu Powder for Oral Solution
Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine 10 mg

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

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1. What is Perrigo Cold & Flu Powder for Oral Solution and what it is used for

Perrigo Cold & Flu Powder for Oral Solution contains the following active substances:

- Paracetamol which is a pain reliever (analgesic) effective against aches and pains including headache and sore throat, and also helps reduce your temperature when you have a fever (antipyretic).
- Guaifenesin which is an expectorant to help loosen mucus (phlegm) when you have a chesty cough.
- Phenylephrine hydrochloride which is a decongestant used to reduce swelling in the passages of the nose to help you breathe more easily.

Perrigo Cold & Flu Powder for Oral Solution is used for the short-term relief of the symptoms of colds and flu, including aches and pains, such as headache and sore throat, nasal congestion, chills and feverishness (high temperature). Loosens stubborn mucus (phlegm) and provides relief from chesty coughs, in adults and adolescents aged 12 years and over.

This medicine should only be used if you have all of the following symptoms – pain and/or fever, a blocked nose and a chesty cough.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Perrigo Cold & Flu Powder for Oral Solution

Do not take Perrigo Cold & Flu Powder for Oral Solution if you:

- are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- have liver or severe kidney disease
- have a heart condition or cardiovascular disorder(s) or blood problems such as anaemia (low red blood cell count).
- have high blood pressure (hypertension).
- have an overactive thyroid (hyperthyroidism).
- have diabetes.
- have pheochromocytoma (a rare tumour of adrenal gland tissue).
- are taking tricyclic antidepressants such as imipramine or amitriptyline.
- are taking beta blockers (e.g. atenolol) or vasodilators (e.g. hydralazine), used to treat high blood pressure (hypertension).
- are taking other paracetamol-containing products.
- 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, isocarboxazid and tranylcypromine.
- have closed angle glaucoma (high pressure inside the eyes).
- have difficulty passing urine, an enlarged prostate or other prostate problems.
- are currently taking other decongestant drugs (e.g. ephedrine and xylometazoline) or stimulants (e.g. dexamfetamine).
- Are pregnant

Warnings and precautions

If you take a painkiller for headaches for more than 3 days, it can make them worse.

Talk to your doctor or pharmacist before taking Perrigo Cold & Flu Powder for Oral Solution if you:

- have a very bad cough or asthma,
- have asthma and are sensitive to acetylsalicylic acid
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes.
- have angina or other cardiovascular disease(s).
- have an autoimmune disorder called myasthenia gravis where muscles become easily tired and weak.
- have an enlarged prostate gland, as this may cause more difficulty in passing urine.
- have severe stomach or intestinal problems.
- have liver or kidney disease.
- are taking a cough suppressant.
- have difficulties in sleeping (insomnia), nervousness, increased body temperature, tremors and/or convulsions.
- have an intolerance to some sugars.
- suffer with phenylketonuria, a rare, inherited metabolic disorder.
- have chronic alcoholism, malnutrition or dehydration

- have Gilbert's Syndrome (familial non-haemolytic jaundice)
- are elderly, adult or adolescent weighing less than 50kg
- If you are taking medicines that affect your liver

Check with your doctor before use if you have liver or kidney problems, are underweight (<50kg), become 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.

You should see your doctor if:

- you develop a high fever, rash or persistent headache.
- you develop signs of other infection such as feeling unwell, night sweats, tiredness, pain, or swelling;
- your symptoms do not get better after three days.

Children and adolescents

Do not give this medicine to children under 12 years of age.

Other medicines and Perrigo Cold & Flu Powder for Oral Solution

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, please see your doctor before taking Perrigo Cold & Flu Powder for Oral Solution:

- If you are taking probenecid speak to your doctor as the dose of Perrigo Cold & Flu Powder for Oral Solution may need to be reduced.
- 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 phenobarbitones.
- Tricyclic antidepressants such as imipramine, amitriptyline.
- Monoamine oxidase inhibitors (MAOI's) such as moclobemide, phenelzine, isocarboxazid and tranylcypromine, used to treat depression.
- Medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyl dopa).
- Aspirin or other NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).
- Chloramphenicol (antibiotic)
- Medicines to treat migraine (e.g. ergotamine and methylsergide).
- Zidovudine as this might cause blood problems (low white blood cell count).
- Phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine).
- Other flu, cold or decongestant products containing sympathomimetic amines.
- If you are going to have blood or urine tests as taking this medicine may affect the results.
- If you are going to have a general anaesthetic, as this may cause changes in heart rhythm.

- If you are taking 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.

Perrigo Cold & Flu Powder for Oral Solution with alcohol

Do not drink alcohol when using this medicine.

Pregnancy and breast-feeding

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.

Based on human experience, phenylephrine hydrochloride causes congenital malformation when administered during pregnancy.

Breastfeeding

This product should not be used during breast-feeding without medical advice.

Driving and using machines

This product could cause dizziness. If you are affected do not drive or operate machinery.

Perrigo Cold & Flu Powder for Oral Solution contains sucrose

Contains 2.1 g of 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 should be taken into account in patients with diabetes.

Perrigo Cold & Flu Powder for Oral Solution contains aspartame (E951)

This medicine contains 12 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.

Perrigo Cold & Flu Powder for Oral Solution contains sodium

This medicine contains 129 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Perrigo Cold & Flu Powder for Oral Solution

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.

For oral use.

Adults, the elderly and adolescents 12 years and over

The recommended dose is 1 sachet every 4 to 6 hours, as required. Do not take more than 4 sachets (4 doses) in any 24-hour period. Do not take more frequently than every 4

hours.

Use in children and adolescents

Do not give to children under 12 years.

Pour the contents of 1 sachet into a standard mug. Fill the mug to below the brim with approximately 250 ml (8 fluid oz) of hot, but not boiling, water. Stir until dissolved, and allow to cool to a drinkable temperature. Drink all the yellow solution within 1½ hours.

Do not exceed the stated dose. If your symptoms persist for more than 3 days or worsen, you must see a doctor or pharmacist.

If you take more Perrigo Cold & Flu Powder for Oral Solution than you should

Immediate medical advice should be sought in the event of overdose, because of the risk of irreversible liver damage. 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.

Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

If you forget to take Perrigo Cold & Flu Powder for Oral Solution

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

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

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.

The following adverse events may represent the most commonly occurring adverse events, though actual frequencies are not available:

- Difficulty sleeping (insomnia),
- diarrhoea, nausea (feeling sick),
- nervousness, tremors, irritability, restlessness or excitability,
- a rise in blood pressure with headache, dizziness, vomiting (being sick) and irregular heart beat (palpitations).

The frequency of the events below is very rare:

- cloudy urine

The frequency of the events below is unknown but considered likely to be rare:

- 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.

- Breathing problems, these are more likely if you have experienced them before when taking other painkillers such as aspirin or ibuprofen.
- Stomach upsets (pain or discomfort), nausea, vomiting, diarrhoea,
- tingling or coolness of the skin,
- liver problems,
- a faster or irregular heartbeat,
- an acute increase of the pressure inside the eye, enlarged eye pupil.
- Problems or pain passing water.

The frequency of the events below is unknown but considered likely to be very rare:

- You may become more prone to bleeding, bruising, fever and infections, such as sore throat and ulcers, due to changes in your blood.

Very rare cases of serious skin reactions have been reported.

If you have previously experienced an allergic reaction (hypersensitivity) when taking decongestants, appetite suppressant and stimulants, you may be at increased risk of developing an allergic reaction when taking this product.

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 HPRC 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 Powder for Oral Solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and sachet. The expiry date refers to the last day of the month.

Do not store above 25°C.

After reconstitution with hot water the solution is stable for 1½ hours.

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 Perrigo Cold & Flu Powder for Oral Solution contains

Each sachet contains the active ingredients: Paracetamol (500 mg), Guaifenesin (200 mg) and Phenylephrine hydrochloride (10 mg).

The other ingredients are: sucrose, citric acid (E330), tartaric acid (E334), sodium cyclamate (E952), sodium citrate (E331), acesulfame potassium (E950), aspartame (E951), powdered menthol flavour [contains natural menthol, corn maltodextrin and arabic gum (E414)], lemon flavour [contains flavouring preparation, natural flavouring substance, corn maltodextrin, arabic gum E414, sodium citrate E331, citric acid E330 and butylated hydroxyanisole E320 (0.01%)], lemon juice flavour [contains flavouring preparation, natural flavouring substance(s), maltodextrin, modified starch E1450 and butylated hydroxyanisole E320 (0.03%)], quinoline yellow (E104).

What Perrigo Cold & Flu Powder for Oral Solution looks like and contents of the pack

Perrigo Cold & Flu Powder for Oral Solution is a powder for oral solution, with an off-white colour and a characteristic citrus/menthol odour, in sachets.

The reconstituted solution is opalescent yellow with a characteristic citrus/menthol odour.

Perrigo Cold & Flu Powder for Oral Solution is available in pack sizes of 5, 6, 10, 14, 15 or 20 sachets although not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Manufacturers:

Omega Pharma International NV
Venecoweg 26
Nazareth, 9810
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Marketing Authorisation Holder:

Chefaro Ireland DAC,
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