

Package leaflet: Information for the User

Panadol Cold & Flu Relief Orange Effervescent Tablets Paracetamol 500mg Caffeine 65mg

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Panadol Cold & Flu Relief Orange tablets carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice.
 - You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Panadol Cold & Flu Relief Orange tablets do

Panadol Cold & Flu Relief Orange provides effective relief from the common symptoms of cold and flu. These symptoms include sore throat, fever, drowsiness, headache and muscular aches and pains.

The tablets contain two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

2. Check before you take Panadol Cold & Flu Relief Orange tablets

Do not take Panadol Cold & Flu Relief Orange tablets:

- **If you have ever had an allergic reaction** to paracetamol, caffeine or to any of the other ingredients (listed in Section 6).
- If you are **taking other medicines containing paracetamol.**
- If you are **under 12 years.**

Ask your doctor before you take this medicine:

- If you have **liver or kidney disease**, including **alcoholic liver disease**, are **underweight (<50kg)** or **malnourished** or **regularly drink alcohol.**
- have severe dehydration
- if you are taking medicines that affect your liver.

During treatment with Panadol Cold & Flu Relief Orange tablets, 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. You may need to **avoid** using this product altogether or **limit the amount** of paracetamol that you take (see section 3).

If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly

- **metoclopramide** (for **nausea** [feeling sick] or **vomiting** [being sick])
- **chloramphenicol** (used to treat infections)
- **cholestyramine** (for **high cholesterol**)
- **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2). If you take **blood thinning drugs** (**anticoagulants** e.g. **warfarin**) and you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding. But you can still take **occasional** doses of Panadol Cold & Flu Relief Orange tablets at the same time as anticoagulants.

This product is not recommended if you are taking lithium.

Taking Panadol Cold & Flu Relief Orange with food and drink:

- Panadol Cold & Flu Relief Orange contains 65mg of caffeine per tablet, therefore avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.

Pregnancy and breastfeeding

Not recommended for use during pregnancy or breastfeeding.

Important information about some of the ingredients of Panadol Cold & Flu Relief Orange tablets

Talk to your doctor or pharmacist if you need 1 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Contains a source of phenylalanine. May be harmful for people with phenylketonuria.

Contains sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to take Panadol Cold & Flu Relief Orange tablets

Panadol Cold & Flu Relief Orange tablets should be dissolved in at least half a tumbler of water immediately before use.

Adults, elderly and children aged 16 years and over:

Take 2 tablets, up to 4 times daily as required. Do not take more than 8 tablets in 24 hours.

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

- weight less than 50kg
- chronic alcoholism
- dehydration
- chronic malnutrition

Children aged 12-15 years:

Take 1 tablet, up to 4 times daily as required. Do not take more than 4 tablets in 24 hours.

Not recommended for children under 12 years of age

- **Do not take more frequently than every 4 hours.**
- **Always use the lowest effective dose to relieve your symptoms.**
- **Do not exceed the stated dose.**
- **This product should be used only when clearly necessary.**
- **If you have a high fever, or if symptoms get worse or persist for longer than 3 days, consult your doctor.**
- **Prolonged use except under medical supervision may be harmful.**
- **If your symptoms continue or your headache becomes persistent, see your doctor.**

If you take too many tablets:

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.

4. Possible side effects

Like all medicines, Panadol Cold & Flu Relief Orange tablets can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor immediately if:

Very Rare (affects less than 1 in 10,000 people)

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- You experience a skin rash or peeling, or mouth ulcers.
- You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatory and experience a similar reaction with this product.
- You experience unexpected bruising or bleeding.
- You experience changes in blood tests that measure the function of your liver.

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

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Other side effects include: insomnia, restlessness, anxiety, irritability, headaches, upset stomach, palpitations, nervousness and dizziness.

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 HPRAs 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 Panadol Cold & Flu Relief Orange tablets**Keep out of the sight and reach of children.**

Do not store above 30°C. Store in the original packaging to protect from moisture.

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

Store in original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Panadol Cold & Flu Relief Orange Effervescent Tablets are round, flat, off-white to yellow tablets with speckles and a break line mark on one side. The score line is not for dividing into equal doses.

Active ingredient Each tablet contains Paracetamol 500mg and Caffeine 65mg.

Other ingredients Sodium hydrogen carbonate, sorbitol (E420), ascorbic acid, sodium laurilsulfate, anhydrous citric acid, anhydrous sodium carbonate, povidone, dimethicone, acesulfame potassium (E950), orange flavour (contains sodium and sulphites), aspartame (E951), carmine (E120) and riboflavin sodium phosphate(E101a).

Packs of Panadol Cold & Flu Relief Orange Effervescent Tablets contain 12, 16 or 24 tablets. Not all pack sizes may be marketed.

The Product Authorisation holder is

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

The manufacturer is Hermes Arzneimittel GmbH, Hans - Urmiller - Ring 52, 82515 Wolfratshausen, Germany.

This leaflet was last revised in May 2025.

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