

Patient information leaflet

Panadol COLD & FLU Relief 500mg/65mg Film-coated tablets Paracetamol & Caffeine

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 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.

In this leaflet:

1. What Panadol Cold & Flu Relief tablets do
2. Check before you take Panadol Cold & Flu Relief tablets
3. How to take Panadol Cold & Flu Relief tablets
4. Possible side effects
5. How to store Panadol Cold & Flu Relief tablets
6. Further information

1. What Panadol Cold & Flu Relief tablets do

Panadol Cold & Flu Relief tablets relieve discomfort in colds, flu and sore throat and help reduce temperature.

They are also used for the relief of headache, backache, rheumatic pain, muscle pain, neuralgia, toothache and period pain.

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 tablets**

Do not take Panadol Cold & Flu Relief 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 any other medicines containing paracetamol.
- If you are under 12 years.

Check with your doctor before use if you:

- have liver or kidney problems, including alcoholic liver disease
- are underweight (<50Kg) or malnourished
- regularly drink alcohol
- suffer from severe dehydration
- are taking medicines that affect your liver

**During treatment with Panadol Cold & Flu Relief tablets, tell your doctor straight away** if you have severe infection or 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 or domperidone (for nausea [feeling sick] or vomiting [being sick])
- cholestyramine (for high cholesterol)
- 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 tablets at the same time as anticoagulants.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

This product is not recommended if you are taking lithium.

### **Pregnancy and breastfeeding**

Not recommended during pregnancy or breastfeeding, unless recommended by your doctor.

### **3. How to take Panadol Cold & Flu Relief tablets**

#### **Adults, elderly and children aged 16 years and over:**

Swallow 2 tablets with water up to 4 times daily as needed.

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 12 - 15 years:**

Swallow 1 tablet with water up to 4 times daily as needed.

Do not take more than 4 tablets in 24 hours.

Not recommended for children under 12 years of age.

- Contains paracetamol
- Do not take more frequently than every 4 hours.
- Do not take more than the recommended dose.
- 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.
- 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.
- Always use the lowest effective dose to relieve your symptoms.

**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.

If your symptoms continue or your headache becomes persistent, see your doctor.

**4. Possible side effects**

Like all medicines, Panadol Cold & Flu Relief tablets can cause side effects, although not everybody gets them. Very rare cases of serious skin reactions have been reported.

**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-inflammatories 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) has also been reported.

**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 HPRA pharmacovigilance, website: [www.hpra.ie](http://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 tablets**

Keep out of the sight and reach of children.

Store below 25°C.

Store in the original container to protect from light. Do not use this medicine after the expiry date (EXP) shown on the carton and blisters. 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 tablets are white, capsule shaped, film-coated tablets with flat edges with a triangular logo and a '+' symbol debossed on one side and blank on the other side.

**Active ingredients:** Each tablet contains Paracetamol 500mg and Caffeine 65mg.

**Other ingredients:** Starch pregelatinised, maize starch, povidone, potassium sorbate (E202), purified talc, stearic acid, croscarmellose sodium.

The film coat contains hypromellose and triacetin.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Packs of Panadol Cold & Flu Relief tablets contain 4, 6, 12, 24, 30, 48, 60 and 96 tablets in blister strips. 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** Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, X35 RY76, Ireland.

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