Patient Information Leaflet Text

Package leaflet: Information for the user Panadol Original 500mg Film-coated tablets paracetamol 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 Original tablets carefully to get the best results from them.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not included in section 4 of this leaflet.

- If you have any further questions, ask your pharmacist.
- Keep this leaflet, you may need to read it again.

What is in this leaflet:

- 1. What Panadol Original tablets are and what they are used for
- 2. Check before you take Panadol Original tablets
- 3. How to take Panadol Original tablets
- 4. Possible side effects
- 5. How to store and dispose of Panadol Original tablets
- 6. Contents of the pack and other information

1. What Panadol Original tablets are and what they are used for

Panadol Original tablets contains the active substance paracetamol which is a painkiller and also reduces your temperature when you have a fever.

Panadol Original tablets are used for fast and effective relief of headaches, toothache, backache, rheumatic and muscle pains and period pain. It also relieves sore throat and the feverishness, aches and pains of colds and flu. Panadol Original tablets also provide relief from the pain associated with osteoarthritis as diagnosed by a doctor.

2. Check before you take Panadol Original tablets

Contains paracetamol. Do not take with any other paracetamol containing products. Do not take Panadol Original tablets:

• if you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in Section 6).

• if you are **under 10 years.**

Check with your doctor before use if you:

- have liver or kidney problems, including alcoholic liver disease
- are underweight or malnourished
- regularly drink alcohol

During treatment with Panadol Original tablets, tell your doctor straight away if:

• 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 or limit the amount of paracetamol that you take.

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]),

- colestyramine (to lower blood 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. However, you can still take **occasional** doses of Panadol Original tablets at the same time as anticoagulants.

Pregnancy and breastfeeding

If necessary, Panadol Original tablets can be used during **pregnancy**. You should use the lowest effective dose for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced. You can take this product whilst **breastfeeding**.

3. How to take Panadol Original tablets

Panadol Original is for oral administration.

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

Take 1-2 tablets every 4 to 6 hours as required.

Children aged 10-15 years:

Give one tablet every 4 to 6 hours as required. Do not give to children for more than 3 days without consulting a doctor.

Children under 10 years:

Do not give to children under 10 years.

- Contains paracetamol.
- Do not take more frequently than every 4 hours.
- Do not take more than 4 doses in 24 hours.
- Do not take more than the recommended dose.
- If symptoms persist consult your doctor.
- Prolonged use except under medical supervision may be harmful.
- 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, because of the risk of irreversible liver damage.

4. Possible side effects

Like all medicines, Panadol Original Tablets can have side effects but not everybody gets them. Stop taking the medicine and tell your doctor immediately if you experience:

Very rare: may affect up to 1 in 10,000 people

• Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath

• Skin rash or peeling, or mouth ulcers

- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

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).

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 and dispose of Panadol Original tablets

Keep this medicine out of the sight and reach of children. Do not store above 25°C.

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

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

The active substance is paracetamol. Each tablet contains 500 mg paracetamol.

The other ingredients are: starch, pregelatinised, povidone, maize starch, potassium sorbate (E 202), talc, stearic acid, hypromellose, triacetin, and carnauba wax.

Panadol Original Tablets are white film-coated capsule shaped tablets with flat edges, with a triangular logo debossed on one side and a break line on one side. Panadol Original tablets are produced in packs of 12, 24, 48 96, or 100 tablets. Not all pack sizes may be marketed.

The Product Authorisation holder is Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland, and all enquiries should be sent to this address.

The manufacturer is GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Ireland.

This leaflet was last revised in April 2025.

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