

PATIENT INFORMATION LEAFLET

PANADOL 500 mg Film Coated Tablets

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 tablets carefully to get the best results from them.

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

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

2. Check before you take Panadol tablets

3. How to take Panadol tablets

4. Possible side effects

5. How to store and dispose of Panadol tablets

6. Further information

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

Panadol 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 tablets also help relieve the pain of osteoarthritis (which has been diagnosed by a doctor).

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

2. Check before you take Panadol tablets

Do not take Panadol 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 taking any other medicines containing paracetamol.
- if you are under 10 years. Check with your doctor before use if you:
- have liver or kidney problems
- are underweight or malnourished
- regularly drink alcohol

During treatment with Panadol 500 mg Film Coated 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.

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),
- blood thinning drugs (anticoagulants e.g. warfarin),
- if 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 tablets at the same time as anticoagulants.
- 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).

Pregnancy and breastfeeding

If necessary, Panadol tablets can be used during pregnancy. You should use the lowest possible 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 Tablets

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 1 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 of age.

- Contains paracetamol.
- Do not take more than the recommended dose.
- Do not take more frequently than every 4 hours.
- Do not take more than 4 doses in 24 hours.

- 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, even if you feel well, because of the risk of delayed, serious liver damage.

4. Possible side effects

Like all medicines Panadol tablets can have side effects, but not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if:

- you experience serious skin reactions, very rare cases of which have been reported.
- 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 severe skin rash or peeling of the skin which may be accompanied by mouth ulcers.
- you may have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction to this product.
- you experience unexplained bruising or bleeding.

These reactions are very rare (may affect up to 1 in 10,000 people).

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 this side effect is not known (cannot be estimated from the available data).

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 tablets

Keep out of the sight and reach of children. Store below 30°C. Do not use this medicine after the expiry date (EXP) which is stated on the outer carton and the blisters. The expiry date refers to the last day of that month. 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 tablets contains the Optizorb™ formulation:

Active ingredient Each tablet contains Paracetamol 500mg.

Other ingredients Pregelatinised starch, calcium carbonate, alginic acid, crospovidone, povidone (K-25), magnesium stearate, colloidal anhydrous silica, opadry white (YS-1-7003), which contains titanium dioxide, hypromellose, macrogol, polysorbate 80 and carnauba wax.

Panadol tablets are white, capsule shaped, film-coated tablets with a “P” within a circle on one face and a ‘-’ on both sides of the breakline on the other. The tablet can be divided into two equal halves.

Panadol tablets are produced in packs of 6, 12, 24, 48 or 96 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 Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, X35 RY76, Ireland.

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