

Package leaflet: Information for the user

Panadol[®] 500 mg 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 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 Contents of the pack and other 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 6 years**.

Check with your doctor before use if you:

- * have liver or kidney problems
- * are underweight or malnourished
- * regularly drink alcohol
- * have a **severe infection** as this may increase the risk of **metabolic acidosis**.
Signs of metabolic acidosis include:
 - deep rapid, difficult breathing

- feeling sick (nausea), being sick (vomiting)
- loss of appetite

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**). 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 tablets at the same time as anticoagulants.

Pregnancy and breastfeeding

Talk to your doctor before taking Panadol tablets if you are **pregnant**. You can take this product whilst **breastfeeding**.

Important information about some of the ingredients

- * Contains parahydroxybenzoates which may cause allergic reaction (possibly delayed).

3 How to take Panadol tablets

Adults, including the elderly, and children aged 12 years and over:

Swallow 2 tablets with water 3 to 4 times a day as needed.
Do not take more frequently than every 4 hours.

Do not take more than 8 tablets in 24 hours.

Children aged 6-12 years:

Give 1/2 to 1 tablet to swallow 3-4 times daily as required.
Do not give more frequently than every 4 hours.
Do not give more than 4 tablets in 24 hours.

Not recommended for children under 6 years.

- * **Contains paracetamol.**
- * **Do not take for more than three days without consulting your doctor.**
- * **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.**

Package leaflet: Information for the user (continued)

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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 rare.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

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

What Panadol contains

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

The other ingredients are pregelatinised starch, calcium carbonate, alginic acid, crospovidone type A, povidone 25, magnesium stearate, colloidal anhydrous silica, parahydroxybenzoates (sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) and sodium methyl parahydroxybenzoate (E219)), carnauba wax, opadry white YS-1-7003 (titanium dioxide, hypromellose, macrogol and polysorbate 80).

What Panadol looks like and contents of the pack

Panadol are a white capsule shaped film coated tablet with convex edges and debossed with a "p" within a circle on one face and a break line on the other. The tablet can be divided into equal doses. Panadol tablets are produced in packs of 24 tablets.

Product procured from within the EU, repackaged and distributed by the **Parallel Product Authorisation Holder:** Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Manufactured by:

GlaxoSmithKline Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Ireland
or
SmithKline Beecham S.A., Ctra. de Ajalvir, Km. 2,500, Alcalá de Henares, Madrid, Spain

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Is this leaflet hard to see or read?

Phone Lexon (UK) Limited, Tel: +44 (0) 1527 505414 for help.