

Panadol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. This medicine is available without prescription, but you still need to use Panadol 500 mg capsules carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If pain lasts for longer than 5 days or fever lasts for longer than 3 days or if these symptoms become worse a doctor must be consulted.

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1. What Panadol 500 mg capsules are and what it is used for

What are Panadol 500 mg capsules?

Panadol 500 mg capsules belong to a group of medicines named analgesics (painkillers).

What are Panadol 500 mg capsules used for?

Panadol 500 mg capsules are used for symptomatic treatment of mild to moderate pain and/or fever.

Panadol 500 mg capsules can be used for headache including migraine and tension

headaches, toothache rheumatic

pain, back pain, muscle pain,

period pain, sore throat, fever,

aches and pains of colds and flu,

pain due to mild arthritis.

2. Check before you take Panadol 500 mg capsules

X Do not take Panadol 500 mg capsules:

- if you have ever had an **allergic reaction** to paracetamol or to any of the other ingredients of this medicine (listed in section 6);

- if you are already **taking other medicines containing paracetamol** to treat pain, fever, symptoms of cold and flu, or to aid sleep.

! Ask your doctor before you take this medicine:

- if you suffer from **mild arthritis** and need to take painkillers every day

- if you have **liver** or **kidney** problems

- if you are **underweight** or **malnourished**

- if you regularly drink alcohol

- if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), suffer from malnutrition, chronic alcoholism or if you are taking flucloxacillin (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 is taken together with flucloxacillin. Symptoms may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

500 mg Capsules

Paracetamol

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. Long-term or frequent use is not advised. Do not exceed the recommended dose. You should use the lowest possible dose and use it for the shortest time possible.

Long-term use of every analgesic to treat headache can worsen the headache. If this occurs, stop taking this product and consult your doctor.

! If you are taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also applies to medicines which you are able to obtain on prescription.

Contact your doctor or pharmacist before you take paracetamol, if you are taking any of the following medicines: **metoclopramide** or **domperidone** (for **nausea** or **vomiting**) or **cholestyramine** (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. But you can still take occasional doses of Panadol 500 mg capsules at the same time as anticoagulants. If you take flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

! Panadol 500 mg capsules with food, drink and alcohol

You can eat and drink normally while taking paracetamol. **Do not drink alcohol** whilst taking

Panadol 500 mg capsules. With chronic alcohol abuse, the dose of paracetamol may not be higher than 2 grams (4 capsules) a day.

! Pregnancy and breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Panadol 500 mg capsules can be used during pregnancy if necessary. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often.

Breast-feeding

Although paracetamol is excreted in small quantities in the maternal milk, it does not have any adverse effect on children who are breastfed. Paracetamol can be used in the recommended dose for a short time by women who breastfeed.

! Driving and using machines

As far as is known, paracetamol does not have any effect on the ability to drive or use machines.

! Panadol 500 mg capsules contain sorbitol

This medicine contains 108 mg sorbitol liquid in each soft capsule. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

! Panadol 500 mg capsules contain propylene glycol

This medicine contains 20 mg propylene glycol in each soft capsule.

3. How to take Panadol 500 mg capsules

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- ✓ Adults and children aged 16 years and older:**
Take 1 to 2 capsules (500 - 1000 mg) at a time, if necessary, repeat every 4 to 6 hours, with a maximum of 8 capsules (4000 mg) every 24 hours.

Children from 10 to 15 years:

- Take 1 capsule (500 mg) at a time, if necessary, repeat every 4 to 6 hours, with a maximum of 4 capsules (2000 mg) every 24 hours.**

The dose of paracetamol for children should be based on the age.

A suitable dosage form has to be used as well.

Do not give for more than 3 days at a time unless your doctor tells you to.

Do not give to children under 10 years.

Method of administration

The capsules should be swallowed whole with a glass of water.

You should take the lowest possible dose and take it for the shortest time possible.

- !**
- Do not take more frequently than every 4 hours.**
 - Do not exceed the recommended dose. This could lead to damage to the liver (see section 4).**
 - Do not use in combination with other paracetamol-containing products.**
 - If the symptoms of pain and/or fever recur, administration can be repeated on the basis of the stated dosage regimen.**
 - If pain lasts for longer than 5 days or fever lasts for longer than 3 days or these symptoms become worse a doctor must be consulted.**

If you take too many tablets

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If your symptoms continue or your headache becomes persistent, talk to your doctor.

If you forget to take Panadol 500 mg capsules

Do not take a double dose to make up for a forgotten dose. Continue your regular dosing schedule.

If you stop taking Panadol 500 mg capsules

If you suddenly stop taking Panadol 500 mg capsules, nothing in particular will occur.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

Stop taking the medicine and tell your doctor immediately if you experience:

- 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.**

- **Metabolic acidosis** (serious condition that can make blood more acidic, see Section 2).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Panadol 500 mg capsules

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 packaging 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 500 mg capsules contain

The active substance is paracetamol. One capsule contains 500 mg paracetamol.

The other ingredients are macrogol 400, purified water, propylene glycol and silica (colloidal anhydrous).

Capsule shell: Gelatin, sorbitol (liquid, partially dehydrated), purified water, titanium dioxide (E171).

What Panadol 500 mg capsules look like and contents of the pack

Panadol 500 mg capsules are white, oval shape soft gelatin capsules.

Panadol 500 mg capsules are supplied in a PVDC/PVC-Alu/PET blister in a carton box. Each pack contains 8, 10, 12 or 16 capsules.

Not all pack sizes may be marketed.

The marketing authorisation holder is Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K. and all enquiries should be sent to this address.

The manufacturer is Haleon UK Trading Limited, The Heights, Weybridge, KT13 0NY, U.K

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