# Package leaflet: Information for the user

Paracetamol 500mg Tablets paracetamol

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

This medicine is available without prescription. Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any passible side effects not listed in this leaflet. See section 4
- includes any possible side effects not listed in this leaflet. See section 4.
  You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### What is in this leaflet

- 1. What Paracetamol 500mg Tablets are and what they are used for
- 2. What you need to know before you take Paracetamol 500mg Tablets
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- 6. Contents of the pack and other information

# 1. What Paracetamol 500mg Tablets are and what they are used for

The name of your medicine is Paracetamol 500mg Tablets. These tablets contain paracetamol (a painkiller).

Paracetamol 500mg Tablets are used to relieve mild to moderate pain including,



headache, migraine, toothache, sore throat, period pains, neuralgia (nerve pain), pains associated with joints and muscles, backache. It is also used to reduce symptoms of rheumatic aches and pains, influenza, feverishness and feverish colds.

2. What you need to know before you take Paracetamol 500mg Tablets

#### Do not take Paracetamol 500mg Tablets if you:

• are allergic (hypersensitive) to paracetamol, or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

# Talk to your doctor or pharmacist before taking Paracetamol 500mg Tablets if you:

- suffer from kidney disease
- suffer from liver disease, particularly if caused by alcohol
- suffer from alcoholism
- suffer from asthma, particularly if your asthma is worsened by aspirin.

Caution should be exercised when taking paracetamol prior to (less than 72 hours before) or at the same time as intravenous busulfan.

#### This medicine contains paracetamol; do not take with any other paracetamol-containing products at the same time.

#### **Other medicines and Paracetamol 500mg Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect or be affected by treatment with Paracetamol 500mg Tablets:

- medicines used to treat bacterial infections (e.g. isoniazid used to treat tuberculosis)
- medicines used to treat epilepsy (fits) (e.g. carbamazepine, phenobarbital, phenytoin, primodone)
- metoclopramide and domperidone (used to treat sickness and nausea)
- oral contraceptives ("The Pill", mini-pill), hormonal implants and HRT
- warfarin and other coumarin medicines (used to thin blood) due to increased risk of bleeding
- probenecid (used to treat gout)
- diflunisal (an anti-inflammatory painkiller)
- colestyramine (used to treat high cholesterol and in diseases of the intestine and liver)
- intravenous busulfan (used in chemotherapy to treat cancer)
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

#### Pregnancy, breast-feeding and fertility

If necessary, Paracetamol 500mg Tablets can be used during pregnancy. 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. 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.

#### **Driving and using machines**

This medicine should not affect your ability to drive or operate machinery.

#### Paracetamol 500mg Tablets contains parahydroxybenzoates and sodium

This medicine contains ethylhydroxybenzoate, methylhydroxybenzoate and propylhydroxybenzoate all of which may cause allergic reactions (possibly delayed).

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

#### 3. How to take Paracetamol 500mg Tablets

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure. Paracetamol 500mg Tablets should be swallowed with water.

# Adults and children 16 years and over

- 1 to 2 tablets every 4 6 hours
- do not take more than 8 tablets in 24 hours
- do not exceed the recommended dose.

### Children 10 - 15 years:

- 1 tablet every 4-6 hours
- · do not take more than 4 tablets in 24 hours
- do not exceed the recommended dose.

Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

#### Children under 10 years of age:

· do not give to children under 10 years.

#### If symptoms persist see your doctor, do not take for more than 3 days unless you have been told to do so by your doctor.

#### If you take more Paracetamol 500mg Tablets than you should

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 you forget to take Paracetamol 500mg Tablets

If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

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

# 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may sometimes happen.

#### If you have an allergic reaction to this medicine see a doctor straight away. An allergic reaction may include:

- · skin rash, peeling of the skin, itching, swollen red areas of the skin, swelling of the mouth, lips, tongue, throat or face
- · shortness of breath, sudden wheezing, fluttering or tightness of the chest or collapse.

#### If you get any of the following side effects, stop taking this medicine and see your doctor as soon as possible:

- · bruising more easily, sore throat or other signs of infection (these may be signs of a blood disorder)
- severe pain in the abdomen and back, with fever (high temperature), loss of appetite, nausea and vomiting (these may be signs of pancreas inflammation), sudden weight loss and yellowing of the eyes and skin
- · worsening of asthma
- · very rare cases of serious skin reactions have been reported.

#### Tell your doctor if you get any of these side effects:

skin rash.

The use of this medicine over a long time can cause kidney problems. If you experience any side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

#### **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 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 Paracetamol 500mg Tablets

Keep this medicine out of the sight and reach of children.

- Store in a dry place below 25°C
- · Store in the original container in order to protect from light; do not transfer to another container
- Do not use this medicine after the expiry date which is stated on the carton 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 Paracetamol 500mg Tablets contain

The active substance is paracetamol 500mg.

The other ingredients are: potato starch, maize starch, talc purified, povidone, stearic acid, sodium starch glycollate, methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216) and magnesium stearate.

# What Paracetamol 500mg Tablets look like and contents of the pack

nol 500mg Tablets are white capsule shaped tablets with a break line 'aracetar one side.

Paracetamol 500mg Tablets are available on general sale in blister pack sizes of 8, 10, 12 and 16 tablets and from pharmacies in blister pack sizes of 20, 24, 28, 30 and 32 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham LL13 9UF, UK.

#### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Paracetamol 500mg Tablets	29831/0158

This is a service provided by the Royal National Institute of Blind People.

#### This leaflet was revised in 08/2024.



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