

PACKAGE LEAFLET: INFORMATION FOR THE USER PARACETAMOL 500MG TABLETS



Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Paracetamol 500mg Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after three days.
- If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paracetamol 500mg Tablets are and what they are used for.
2. Before you take Paracetamol 500mg Tablets.
3. How to take Paracetamol 500mg Tablets.
4. Possible side effects.
5. How to store Paracetamol 500mg Tablets.
6. Further information.

1. WHAT PARACETAMOL 500MG TABLETS ARE AND WHAT THEY ARE USED FOR:

Paracetamol belongs to a group of medicines called analgesics. These medicines work by relieving pain and fever.

It is used to relieve mild to moderate pain, such as headache, migraine, neuralgia, toothache, sore throat, period pain, aches and pains, muscle pains and backache. It can also relieve the symptoms of rheumatic aches and pains, influenza, feverishness and feverish colds.

2. BEFORE YOU TAKE PARACETAMOL 500MG TABLETS:

Do not take Paracetamol 500mg Tablets if you have had a reaction or been told that you are allergic to paracetamol or any of the other ingredients in the tablet. Check by reading the list of ingredients in Section 6.

Take special care with Paracetamol 500mg tablets:

- If you have liver disease, particularly when caused by alcohol abuse, or kidney problems.
- If your alcohol consumption is excessive.
- If you have asthma that is made worse by taking aspirin or other painkillers.

Taking other medicines: Taking another medicine while you are taking paracetamol can affect how it or the other medicine works. Make sure that your doctor knows what other medicines you are taking. Do not take any other medicines while you are taking paracetamol unless you have told your doctor or pharmacist and asked for advice. This includes medicines you may have bought yourself.

Examples of medicines that can affect Paracetamol 500mg Tablets are;

- Metoclopramide and domperidone, drugs used in the treatment of nausea/vomiting.
- Colestyramine, a cholesterol-lowering drug. Ideally, you should not take paracetamol within one hour of taking your colestyramine.
- Blood thinning agents, such as warfarin.
- Carbamazepine, phenobarbital, phenytoin, primidone and lamotrigine, used in the treatment of epilepsy.
- Isoniazid, used to treat tuberculosis.
- Diflunisal, a painkiller.
- Oral contraceptives.
- Probenecid, used to treat gout.

If you have any doubts about whether you should take this medicine then talk to your doctor.

Do not take any other products that contain paracetamol whilst taking Paracetamol 500mg Tablets.

Pregnancy and breastfeeding: Before taking this medicine, you should let your doctor or pharmacist know if you are pregnant or breast-feeding or wish to become pregnant or start breast-feeding.

3. HOW TO TAKE PARACETAMOL 500MG TABLETS:

Dose: Unless otherwise directed by your doctor-

Adults and children over 12 years: One to two tablets (500mg-1000mg) to be taken orally with water, every four hours. **Maximum daily dose:** Eight tablets (4.0g) in any 24 hour period in divided doses.

Children 6 to 12 years: ½ to one tablet (250mg-500mg) every four hours. **Maximum daily dose:** Four tablets (2.0g) in any 24 hour period in divided doses.

The dose should not be given more frequently than every four hours and not more than four times in any 24-hour period.

Do not give to children under six years of age except on the advice of a doctor.

Warning: Do not exceed the stated dose

If symptoms persist consult your doctor. Do not take for more than three days without consulting your doctor.

If you miss a single dose of Paracetamol 500mg Tablets, do not worry and take your next dose at the normal time. **Do not take a double dose to make up for a forgotten dose.**

If you take more Paracetamol 500mg Tablets than you should, you should contact your doctor, pharmacist or nearest hospital casualty department immediately. Take this leaflet and any tablets you have left to show the doctor or pharmacist.

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, Paracetamol 500mg Tablets can cause side-effects, although not everybody gets them. The side-effects that some other patients have had with Paracetamol 500mg Tablets include skin rashes and blood problems, which may cause sore throat, mouth ulcers and fever or a tendency to bleed or bruise easily. Taking high doses of paracetamol for a long time can cause kidney damage.

Patients with asthma that is made worse by taking aspirin or other painkillers may find that paracetamol also causes wheezing.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PARACETAMOL 500MG TABLETS:

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original package in order to protect from light.

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month. Do not use the tablets if they show signs of "going off" such as discolouration. 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:

What Paracetamol 500mg Tablets contain:

The active substance in the tablets is paracetamol.

The other ingredients are potato starch, pregelatinised maize starch, talc, povidone, stearic acid, sodium starch glycolate, nipasept (ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216) and methyl hydroxybenzoate (E218) and magnesium stearate. The sodium content is less than 0.1mg per tablet.

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

Paracetamol 500mg tablets are white, flat, circular tablets, with a breakline on one side and $\frac{500}{500}$ on the other side.

They are available in blister packs containing 2, 4, 6, 8, 10, 12 and 16 tablets from supermarkets and shops, in packs of 20, 24, 28, 30 and 32 from pharmacies and in packs of 48, 50, 96, 100, 240, 252, and 504 on prescription. Also available on prescription in containers of 25, 50, 100, 250, 300, 500, 1000, 5000 and 2500 tablets.

Not all pack sizes and types are actually 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.

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