

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 500 mg film coated tablets

Paracetamol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects or if you notice any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

What is in this leaflet

1. What Paracetamol 500 mg film coated tablets are and what they are used for
2. What you need to know before you take Paracetamol 500 mg film coated tablets
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1. WHAT PARACETAMOL 500 MG FILM COATED TABLETS ARE AND WHAT THEY ARE USED FOR

This medicine contains paracetamol. It belongs to a group of medicines called analgesics (painkillers) and is used to treat pain (including headache, toothache, back and period pain) and cold or flu symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL 500 MG FILM COATED TABLETS

Do not take Paracetamol 500 mg film coated tablets:

- If you are allergic to paracetamol or any of the other ingredients in Paracetamol 500 mg film coated tablets (listed in section 6).
- If you are taking other medicines containing paracetamol.

Take special care when using Paracetamol 500 mg film coated tablets

- if you are malnourished or have past experience of alcohol abuse.
- In treatment of fever conditions in children.
- Use with caution in renal, liver and kidney function.
- During long-term (> 3 months) use of Paracetamol 500 mg film coated tablets with intake every other day or more often, headaches can be caused or exacerbated and may prevail if not treated properly. Headache suspected to be induced by use of Paracetamol 500 mg film coated tablets requires immediate medical attention.

Taking other medicines with Paracetamol 500 mg film coated tablets

Refer to your doctor or pharmacist if you are taking or have recently taken other medicines, including any prescribed.

Some other medicines may affect or be influenced by Paracetamol 500 mg film coated tablets. Some of these drugs are mentioned below

- Medicine for epilepsy.
- Dicoumarol (blood thinning agents), for example, warfarin.
- Chloramphenicol (antibiotic), but not by local application of eye drops.
- Probenecid (gout medicine).
- Fluclloxacillin (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.

Refer to your doctor or pharmacist if you are taking any medicine.

Pregnancy and breast-feeding

If necessary, Paracetamol 500 mg film coated tablets can be used during pregnancy. 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.

It may enter breast milk, but the effect on nursing infants is not likely.

Driving and using machines

The product is not expected to affect the ability to drive a car or operate machinery.

3. HOW TO TAKE PARACETAMOL 500 MG FILM COATED TABLETS

Adults, the elderly and children 16 years and over: One or two tablets to be taken every four to six hours as necessary up to four times daily. Maximum dose of 8 tablets in 24 hours.

Children and adolescents

- Children 12-15 years: One tablet every four to six hours when necessary to a maximum of 4 doses in 24 hours. (Maximum of four tablets in 24 hours)

Use in children: Paracetamol 500 mg film coated tablets should not be given to children under 12 years of age.

- Do not give for more than 3 days without consulting a doctor.
- Do not take more frequently than every 4 hours.
- Do not take more than the recommended dose.

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. If your symptoms continue or your headache becomes persistent, **see your doctor**.

Symptoms of overdose are observed after 2-3 days. The symptoms are loss of appetite, nausea, vomiting, pain in the abdomen, jaundice and discoloration of urine and stools. In severe cases, life-threatening liver injury may occur.

If you forget to take Paracetamol 500 mg film coated tablets

If you forget to take a dose at the right time, take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol 500 mg film coated tablets can have side effects but not everybody gets them. A small number of people have had side effects. 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, 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.

Very rare cases of serious skin reactions have been reported.

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 PARACETAMOL 500 MG FILM COATED TABLETS

Keep out of the sight and reach of children.

This medicine does not require any special storage condition.

Do not use after the expiration date as indicated on the package. The expiry date refers to the last day of the 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 are Paracetamol 500 mg film coated tablets**

The active ingredient is paracetamol.

Each Paracetamol 500 mg film coated tablets contains 500 mg of paracetamol.

The other ingredients are:

For the tablet core: pregelatinized starch, maize starch, talc, povidone, magnesium stearate.

For the tablet coating: hypromellose (E464), titanium dioxide (E171), macrogol (E1521).

What Paracetamol 500 mg film coated tablets look like and contents of the pack

White coloured, caplet shaped, film coated tablets with 'K', bisect break line and '01' on one side and plain on the other side.

Paracetamol 500 mg coated tablets are available in blister packs of 32 & 100 tablets and HDPE bottles of 100, 300, 500 & 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Dawa Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, UK.

Manufacturer

Drugsrus Limited, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, UK.

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