

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracetamol 1000 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, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Paracetamol 1000 mg film coated tablets are and what they are used for
2. What you need to know before you take Paracetamol 1000 mg film coated tablets
3. How to take Paracetamol 1000 mg film coated tablets
4. Possible side effects
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1. WHAT PARACETAMOL 1000 MG FILM COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Paracetamol 1000 mg film coated tablets are used for the management of mild to moderate pain and fever. The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL 1000 MG FILM COATED TABLETS**Do not take Paracetamol 1000mg film coated tablets if you**

- are allergic (hypersensitive) to paracetamol or any of the other ingredients of this medicine (listed in Section 6: Contents of the pack and other information)
- are under 16 years old
- have a body weight of less than 50 Kg.

Do not take Paracetamol 1000 mg film coated tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Paracetamol 1000 mg film coated tablets.

Take special care when using Paracetamol 1000 mg film coated tablets

Talk to your doctor or pharmacist before taking Paracetamol 1000 mg film coated tablets if:

- you have moderate to severe kidney or liver problems, including acute hepatitis or liver problems caused by excessive alcohol consumption
- you have a condition called Gilbert's syndrome which can cause yellowing of the skin or whites of the eyes (mild jaundice)
- you are taking other medicinal products which affect your liver
- you have a hereditary enzyme disorder called glucose-6-phosphate dehydrogenase deficiency
- you have a blood disorder called haemolytic anaemia which causes a reduced number of red blood cells, pale yellow skin and weakness or breathlessness
- you are suffering from dehydration or nutritional problems (chronic malnutrition)
- you have an addiction to alcohol
- you are already **taking any other products that contain paracetamol**.

If this applies to you then do not take Paracetamol 1000 mg film coated tablets without first speaking to your doctor or pharmacist.

Taking other medicines with Paracetamol 1000 mg film coated tablets

Refer to your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription. Some other medicines may affect or be influenced by Paracetamol 1000 mg film coated tablets. In particular it is important to tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines used to thin the blood, such as warfarin, as paracetamol may increase their effect
- medicines used to stop you feeling sick (nausea) or vomiting (e.g. metoclopramide or domperidone).
- products containing codeine (used to help suppress coughs and relieve pain)
- medicines used to treat high cholesterol (e.g. cholestyramine)

- the antibiotic chloramphenicol (used to treat infections) but not by local application of eye drops
- probenecid (a medicine used to treat high levels of uric acid in the blood stream i.e. gout)
- medicines used to treat fever or mild pain (e.g. salicylamide).
- medicines to treat stomach acid
- isoniazid (used to treat tuberculosis)
- zidovudine (used to treat HIV),
- antiepileptic medicines used to treat convulsions (such as phenobarbital, carbamazepine, phenytoin, primidone and glutethimide)
- St John's Wort (a herbal remedy)
- rifampicin (used to treat infections)
- 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.

Always check the leaflet that comes with your other medicine.

Do not take Paracetamol 1000 mg film coated tablets if you are taking any other medicines containing paracetamol.

This includes some other painkillers, cough and cold remedies. This also includes a wide range of other medicines available on prescription and over the counter.

Taking Paracetamol 1000 mg film coated tablets with food and drink

You should not drink alcohol whilst taking these tablets. Taking Paracetamol 1000 mg film coated tablets with alcohol can increase your chances of getting side effects.

Paracetamol 1000 mg film coated tablets can be taken with or without food.

Pregnancy and breast-feeding

If necessary, Paracetamol 1000 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.

Talk to your doctor if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Paracetamol 1000 mg film coated tablets have not been shown to affect your ability to drive or operate machinery.

3. HOW TO TAKE PARACETAMOL 1000 MG FILM COATED TABLETS**Adults and children aged 16 years and over:**

Take 1 tablet as prescribed

- Do not take more frequently than every 4 hours.
 - Do not take more than 4 tablets in 24 hours.
 - Do not exceed the stated dose.
 - Do not take with other paracetamol containing products.
 - Do not give to children under 16 years.
- 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 symptoms persist consult your doctor.

If you take more Paracetamol 1000 mg film coated tablets

Immediate medical advice should be sought in the event of over dosage because of the risk of irreversible liver damage. It is important to contact your doctor even if you feel well.

Contact your nearest hospital emergency department or tell your doctor immediately and say exactly how much you have taken. Your doctor will advise you what to do.

Remember to take the pack and any remaining tablets with you. This is so the doctor knows what you have taken.

Symptoms of paracetamol overdose in the first 24 hours are paleness of the skin, feeling sick (nausea), vomiting, lack of appetite, and abdominal pain. Liver damage may become apparent 12 to 48 hours after taking paracetamol.

If you forget to take Paracetamol 1000 mg film coated tablets

If you forget to take a dose at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. You must allow at least 4-6 hours between doses.

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

PHARMACODE

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol 1000 mg film coated tablets cause side effects, although not everybody is affected. The frequency of these side effects is not known but experience indicates that side effects with paracetamol are rare and serious reactions are very rare.

Stop taking Paracetamol 1000 mg film coated tablets and see a doctor or go to a hospital straight away if:

- you experience a serious allergic reaction (anaphylaxis) such as swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- you have serious illness with blistering of the skin, mouth, eyes and genitals or an itchy, lumpy, skin rash.

The following side effects have also been reported. If you experience any of the following please tell your doctor or pharmacist:

- blood problems (such as agranulocytosis or thrombocytopenia), increased risk of bleeding, bruising more easily than usual or getting more infections than usual
- difficulty in breathing or wheezing (particularly if you have asthma and are allergic to aspirin or anti-inflammatory medicines (NSAIDs))
- liver problems.

Very rare cases of serious skin reactions have been reported.

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

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 1000 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 is Paracetamol 1000 mg film coated tablets

The active ingredient is paracetamol.

Each Paracetamol 1000 mg film coated tablet contains 1000 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 1000 mg film coated tablets look like and contents of the pack

White coloured, caplet shaped, film coated tablets, with 'K', bisect break line '02' on one side and break line on the other side.

Paracetamol 1000 mg film coated tablets are available in blister packs of 12, 16 & 100 tablets and HDPE Bottles of 32, 100, 300 & 500 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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