

<i>Title:</i> Paracetamol 500mg (100’s) PIL	<i>Colours (Printed)</i> <div><div>Black</div><div>Process</div></div>
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Package leaflet: Information for the patient

## Paracetamol 500 mg Tablets

**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.

- 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 is and what it is used for
2. What you need to know before you take Paracetamol Tablets
3. How to take Paracetamol Tablets
4. Possible side effects
5. How to store Paracetamol Tablets
6. Contents of the pack and other information

### 1. What Paracetamol is and what it is used for

Paracetamol Tablets contain paracetamol, which relieves pain (analgesic) and reduces the body temperature in fever (antipyretic). The tablets are recommended for use in treatment of mild to moderate pain and/or fever. Paracetamol Tablets are used for the relief of headache, tension headache, migraine, backache, rheumatic and muscle pain, toothache and period pain. They also relieve sore throat and the fever, aches and pains of colds and flu and are recommended for the relief of pain due to mild arthritis.

### 2. What you need to know before you take Paracetamol Tablets

#### Do not take Paracetamol Tablets:

- if you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in Section 6)
- if you are taking other medicines containing paracetamol.
- if you are taking other medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Do not take more medicine than recommended in section 3 of the leaflet (How to take Paracetamol Tablets).

Concomitant use of this medicinal product with other medicines containing paracetamol, such as flu and cold medicines, should be avoided since high doses may lead to liver damage. Do not use more than one medicine containing paracetamol without talking to your doctor.

#### Warnings and precautions

- if you suffer from mild arthritis and need to take painkillers every day.
- regularly drink alcohol
- have a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

**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.

Talk to your doctor , pharmacist or nurse before taking Paracetamol Tablets

- if you are suffering from kidney problems
- if you are suffering from liver problems, including alcoholic

liver disease

- if you have Gilbert’s syndrome (mild jaundice)
- if you have hemolytic anemia (abnormal breakdown of red blood cells)
- if you are an asthmatic and sensitive to aspirin
- if you are suffering from dehydration or chronic malnutrition
- if you have fever after paracetamol therapy
- if you suffer from glucose-6-phosphate dehydrogenase deficiency (enzyme deficiency).

During treatment with Paracetamol Tablet, tell your doctor straight away if:

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

#### Other medicines and Paracetamol Tablets

Talk to your doctor or pharmacist if you are taking any other medicines, including medicines obtained without a prescription.

Tell your doctor before you take Paracetamol Tablets if you are taking;

- Drugs to thin the blood (anti-coagulant drugs e.g. warfarin) 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 Paracetamol Tablets at the same time as anticoagulants.
- Medicines used to relieve sickness (e.g. metoclopramide, domperidone)
- Medicines used to treat high cholesterol (cholestyramine)
- Probenecid (medicine used to treat high levels of uric acid in the blood stream i.e. gout)
- Medicines to treat fever or mild pain (aspirin, salicylamide)
- Drugs such as rifampicin (drug that helps to fight infection) and some antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone (drugs used to treat or cure convulsions)
- Medicines used to treat epilepsy (lamotrigine)
- Medicines to treat tuberculosis (isoniazid)
- Medicines to treat HIV infections (zidovudine)

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)

#### Effects of Paracetamol Tablets on laboratory tests

Uric acid and blood sugar tests may be affected.

#### Pregnancy and breast-feeding

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

You can take this product whilst breast feeding.

#### Driving and using machines

Paracetamol Tablets have no effect on the ability to drive and use machines.

### 3. How to take Paracetamol Tablets

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

The recommended dose is:

Adults, the elderly and children aged 16 years and over:

- Take one or two tablets every 4-6 hours as needed.
- Do not take more than 8 tablets (4 grams) in 24 hours.

#### Use in children and adolescents

Children aged 10 to 15 years:

- Give one tablet every 4-6 hours as needed.
- Do not give more than 4 tablets (2 grams) in 24 hours.

- Do not take more frequently than every 4 hours.
- Do not take more than the recommended dose.
- Do not give to children under 10 years.
- Do not give for more than 3 days at a time unless your doctor tells you to.

The use of high daily doses of paracetamol should be avoided for extended periods of time as it increases the risk of adverse effects such as liver damage.

If pain persists for more than 5 days, fever for more than 3 days or the pain or fever gets worse or other symptoms appear, you should stop treatment and consult your doctor.

#### If you take more Paracetamol 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 your symptoms continue or your headache becomes persistent, see your doctor.

#### If you forget to take Paracetamol Tablets

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. The minimum time interval between two doses should be 4 to 6 hours.

Do not take a double dose to make up for a forgotten dose.

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

### 4. Possible side effects

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

**You should stop taking Paracetamol Tablets and see your doctor immediately if you experience symptoms like swelling in the face, tongue or throat, difficulty swallowing, red and itchy swellings on the skin and difficulty in breathing.**

#### Rare (affects less than 1 in 1,000 patients):

- Bleeding problems or clotting disorders (platelet disorders), decreased formation of cells, severe decrease in white blood cells which may lead to severe infections (agranulocytosis), frequent infections due to poorly functioning white blood cells or decrease in white blood cells (leucopenia), reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia), abnormal breakdown of red blood cells, which may cause weakness or pale skin (haemolytic anaemia), decrease in blood count (pancytopenia), reduced neutrophil count in blood (neutopenia).
- Allergies (excluding swelling on the face, mouth and hands)
- Depression, confusion, sensing unreal things
- Tremor, headache
- Abnormal vision
- Abnormal accumulation of fluid under the skin (oedema)
- Stomach pain, diarrhoea, nausea (feeling sick), vomiting, bleeding (haemorrhage)
- Abnormal liver function, liver failure, death of liver cells (hepatic necrosis), jaundice
- Dizziness, feeling of general discomfort or uneasiness (malaise), fever, drowsiness, drug interaction
- Overdose and poisoning.

#### Very rare (affects less than 1 in 10,000 patients):

- 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.
- Damage caused to the liver (hepatotoxicity)
- Immediate severe allergic reaction (hypersensitivity reaction requiring discontinuation of treatment)

- Low levels of glucose in the blood (hypoglycemia)
- Cloudy urine and kidney disorders
- Life-threatening skin disease causing rash, skin peeling and sores (epidermal necrolysis) or mouth ulcers
- Allergin reaction of the skin (erythema multiforme)
- Severe life-threatening skin disease causing rash, skin peeling and sores (Stevens-Johnson syndrome)
- Accumulation of fluid in the voice box (larynx)
- Severe allergic reaction (anaphylactic shock)
- Decrease in red blood cells (anemia)
- Severe kidney impairment (renal alteration)
- Kidney disorder (nephrite interstitial)
- Blood in urine (haematuria)
- Inability to urinate (anuresis)
- Stomach ulcers and bleeding (gastrointestinal effects)
- Uneasiness.

Frequency “Not known” (frequency cannot be estimated from the available data): “A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)”

#### Reporting of side effects

If you get any side effects, talk to your doctor or 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](http://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 Tablets

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

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

Do not use this medicine after expiry date which is stated on the carton, bottle or the blister 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 Tablet contains

- The active substance is paracetamol. Each tablet contains 500 mg of paracetamol.

- The other excipients are pregelatinised starch, povidone and magnesium stearate.

#### What Paracetamol Tablets looks like and contents of the pack

Paracetamol 500 mg Tablets are white to off white, caplet shaped tablets, plain on one side and a break-line on the other side.

The tablets are supplied in blister packs of 16, 20 & 100 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

##### UK

RxFarma, Colonial Way, Watford, WD24 4YR, United Kingdom

##### Manufacturer

Rx Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR United Kingdom

**If you would like this leaflet in different format or want to report any side effects please contact marketing authorisation holder listed above.**

**This leaflet was last revised in April 2025.**