

Package leaflet: information for the user

Paracetamol Farmalider 500 mg tablets

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

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

Paracetamol belongs to the group of medicinal products called analgesics and antipyretics. Paracetamol is indicated for the symptomatic treatment of mild to moderate pain (e.g. headache, toothache, dysmenorrhea) and fever.

2. What you need to know before you take Paracetamol Farmalider

Do not take Paracetamol Farmalider:

- If you are allergic 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 Farmalider:

- if you have kidney disease
- if you have liver disease (including Gilbert's Syndrome and alcoholic liver disease)
- if you suffer from acute hepatitis
- if you are taking other drugs which may affect hepatic function
- if you have problems of glucose-6-phosphate dehydrogenase deficiency
- if you suffer from haemolytic anaemia

During treatment with Paracetamol Farmalider, 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).

You should not take any other medicine containing paracetamol concurrently.

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.

Do not exceed the stated dose.

Do not exceed 4 g (8 tablets) in 24 hours in adults, the elderly and children over 16 years.

Do not exceed 2 g (4 tablets) in 24 hours in children over 10 years.

Paracetamol can alter the following laboratory test:

- Uric acid using phosphotungstic acid
- Blood-glucose using glucose-oxidase-peroxidase

Children

Do not use in children under the age of 10. In children aged under 10 years, ask your doctor or pharmacist as there are other presentations with doses that are more suitable for this patient group.

Other medicines and Paracetamol Farmalider

Tell your doctor or pharmacist if you are using or have recently used any other medicine.

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).

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for nausea [feeling sick] or vomiting [being sick]) or **colestyramine** (to lower **blood cholesterol**) or **opioids** [for acute pain] or **chloramphenicol** [for bacterial infection]. 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 Farmalider at the same time as anticoagulants.

Paracetamol Farmalider with food, drink and alcohol:

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| Use of paracetamol in patients who consume alcohol regularly (three or more alcoholic drinks daily – beer, wine, liquor.... daily) can cause liver damage. |
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Taking this medicinal product with food does not affect its efficacy.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If necessary, Paracetamol Farmalider 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.

Driving and using machines

No effects on the ability to drive and use machinery have been described.

3. How to take Paracetamol Farmalider

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 16 years and over: take one or two tablets up to 4 times a day. Do not exceed 4 g (8 tablets) in 24 hours.

Children 10 to 15 years of age: take one tablet up to 4 times a day. Do not exceed 2 g (4 tablets) in 24 hours.

Not recommended for children under 10 years of age.

The dose should not be repeated more frequently than every 4 hours and not more than 4 doses should be taken in any 24-hour period.

If you take more Paracetamol Farmalider than you should:

If you have taken more paracetamol than you should, seek immediate advice from your doctor or call the Toxicological Information Service. In case of overdose, go to a medical centre immediately, even if you have no symptoms. The symptoms of overdose in the first 24 hours include: pallor, nausea, vomiting, loss of appetite, and abdominal pain.

Treatment of overdose is more effective in the first 4 hours of taking the medicinal product.

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 Farmalider

Do not take a double dose to make up for a forgotten tablet, simply take the missed dose when you remember, taking the following doses at the intervals indicated in each case (at least 4 hours).

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

4. Possible side effects

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

This medicinal product can cause the following side effects:

Rare (may affect up to 1 in 1,000 people): discomfort, drop in blood pressure (hypotension), difficulty breathing (bronchospasm), asthma and increase in transaminase levels in the blood.

Very rare (may affect up to 1 in 10,000 people): kidney diseases, cloudy urine, allergic dermatitis (skin rash), jaundice (yellowing of the skin) blood disorders (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia), and hypoglycaemia (drop in blood sugar),

angioedema (swallowing), anuria (your body is not producing any urine) and haematuria (blood in the urine), interstitial nephritis (kidney inflammation).

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)”

Paracetamol can cause liver damage when taken at high doses or in prolonged treatments.

If you have any side effects, tell your doctor or pharmacist, even those not included in this leaflet.

There have been very rare cases of serious skin reactions.

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 Yellow Card Scheme at Website: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Paracetamol Farmalider

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

Do not use this medicine after the expiry date which is stated on the container (after EXP). The expiry date refers the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Farmalider contains

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

The other ingredients are: pregelatinised starch maize (gluten-free), stearic acid, povidone, crospovidone, microcrystalline cellulose and magnesium stearate (vegetable source).

What Paracetamol Farmalider looks like and contents of the pack

Paracetamol Farmalider is supplied in tablet form for oral administration in containers 1, 10, 12, 16, 20, 30, 50 and 60 tablets.

Not all pack sizes may be marketed

The dimensions of the tablet are 18.3 ± 0.2 mm (length) x 8.2 ± 0.2 mm (width) x 5.1 ± 0.2 mm (thickness).

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

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