

Anverso /
Front

Laetus
Pharmacode



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 pharmacist.
- 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.
- You must talk to your doctor if your fever gets worse or if it does not improve after 3 days, and if pain does not improve or gets worse after 5 days.

What is in this leaflet:

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

1. What Paranor is and what it is used for

Paracetamol belongs to a group of medicines called analgesics and antipyretics.

This medicine is used for the symptomatic treatment of occasional mild to moderate pain, such as muscle pain, back pain, headache, toothache and period pains. Feverish conditions.

2. What you need to know before you take Paranor

• Do not take Paranor:

- If you are allergic (hypersensitive) to paracetamol or any of the other ingredients of this medicine,
- if you have any liver disease.

• Warnings and precautions

- Do not take more medicine than the amount recommended in section 3. How to take Paranor.
- Simultaneous use of this medicine with other medicines containing paracetamol, such as medicines to treat flu and cold, 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.
- If you suffer from anaemia (decreased levels of haemoglobin in blood, caused or not by a decrease of red blood cells), heart or lung diseases or kidney dysfunction, avoid long-term treatment with Paranor;
- If you suffer from a severe renal impairment, the interval between two intakes should be at least 8 hours.
- If you usually consume alcohol, since it may cause liver damage; If you suffer from chronic alcoholism, you should not take more

- than 2 g/day of paracetamol;
- If you are an asthmatic patient sensitive to acetylsalicylic acid.

Interference with analytical tests

If you are going to undergo any analytical test (including blood tests, urine tests, cutaneous testing for allergy diagnosis, etc.), tell your doctor that you are taking this medicine, since it may alter the results.

• Other medicines and Paranor:

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including oral contraceptives, medicinal plants and medicines obtained without a prescription.

Paracetamol interacts with: oral medicines to prevent blood clotting (e.g. warfarin, acenocoumarol); ethyl alcohol; anticonvulsants (e.g. phenytoin, phenobarbital, methylphenobarbital, primidone); chloramphenicol; oestrogens; loop diuretics; isoniazid; lamotrigine; probenecid; propranolol; rifampicin; anticholinergics (e.g. glycopyrronium, propantheline); ion exchange resins (cholestyramine); zidovudine.

• Pregnancy, breast-feeding and fertility

Pregnancy: Ask your doctor or pharmacist for advice before using any medicine

If necessary, Paranor 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.

Breast-feeding: Ask your doctor or pharmacist for advice before using any medicine. Paracetamol may pass into breast milk, thus breast-feeding women should talk to their doctor before using this medicine.

• Driving and using machines

There is no evidence of negative effects on the ability to drive vehicles or use machines.

3. How to take Paranor

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

Paranor is for oral use. The tablet can be divided into equal halves. The tablets may be swallowed directly or in halves with a glass of water.

The recommended dose is:

Adults: Doses from half a tablet to 1 tablet. (325-650 mg) every 4-6 hours. Do not exceed 3 g in 24 hours.

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 pain or fever worsen or other symptoms appear, you should



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suspend treatment and talk to your doctor.

Children: A dosage schedule of 10 mg/kg of weight per intake may be established, with a minimum interval of 4 hours, or 15 mg/kg of weight per intake every 6 hours. The approximate ages are only indicative.

The following doses may be repeated with a minimum interval of 4 hours, without exceeding a total of 5 intakes in 24 hours.

Children aged 6 to 10 years: half a tablet (325 mg) every 4 to 6 hours, to a maximum of 2 to 3 tablets (1300-1950 mg) in 24 hours, depending on the child's weight.

Children 11 years: half a tablet (325 mg) every 4 to 6 hours, to a maximum of 4 tablets (1950 mg) in 24 hours.

Teenagers from 12 years: 1 tablet (650 mg) every 4 to 6 hours, to a maximum of 4 tablets (2600 mg) in 24 hours.

• **If you take more Paranor than you should**

Symptoms include vomiting, dizziness, loss of appetite, jaundice (proved by yellowing of the skin and mucosa), abdominal pain, kidney and liver failure. Patients who intake overdoses must be rapidly treated at a healthcare centre although they do not show important symptoms or signs since, despite they can cause death, they do not usually appear immediately after the intake, but from the third day. Death can occur due to hepatic necrosis. Additionally, acute kidney failure may appear.

Contact your doctor or pharmacist immediately or call the Toxicology information service specifying the medicine and the amount taken.

Information for the doctor: In all cases it will be necessary to proceed with aspiration and gastric lavage, preferably within 4 hours after ingestion. There is a specific antidote for toxicity produced by paracetamol: N-acetylcysteine.

• **If you forget to take Paranor**

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

If you forget to take your dose, take it as soon as you remember. However, if the time of the following dose is close, skip the missed dose and take the following dose at your usual time.

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

4. Possible side effects

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

Reported side effects are classified by frequency of occurrence: Very common (may affect more than 1 in 10 patients); common (may affect up to 1 in 10 patients); uncommon (may affect up to 1 in 100 patients); rare (may affect up to 1 in 1,000 patients); very rare (may affect up to 1 in 10,000 patients). Side effects are generally rare or very rare.

General disorders and administration site conditions.

Rare: Malaise. *Very rare:* Allergic reactions which can range from a simple skin rash (reddening or swelling of the skin) or urticaria (hives) to anaphylactic shock (serious allergic reaction).

Gastrointestinal disorders: *Rare:* Increased levels of hepatic transaminases (liver enzymes). *Very rare:* Hepatotoxicity

(jaundice).

Metabolism and nutrition disorders: *Very rare:* Decreased blood glucose. **Blood and lymphatic system disorders:** *Very rare:* Decreased blood cells. **Vascular disorders:** *Rare:* Hypotension (decreased blood pressure). **Renal and urinary disorders:** *Very rare:* Sterile pyuria (cloudy urine), renal adverse effects.

Severe skin reactions have very rarely been reported.

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

5. How to store Paranor

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

No special storage conditions are required. Store in the original package.

Do not use this medicine after the expiry date which is stated on the container after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Dispose of containers and medicines you no longer need at the recycling containers at your pharmacy. If you are not sure, ask your pharmacist how to throw away medicines and packages you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paranor 650 mg contains

The active substance is paracetamol. Each tablet contains 650 mg of paracetamol.

The other ingredients are: Povidone, pregelatinised maize starch and stearic acid.

What Paranor looks like and contents of the pack

Paranor 650 mg are tablets. Tablets are white or off-white, biconvex, elongated, scored and divisible. It is presented in packs of 20 or 40 tablets packed in PVC/Aluminium blisters.

Marketing Authorisation Holder and Manufacturer:

Laboratorios Normon, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

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