

Package leaflet: Information for the user

paracetamol cinfa 650 mg film-coated tablets

Paracetamol

Read all of this leaflet carefully before you start taking this medicine.

- 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.

What is in this leaflet

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

1. What paracetamol cinfa is and what it is used for

Paracetamol cinfa is effective in reducing pain and fever.

Paracetamol cinfa is used for:

- relieving moderate pain such as:
 - o musculoskeletal pain
 - o arthrosis (a degenerative joint condition)
 - o rheumatoid arthritis (inflammation of the joints, usually including the hands and feet, leading to swelling and pain)
 - o headache
 - o toothache
 - o painful menstrual periods
- Febrile states.

2. What you need to know before you take paracetamol cinfa

Do not take paracetamol cinfa

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

Warnings and precautions

- if you suffer from kidney, heart disease or anaemia (reduced blood haemoglobin, which may occur because of a low red blood cell count), you should talk to your doctor before taking paracetamol cinfa,
- if you are a chronic alcoholic be careful not to take more than 2 g of paracetamol cinfa a day,
- if you are asthmatic and allergic to aspirin take special care because paracetamol cinfa may produce a cross-reaction.

The recommended dose should not be exceeded.

You should consult your doctor for use in children under 15 years old or in treatments for more than 10 days.

We recommend consulting your doctor or pharmacist if you have to undergo a blood or urine test.

Using other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Chloramphenicol (antibiotic).
- Oral anticoagulants, medicines that avoid the formation of blood clots (acenocoumarol, warfarin).
- Oral contraceptives and oestrogen-based treatments.
- Anti-epileptics, to treat epileptic episodes (lamotrigine, phenytoin or other hydantoin, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Antituberculosis medicines (isoniazid, rifampicin).
- Barbiturates (used as hypnotics, sedatives and anticonvulsants).
- Cholestyramine (used to lower blood cholesterol).
- Medicines used to treat gout (probenecid and sulfinpyrazone).
- Some medicines used to increase urine output (loop diuretics such as furosemide).
- Medicines used to obtain relief from spasms or contractions of the stomach, intestine and bladder (anticholinergic agents).
- Medicines used for the heart (digitalis glycosides).
- Metoclopramide and domperidone (used to prevent nausea and vomiting).
- Propranolol used to treat high blood pressure (hypertension) and alterations in heart rhythm (arrhythmias).
- Zidovudine (used to treat HIV infections).

Simultaneous use with other analgesics (medicines used to treat pain) is to be avoided, unless approved by the doctor. We do not recommend prolonged and simultaneous use of paracetamol with salicylates (an anti-inflammatory drug, e.g. aspirin) because chronic administration at high doses of both analgesics significantly increases the risk of kidney toxicity.

To avoid the risk of overdose, you should ensure you do not take other medicines that contain paracetamol.

Interferences with diagnostic tests:

If you are undergo a diagnostic test (blood, urine analysis, etc.) tell your doctor you are being treated with paracetamol cinsa as this may alter the results.

Paracetamol cinsa with food and drink

Use in people who usually consume alcohol may lead to liver damage as ethanol may increase paracetamol's liver toxicity.

Pregnancy and breast-feeding

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

Pregnancy:

We do not recommend its use during the first three months (first trimester) of pregnancy and in case it is used, always assess the possible risks and benefits of the treatment.

If necessary, paracetamol cinsa can be used during pregnancy. It is important to use the lowest possible dose that reduces pain or fever and it should be used for as short time as possible. Talk

to your doctor if the pain or fever does not decrease or if you need to take the medicine more often.

Breast-feeding:

Paracetamol enters breast milk therefore, breastfeeding women should consult their doctor before using this medicine.

Driving and using machines

It is not expected to have any effect that modifies ability to drive and handle machines.

Important information about some of the ingredients of paracetamol cinsa

This medicine may produce stomach problems and diarrhoea as it contains hydrogenated castor oil.

3. How to take paracetamol cinsa

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

Paracetamol cinsa is taken orally. Swallow tablets whole without chewing. Swallow tablets with sufficient liquid (a glass of water).

If you want to take half the dose the tablet should be divided along the score line.

Adults:

Dose of half a tablet (325 mg) to 1 tablet (650 mg) every 4-6 hours. Do not exceed 6 tablets (4 g) in 24 hours.

Patients with kidney or liver conditions: should consult their doctor.

Elderly patients: your doctor may recommend reducing the dose.

Children:

- between 6 and 11 years of age: the recommended dose is half a tablet (325 mg) every 4-6 hours. Do not take more than 2 and a half tablets in 24 hours.
- over 12 years of age: the recommended dose is 1 tablet (650 mg) every 4-6 hours. Do not take more than 5 tablets in 24 hours.

Always use the lowest effective dose.

Administration of the preparation is linked to the existence of pain or fever. As the symptoms subside, the treatment should be discontinued.

If you take more paracetamol cinsa than you should

In case of overdose or accidental ingestion, report to a medical centre immediately, specifying the medicine and the amount taken. It is recommended to take the package and the leaflet of the medicine to the healthcare provider.

In the event of overdose, quickly report to a medical centre even if there are no symptoms, since these often only appear up to three days later, even in cases of severe intoxication.

The symptoms of overdose can include: dizziness, vomiting, loss of appetite, yellow colouring of the skin and the eyes (jaundice), and abdominal pain.

The period in which the management of overdose offers maximum efficacy is within four hours after overdose.

Patients treated with barbiturates, or patients with chronic alcoholism, may be more susceptible to paracetamol overdose toxicity.

If you forget to take paracetamol cinfa

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

If you forgot to take a dose of paracetamol when due, take the dose when you remember and then wait for the recommended time between doses (at least 4 h) before you take the next dose.

If you stop taking paracetamol cinfa

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.

The side effects have been classified on the basis of the following frequency definitions: Common (at least 1 of every 100 patients), uncommon (at least 1 of every 1000 patients), rare (at least 1 of every 10,000 patients) and very rare (less than 1 of every 10,000 patients).

General disorders:

Rare: malaise.

Very rare: allergic reactions (hypersensitivity) that vary from simple skin rash (skin reddening or inflammation) or urticaria (hives) and anaphylactic shock (type of serious allergic reaction).

Gastrointestinal disorders:

Rare: increased liver enzyme levels (liver transaminases).

Very rare: liver toxicity and jaundice (yellow skin and mucosa).

Metabolism and nutrition disorders:

Very rare: hypoglycaemia (reduced blood sugar levels).

Blood and lymphatic system disorders:

Very rare: reduced blood platelets (thrombocytopenia), reduced white blood cells (agranulocytosis, leukopenia or neutropenia), haemolytic anaemia (reduced red blood cells).

Vascular disorders:

Rare: hypotension (reduced blood pressure).

Kidney disorders:

Very rare: sterile pyuria (cloudy urine), kidney side effects.

Skin and subcutaneous tissue disorders:

Very rarely cases of severe skin reactions have been reported.

5. How to store paracetamol cinfa

Do not store at a temperature above 25°C

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

Shelf life:

Do not use paracetamol cinfa after the expiry date which is stated on the pack 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**What paracetamol cinfa contains**

- The active substance is paracetamol.
- The other ingredients are:
 - Tablet core: anhydrous colloidal silica, corn starch, microcrystalline cellulose (E-460), magnesium stearate (E-470b), sodium carboxymethyl starch (type A), hydrogenated ricine oil, povidone (E-1201).
 - Tablet coating: macrogol 6000, hypromellose 606 and hypromellose 615 (E464).

contents of the pack

Each pack contains 20, film-coated tablets.

Marketing authorisation holder

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte (Navarre)-Spain

Manufactured by:

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31620 Huarte (Navarre)-Spain

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Tel.: 2470 1927
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HK Reg.No. : HK-63129

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Package leaflet: information for the user

paracetamol cinfa 1 g 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 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

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6. Contents of the pack and other information

1. What paracetamol cinfa is and what it is used for

Paracetamol cinfa belongs to a group of medicines called analgesics and antipyretics. It is used for the symptomatic treatment of mild to moderate pain and fever in adults and adolescents over 15 years of age and weighing over 50 kg.

2. What you need to know before you take paracetamol cinfa

Do not take paracetamol cinfa

- 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 cinfa.

- Do not take more than the dose recommended in section 3, "How to take paracetamol cinfa".
- Simultaneous use of this medicine with other medicines containing paracetamol, such as medicines for the common cold, should be avoided, since high paracetamol doses may damage the liver. Do not use more than one medicine containing paracetamol without first consulting the doctor.
- Chronic alcoholics should take care not to take more than 2 g of paracetamol in 24 hours.
- Because it contains 1 g of paracetamol, patients with kidney disease cannot take this medicine. Patients with liver, heart or lung diseases and patients with anaemia must consult their doctor before taking this medicine.
- When being treated with a medicine for epilepsy you should consult your doctor before taking this medicine because when used at the same time, there is reduced efficacy and increased liver toxicity of paracetamol, especially in treatments with high doses of paracetamol.
- Talk to your doctor before taking this medicine if you have asthma and are sensitive to aspirin.
- Paracetamol may cause serious skin reactions such as *acute generalised exanthematous pustulosis* (AGEP), Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN), that

may prove fatal. Patients are to be informed about the signs of serious skin reactions, and the medicine should be suspended at the first sign of skin rash or any other sign of hypersensitivity.

Children and adolescents

Because of its paracetamol dose, this medicine should not be used in children or adolescents under 15 years of age (and weighing less than 50 kg). Ask your doctor or pharmacist about the other available presentations allowing adequate dosing in such patients.

Interaction with laboratory tests

If you are going to have a laboratory test (including blood or urine tests, etc.), tell the doctor that you are taking this medicine, since it can alter the test results.

Paracetamol may alter the values of the laboratory test measurements of uric acid and glucose.

Other medicines and paracetamol cinfa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, if you are using any of the following medicines, since it may be necessary to modify the dose of some of them or discontinue the treatment:

- Medicines to prevent blood clots: Oral anticoagulants (acenocoumarol, warfarin).
- Medicines to treat epilepsy: Antiepileptic agents (lamotrigine, phenytoin or other hydantoin, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Medicines to treat tuberculosis (isoniazid, rifampicin).
- Medicines to treat depression and seizures: Barbiturates (used as hypnotics, sedatives and anticonvulsants).
- Medicines used to lower blood cholesterol (cholestyramine).
- Medicines used to increase urine output (loop diuretics such as furosemide).
- Medicines used to treat gout (probenecid and sulphinyprazole).
- Medicines used to prevent nausea and vomiting: metoclopramide and domperidone.
- Medicines used to treat high blood pressure (hypertension) and heart rhythm abnormalities (arrhythmias): propranolol.

Paracetamol cinfa with food, drink and alcohol

The use of paracetamol by patients who regularly consume alcohol (three or more alcoholic beverages - beer, wine, spirits - a day) may cause liver damage.

Taking this medicine with food does not affect its efficacy.

Pregnancy and breast-feeding

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

If necessary, paracetamol cinfa can be used during pregnancy. It is important to use the lowest possible dose that reduces the pain or fever and it should be used for as short a time as possible. Talk to your doctor if the pain or fever does not decrease or if you need to take the medicine more often.

Paracetamol enters breast milk and, therefore, breast-feeding women should ask their doctor or pharmacist before taking this medicine.

Driving and using machines

Paracetamol has no or negligible influence on the ability to drive and use machines.

3. How to take paracetamol cinfa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your

doctor or pharmacist if you are not sure.

This medicine is taken orally.

According to your preference, tablets should be swallowed directly or split into two and taken with a glass of liquid, preferably water.

The recommended dose is:

Adults and adolescents over 15 years of age and weighing over 50 kg

The recommended dose is one or half a tablet (1 g - 500 mg of paracetamol), as required. At least 4 hours should be left between doses. More than 4 tablets (4 g) must not be taken in 24 hours.

Elderly patients

Your doctor will tell you the frequency and whether the dose needs to be reduced.

Patients with liver diseases

You should take the minimum amount of medicine prescribed by your doctor and leave at least 8 h between each dose. You must not take more than 2 grams of paracetamol in 24 hours, distributed over 2 doses.

Patients with kidney diseases

Consult your doctor before taking this medicine. The maximum quantity is half a tablet (500 mg) per dose. Depending on your illness, your doctor will tell you whether the medicine should be taken with an interval of at least 6 or 8 hours.

Do not take more than 2 grams of paracetamol in 24 hours in several doses, and in no case should the quantity exceed 500 mg per dose.

Children and adolescents

Do not use in children under the age of 15

The tablet can be divided into equal doses.

This medicine should only be taken when the symptoms (pain or fever) are present. As the symptoms subside, the treatment should be discontinued.

High daily doses of paracetamol for long periods of time are to be avoided, since they increase the risk of adverse effects such as liver damage.

If the pain lasts for more than 5 days, the fever for more than 3 days, or either the pain or fever worsens or other symptoms appear, you should consult your doctor and reassess the clinical situation.

If you take more paracetamol than you should

In case of an overdose or accidental ingestion, notify your doctor or pharmacist immediately or call the Toxicology Information Service, telephone +34 91 562 04 20, specifying the medicine and the amount ingested.

The symptoms of overdose may be: dizziness, vomiting, loss of appetite, yellow colouring of the skin and the eyes (jaundice), and abdominal pain.

In the event of an overdose, quickly report to a medical centre even if there are no symptoms, since these often only appear up to three days later, even in cases of severe intoxication.

In the event of overdose, its treatment is more effective if started within four hours after the overdose.

In patients treated with barbiturates, or in patients with chronic alcoholism, a paracetamol overdose may be more toxic than in the rest of patients.

If you forget to take paracetamol cinfa

Do not take a double dose to make up for missed doses, just take the forgotten dose when you remember and take subsequent doses with the time between doses indicated in each case (at least four hours).

If you stop taking paracetamol cinfa

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.

The possible side effects are:

Rare side effects (can affect 1 out of every 1000 people): malaise, lowered blood pressure (hypotension) and increased blood transaminase levels.

Very rare side effects (can affect up to 1 out of every 10,000 people): kidney diseases, cloudy urine, allergic dermatitis (skin rash), jaundice (yellow skin colour), blood abnormalities (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar). Very rarely cases of severe skin reactions have been reported.

Paracetamol may damage the liver when taken at high doses or during prolonged treatments.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

Talk to your doctor or pharmacist if you experience any kind of side effects, even if they are not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store paracetamol cinfa

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

Do not store at a temperature above 25°C.

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. 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 cinfa contains

The active substance is paracetamol.

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

What the product looks like and contents of the pack

Paracetamol cinfa 1 g tablets are supplied in the form of oblong, biconvex scored white tablets for administration via the oral route.

The product is supplied in packs containing 20 tablets.

Marketing authorisation holder and manufacturer**Marketing authorisation holder**

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