

Package leaflet: Information for the user

paracetamol cinfa 1g tablets

Please read this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet, as you may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others even if they have the same symptoms, as it may harm them.
- If you get any side effects, talk to your doctor or pharmacist, even for side effects not listed in this leaflet. (see section 4)

In this leaflet:

1. What paracetamol cinfa is and what it is used for.
2. Before taking paracetamol cinfa.
3. How to take paracetamol cinfa.
4. Possible side effects.
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1. What Paracetamol cinfa is and what it is used for

This drug belongs to a group of drugs called analgesics and antipyretics. paracetamol cinfa is indicated for the symptomatic treatment of mild to moderate pain and fever in adults and adolescents over 15 years.

2. Before taking paracetamol cinfa

Do not take paracetamol cinfa

If you are allergic to paracetamol or to any of the other ingredients in this medicine (listed in section 6).

Warnings and Precautions

Do not take more than the dose recommended in section 3, "How to take paracetamol cinfa", and check you are not taking any other medicines that contain paracetamol simultaneously.

Patients with asthma who are sensitive to aspirin should consult their doctor before taking this medicine.

Consult your doctor, pharmacist or nurse before taking Paracetamol Cinfa:

- If you have liver, kidney, heart or lung disease or anaemia (decreased haemoglobin level in the blood, due to a decrease in red blood cells); if you have Gilbert's syndrome (mild jaundice); if you are dehydrated or suffer chronic malnutrition.

- You should consult your doctor before taking this drug if you are taking medication to treat epilepsy. When used at the same time, this decreases the effectiveness and increases the potential hepatotoxicity of paracetamol, particularly in treatments with high doses of paracetamol.
- Chronic alcoholics should be careful not to take more than 2g/24 hours of paracetamol.
- If the pain continues for more than 5 days, the fever continues for more than 3 days, the pain or fever worsens or other symptoms develop, you should consult a doctor to re-evaluate the clinical situation.

Children and adolescents

Children under 12 should consult their doctor or pharmacist, as there may be other paracetamol products available with a more suitable dose for these patients.

Interference with analytical tests

If you are having any analytical tests (for example, blood or urine), tell your doctor that you are taking this medication as it can alter the results.

Paracetamol may alter the values of analytical determinations of uric acid and glucose.

Taking paracetamol cinsa with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might need to take other drugs.

In particular, if you are using any of the following medicines, you may need to change the dose of some or discontinue their treatment:

- Medicines to prevent blood clots: Oral anticoagulants (acenocoumarol, warfarin).
- Medicines to treat epilepsy: Antiepileptic drugs (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 to lower cholesterol levels in blood (cholestyramine).
- Medicines used to increase urine output (loop diuretics such as furosemide group drugs).
- Medicines used to treat gout (probenecid and sulfinpyrazone).
- Medicines used to prevent nausea and vomiting: metoclopramide and domperidone.
- Medicines used to treat high blood pressure (hypertension) and alterations in heart rhythm (arrhythmia): Propranolol.

Do not use with other analgesics (medications that reduce pain) without consulting a doctor.

As a general rule, you should inform your doctor or pharmacist if you are being treated with other medications. When undergoing oral anticoagulant therapy, occasionally it can be given as a painkiller of choice.

Taking paracetamol cinsa with food, drink and alcohol

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

Taking this medication with food does not affect its efficacy.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking any medicine.

If you are pregnant or believe you might be pregnant, contact your doctor before taking this medicine. The use of drugs during pregnancy can be dangerous for the embryo or foetus, and should be monitored by your doctor.

Breastfeeding

Consult your doctor or pharmacist before taking any medicine.

Paracetamol passes into breast milk, so women who are breastfeeding should consult their doctor or pharmacist before taking this medicine.

Driving and using machines

The influence of paracetamol on the ability to drive and use machines is nil or negligible.

3. How to take paracetamol cinfra

Follow the directions for taking this medicine exactly as provided by your doctor or pharmacist. If in doubt, refer back to your doctor or pharmacist.

The recommended dose is:

- *Adults and adolescents over 15 years (and weighing more than 50kg):* The usual dose is 1 or half a tablet (1g, 500 mg of paracetamol) as needed. The dose must be administered at least 4 hours apart, and with no more than 4 tablets (4g) in a 24 hour period.

- *Adults and adolescents over 12 years (and weighing more than 43kg):* The usual dose is half a tablet (500 mg of paracetamol). The dose must be administered at least 4 hours apart, and with no more than 5 doses (2.5g or two and a half tablets) in a 24 hour period.

- *Patients with liver disease:* You should consult your doctor before taking this medication, and take the amount of medicine prescribed by your doctor with a minimum interval between doses of 8h. No more than 2g of paracetamol divided in 2 doses should be taken in a 24-hour period.

- *Patients with kidney disease:* You should consult your doctor before taking this medication. Take a maximum of half a tablet (500mg) per dose. Depending on your disease, your doctor will inform you if you should take your medication with a minimum interval of 6 or 8 hours.

No more than 2g of paracetamol divided in various doses should be taken in a 24-hour period, and no more than 500mg should be taken at a time.

- *Elderly patients:* You should consult your doctor.

- *Use in children:* Do not use in children under 12 years.

Method of administration

Paracetamol cinfa should be taken orally.

The tablet can be divided into equal doses.

Depending on your preference, the tablets may be ingested directly, broken in half or taken with the help of a glass of liquid, preferably water.

Consult your doctor or pharmacist if you have any questions.

If you feel that the effect of paracetamol cinfa is too strong or too weak, talk to your doctor or pharmacist.

When less than 1g of paracetamol per dose is required, you should take other available paracetamol products to suit the required dosage.

If you take more paracetamol cinfa than you should

Consult your doctor or your pharmacist immediately. For accidental ingestion or overdose, go to a medical centre immediately indicating the medicine and the amount ingested.

If you have taken an overdose, immediately go to a medical centre even if you have no symptoms, as these often do not become apparent until 3 days after taking the overdose, even in cases of severe poisoning.

Symptoms of overdose may include: dizziness, vomiting, loss of appetite, yellowish colouration of the skin and eyes (jaundice) and abdominal pain.

Treatment of an overdose is most effective if started within 4 hours after ingestion of the drug.

Patients taking barbiturates or chronic alcoholics may be more susceptible to the toxicity of a paracetamol overdose.

If you forget to take Paracetamol Cinfa

Do not take a double dose to make up for a missed dose; just take the missed dose when you remember, while following the required separation between doses indicated in each case (at least 4 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, paracetamol cinfa can cause side effects, although not everybody gets them.

Rare adverse effects that may occur (in no more than 1 per 1,000 people) are: discomfort, lowering of blood pressure (hypotension) and increased transaminase levels in the blood.

Very rare side effects that may occur (in no more than 1 per 10,000 people) are:

Kidney disease, cloudy urine, allergic dermatitis (rash), jaundice (yellowish colouration of the skin), blood disorders (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar). Cases of severe skin reactions have been reported.

Paracetamol may cause liver damage when taken in high doses or during prolonged treatment.

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

Very rare cases of severe skin reactions have been reported.

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 paracetamol cinfa after the expiry date on the carton after "EXP". The expiry date is the last day of that month.

Medicines should not be disposed of via wastewater or household waste. If in doubt, ask your pharmacist how to dispose of medicines you no longer require. This helps to protect the environment.

6. Contents of the pack and other information

paracetamol cinfa composition

- The active ingredient is paracetamol.
- The other ingredients are: Corn starch, stearic acid, povidone, crospovidone, microcrystalline cellulose and magnesium stearate of vegetable origin.

contents of the pack

paracetamol cinfa 1g is in packs of 20 tablets.

Marketing authorisation holder and manufacturer

LABORATORIOS CINFA, SA
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