

## **Package leaflet: information for the user**

### **paracetamol cinfa 650 mg film-coated 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 symptoms 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 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 belongs to a group of medicines called analgesics and antipyretics.

This medicine is used for the occasional treatment of mild to moderate pain and fever.

#### **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 exceed 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 flu and the common cold, should be avoided, since high doses of paracetamol may damage the liver. Do not use more than one medicine containing paracetamol without first consulting your doctor.
- Asthmatic patients who are sensitive to acetylsalicylic acid should consult their doctor before taking this medicine.
- If you suffer from liver, kidney, heart or lung disease, or you have anaemia (reduced blood haemoglobin, whether or not because of reduced red blood cells) or chronic malnutrition or dehydration, you should consult your 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, the efficacy of paracetamol is reduced, and its liver toxicity increased, especially in treatments with high doses of paracetamol.
- Chronic alcoholics should take care not to take more than three 650 mg tablets of paracetamol in 24 hours.

### **Children and adolescents**

This medicine should not be used in children under 6 years of age (weighing below 22 kg), as the administration of doses of less than 325 mg of paracetamol is not permitted.

In children and adolescents under 15 years of age talk to your doctor or pharmacist, as other more suitable dosage forms of paracetamol may be available for these patients.

### Interaction with laboratory tests

If you are to undergo any laboratory tests (including blood or urine tests, skin tests with allergens, etc.), tell your doctor that you are taking this medicine, because it may alter the results of such tests. 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.

Paracetamol may interact with the following medicines:

- Medicines to prevent blood clots: oral anticoagulants (acenocoumarol, warfarin).
- Medicines used to prevent nausea and vomiting: metoclopramide and domperidone.
- Medicines used to treat high blood pressure (hypertension) and heart rhythm abnormalities (arrhythmias): propranolol.

Simultaneous use with other analgesics (medicines used to treat pain) should be avoided, unless approved by your doctor.

In case of treatment with oral anticoagulants, it may be administered occasionally as the analgesic of choice.

### **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 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 do not decrease or if you need to take the medicine more often.

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

### **Driving and using machines**

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

### **Paracetamol cinfa contains castor oil**

This medicine may cause an upset stomach and diarrhoea as it contains castor oil.

### **Paracetamol cinfa contains sodium**

This medicine contains less than 23 mg (1 mmol) of sodium per tablet; it is essentially "sodium-free".

## **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.

The recommended dose is:

**Adults and adolescents over 15 years of age (and weighing over 50 kg)**

The recommended dose for adults is half to 1 tablet (325 mg to 650 mg of paracetamol) every 4-6 hours. Do not take more than 4 and a half tablets (approximately 3 g) every 24 hours.

The minimum interval between doses must be no less than 4 hours.

Adults with a low weight (40 kg or less) can follow the dosage recommendations for children, although there are other more suitable dosage forms of paracetamol for these patients; talk to your doctor or pharmacist.

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.

**Patients with kidney or liver disease**

Consult your doctor.

**Elderly patients**

Consult your doctor.

**Use in children and adolescents**

The doses defined based on weight must be respected. The child's age by weight is for information purposes only.

The recommended daily dose of paracetamol is approximately 60 mg/kg/day, distributed in 4 or 6 daily doses, in other words 15 mg/kg every 6 hours or 10 mg/kg every 4 hours.

*Children under 6 years of age*

Talk to your doctor, as there are other more suitable dosage forms for these patients.

*Children weighing between 22 and 33 kg (approximately 6 to 9 years of age):*

Half a tablet (325 mg) of paracetamol every 4-6 hours, depending on the child's weight, up to a maximum of 2-3 tablets (1300-1950 mg of paracetamol) every 24 hours, depending on the patient's weight. The time interval between each administration, and the maximum daily dose, will depend on the patient's weight.

*Children weighing between 33 and 43 kg (approximately 10 to 12 years of age):*

Half a tablet (325 mg of paracetamol) every 4 hours up to 1 tablet every 6 hours, depending on the patient's weight. The maximum dose will be 3-4 tablets of paracetamol (1950-2600 mg of paracetamol) every 24 hours, depending on the patient's weight.

*Adolescents weighing more than 43 kg (over 13 years of age):*

One tablet (650 mg of paracetamol) every 4-6 hours, but no more than 4 tablets every 24 hours (2600 mg of paracetamol).

If the pain lasts for more than 5 days (more than 3 days in children) or 2 days for sore throat, the fever lasts for more than 3 days, or if the pain or fever worsen or other symptoms appear, stop the treatment and consult your doctor.

**Method of administration**

The tablets should be taken orally with a glass of water.

The tablet can be divided into equal doses.

For fast pain relief, take this medicine without food.

If you think the effects of paracetamol are too strong or too weak, tell your doctor or pharmacist.

### **If you take more paracetamol cinsa than you should**

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately, specifying the medicine and the amount ingested. 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 eyes (jaundice) and abdominal pain.

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

Treatment includes:

- Gastric lavage.
- Oral administration of activated charcoal.
- Haemodialysis.
- Administration of suitable doses of acetylcysteine.

Patients treated with barbiturates (a type of sedative) or patients with chronic alcoholism may be more susceptible to paracetamol overdose toxicity.

### **If you forget to take paracetamol cinsa**

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

Take the forgotten dose as soon as you remember and take subsequent doses with the time between doses indicated in each case (4-6 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.

**Rare side effects** (may affect up to 1 in 1,000 people): malaise, lowered blood pressure (hypotension) and increased blood transaminase levels.

**Very rare side effects** (may affect up to 1 in 10,000 people): Kidney diseases, cloudy urine, serious skin reactions, allergic dermatitis (skin rash), jaundice (yellow skin colour), blood abnormalities (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar).

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

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

## **5. How to store paracetamol cinsa**

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 containers and 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. Each tablet contains 650 mg of 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) (potato), hydrogenated castor oil, povidone (E-1201).
- Tablet coating: macrogol 6000, hypromellose 606 and hypromellose 615 (E-464).

### **What paracetamol cinfa looks like and contents of the pack**

paracetamol cinfa 650 mg film-coated tablets are oblong, coated, biconvex, white tablets scored on one side and with the code on the other.

Each pack contains 20 film-coated tablets.

## **MARKETING AUTHORISATION HOLDER**

Laboratorios Cinfa, S.A.  
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