

## 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 cinfa as this may alter the results.

### **Paracetamol cinfa 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.

#### **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 cinfa**

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

### **3. How to take paracetamol cinfa**

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

paracetamol cinfa 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 cinfa 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 cinsa**

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 cinsa**

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 cinsa 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 cinsa 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.  
C/ Olaz-Chipi, 10 - Polígono Industrial Areta 31620  
Huarte - Pamplona (Navarre)-Spain

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