

## Package leaflet: Information for the patient

### ParaCeta 500 mg tablets

(paracetamol)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

This medicine is available without a prescription. However, in order to get the best results from the treatment, you must carefully follow the instructions for use of the medicine.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- 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 a doctor if you do not feel better or if you feel worse after 3 days.

#### What is in this leaflet

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

#### 1. What ParaCeta is and what it is used for

ParaCeta 500 mg tablets is an analgesic and antipyretic and is used for the symptomatic treatment of most conditions associated with mild to moderate pain and fever, e.g. headache, including migraine, toothache, back pain, rheumatic and muscular pain, menstrual pain, sore throat.

#### How ParaCeta works

ParaCeta contains paracetamol - analgesic and antipyretic. ParaCeta does not irritate the stomach.

#### 2. What you need to know before you use ParaCeta

**Remember: ParaCeta contains paracetamol.**

**Do not take with other medicines containing paracetamol.**

Do not take ParaCeta if you are allergic to paracetamol or any of the other ingredients.

**Ask your doctor or pharmacist for advice before taking ParaCeta if:**

- you have kidney or liver disease;
- you are taking metoclopramide, domperidone (used to treat nausea and vomiting) or cholestyramine used to lower cholesterol;
- you are taking anticoagulants - medicines used to thin the blood;
- you must take a painkiller every day for a long time;
- you have had trouble breathing when using this or a similar medicine in the past;
- you abuse alcohol;
- you are pregnant or breast-feeding.

## **Other medicines and ParaSeta**

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

## **Pregnancy and breast-feeding**

Epidemiological studies in human pregnancy did not indicate any risk with paracetamol at the recommended doses.

Paracetamol is excreted in breast milk, but not in clinically relevant amounts. The available data do not indicate that paracetamol is contraindicated during lactation.

## **3. How to take ParaCeta**

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

For oral use.

### **Adults, including those over 60, and children 12 years and older:**

2 (two) tablets every 4 hours as needed. Do not take at intervals of less than 4 hours and do not exceed 8 tablets (4000 mg paracetamol) for a period of 24 hours.

**Children (from 6 to 12 years)** – ½ (half) to 1 (one) tablet to be given every 4 hours if necessary. No more than 4 tablets should be given in 24 hours.

Do not give children more than 3 (three) days without consulting a doctor.

Do not give to children under 6 years of age.

If symptoms persist, consult your doctor.

**Do not exceed the recommended dose.**

### **If you take more ParaCeta than you should**

Taking too much can damage the liver. If you take more than the recommended dose, seek medical attention immediately, even if you feel well.

### **If you forget to take ParaCeta**

Take the dose when you remember. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking ParaCeta**

ParaCeta can be stopped at any time, depending on your condition.

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.

Side effects with paracetamol are rare. Allergic reactions may occur, e.g. rash. Although rare, changes in the blood picture may occur. Stop taking the medicine and consult your doctor if:

- you notice an allergic reaction such as itching, rash, breathing problems, swelling of the lips, tongue, throat or face;

- mouth ulcers appear;
- you have had trouble breathing when using acetylsalicylic acid or non-steroidal anti-inflammatory drugs;
- you have unexpected bleeding or a tendency to bruise.

### **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. You can also report side effects directly via the national reporting system:

Bulgarian Drug Agency 8  
 Damyan Gruev Str.  
 1303 Sofia  
 Tel.: + 359 2 890 34 17  
 website: [www.bda.bg](http://www.bda.bg)

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

## **5. How to store ParaCeta**

Keep this medicine out of the sight and reach of children.  
 Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton. 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 ParaCeta contains**

- The active substance is paracetamol
- The other ingredients are: lactose monohydrate, povidon, corn starch, sodium starch glycolate (type A), magnesium stearate, silica, colloidal, anhydrous

### **What ParaCeta looks like and contents of the pack**

Each carton of ParaCeta 500 mg tablets consists of 1 blister containing 10 white round tablets with a score line on one side.

### **Marketing Authorisation Holder and Manufacturer:**

Tchaikapharma High Quality Medicines Inc.  
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*For any information about this medicine, please contact the Marketing Authorization Holder:*

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