

## **PACKAGE LEAFLET: Information for the patient**

### **PARACETAMOL**

Tablets – 500 mg

(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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Paracetamol is and what it is used for
2. Before you take Paracetamol
3. How to take Paracetamol
4. Possible side effects
5. How to store Paracetamol
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### **1. WHAT PARACETAMOL IS AND WHAT IT IS USED FOR**

The place and mechanism of the analgesic effect of paracetamol are not completely elucidated. Paracetamol lowers temperature by directly acting in the center of thermoregulation in the hypothalamus; this center stimulates the process of temperature lowering through peripheral vasodilatation and through sweating. Paracetamol is as effective as aspirin in the inhibition of prostaglandin-synthetase in the central nervous system, but the peripheral inhibition of the synthesis of prostaglandins is minimal, which may be the cause for the absence of antirheumatic or anti-inflammatory effects that are with clinical importance. The analgesic and antipyretic

effects of paracetamol are generally comparable with those of aspirin, but aspirin has a better effect than paracetamol against pain with an inflammatory origin.

Paracetamol does not inhibit the aggregation of thrombocytes and does not cause ulcers in the digestive tract.

Paracetamol is indicated as a suitable analgesic and antipyretic, especially in aspirin - sensitive patients, for patients with blood coagulation disorders or with stomach ulcer:

- in mild to moderate severe pain with different localizations (headache, toothache, neuralgia, myalgia, menstrual pain, post-traumatic and post-surgical pain);
- for temperature lowering in fever conditions.

## **2. BEFORE YOU TAKE PARACETAMOL**

### **Do not take Paracetamol if you:**

- are hypersensitive to paracetamol or to any of the excipients of the tablet;
- have a severe liver or kidney damage;
- have head and brain damage;
- have high intracranial pressure;
- have genetic glucose-6-phosphate dehydrogenase deficiency;
- have respiratory disorders.

### **Take special care with Paracetamol**

Ask your doctor before taking Paracetamol.

Care should be taken:

- in patients with mild renal failure;
- in patients with hepatic impairment (mild to moderate hepatic insufficiency, Gilbert Syndrome, acute hepatitis);
- in concomitant administration of drugs that affect the liver function;
- in patients who suffer from haemolytic anemia;
- in patients with alcohol dependence;
- in patients who suffer from chronic dehydration and malnutrition;
- in the period of pregnancy and breastfeeding;
- during long-term use; in this case the liver function tests should be performed.

During treatment with paracetamol, before taking any other drug, make sure it does not contain the same active substance, as high doses of paracetamol may cause serious side effects.

### **Taking other medicines**

Concomitant treatment with other drugs may affect or be affected by paracetamol.

Please contact your doctor or pharmacist if you are taking or you have recently taken other drugs, including those taken without a prescription. Do not forget to inform your doctor for the treatment with Paracetamol if you have been given another drug during treatment, especially the following:

- metoclopramide, domperidone – increase the speed of absorption of paracetamol
- cholestyramine – reduces the speed of absorption of paracetamol
- warfarin, other coumarins – the anticoagulant effect may be enhanced by prolonged daily use of paracetamol with increased risk of bleeding.
- rifampicin, barbiturates, some anti-epileptic drugs (carbamazepine, hydantoins) – have the same metabolic pathway as paracetamol.
- zidovudine – neutropenia often occurs probably due to the reduced metabolism of zidovudine.
- isoniazid – reduces paracetamol clearance.
- chloramphenicol – paracetamol increases its plasma concentration.

Other drugs that can interact with Paracetamol are:

- sulfinpyrazone;
- ethyl alcohol;
- active charcoal;
- intravenous busulphan.

### **Pregnancy and breastfeeding**

If necessary, Paracetamol can be used during pregnancy. You should use the lowest possible dose that reduces your pain and / or your fever and use it for the shortest time possible. Contact your doctor if the pain and / or fever are not reduced or if you need to take the medicine more often.

Paracetamol should be used according medical advice during breastfeeding. You should know that paracetamol passes into breast milk.

### **Driving and using machines**

Paracetamol does not affect driving and using machines.

### **3. HOW TO TAKE PARACETAMOL**

Always take Paracetamol as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Take the tablets orally. Swallow each tablet with water.

*Adults:* from 0.5 - 1 g, 3 - 4 times daily. The maximal daily dose for the short - term treatment is 4 g, while for the long - term treatment 2.5 g.

*Adolescents 12 – 15 years old:* 1 tablet, which can be repeated after 4 – 6 hours. 4 doses per day should not be exceeded.

*Children 6 – 12 years old:* ½ tablet, 3 – 4 times daily.

*Children under 6 years of age:* the use of tablets is not recommended.

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

If you take more Paracetamol than you should or if the children have taken this drug incorrectly, please contact your doctor, hospital, or call the emergency to take an opinion for the risk and advice for the actions to be taken.

Symptoms of overdose include: nausea, vomiting, anorexia, abdominal pain and severe hepatic damage.

### **If you forget to take Paracetamol**

If you forget a dose (or more doses), take the following dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for the forgotten dose (doses).

If you have any other question on the use of this medicinal product, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all other drugs, paracetamol may cause side effects, although not everybody manifests them. Inform your doctor for the following side effects that may appear to you:

- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath, rash or hives;

Very rare cases of serious skin reactions have been reported.

Side effects are listed below according to their frequency:

**Very common:** can affect more than 1 in 10 patients.

**Common:** can affect 1 to 10 patients among 100.

**Uncommon:** can affect 1 to 10 patients among 1,000.

**Rare:** can affect 1 to 10 patients among 10,000.

**Very rare:** can affect less than 1 patient in 10,000.

**Not known:** frequency cannot be estimated from the available data.

##### Rare side effects

Agranulocytosis, thrombocytopenia, leucopenia, hemolytic anemia, neutropenia, hypersensitivity (excluding angioedema), depression, confusion, hallucinations, tremor, headache, abnormal vision, oedema, hemorrhage, abnormal pain, diarrhea, nausea, vomiting, increased transaminases, jaundice, hepatic necrosis, pruritus, rash, sweating, purpura, urticaria, angioedema, dizziness (excluding vertigo), malaise, pyrexia, sedation, overdose, and poisoning.

##### Very rare side effects

Pancytopenia, hypersensitivity (angioedema, nausea, hypotension, hyperhidrosis, shock, anaphylactic reaction), hypoglycemia, bronchospasm in patients sensitive to aspirin and other NSAIDS, hepatotoxicity, serious skin reactions, renal impairment, nephrite interstitial, hematuria (blood in urine), enuresis (involuntary urination).

##### Unknown side effects

Acute generalized exanthematous pustulosis, toxic necrolysis, drug-induced dermatosis, Stevens-Johnson syndrome.

If any of the side effects worsen, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **5. HOW TO STORE PARACETAMOL**

Keep out of the sight and reach of children!

Do not use Paracetamol after the expiry date which is stated on the package.

Do not store above 25°C!

Store in the original packaging to protect it from light!

## **6. FURTHER INFORMATION**

### **What Paracetamol contains**

**The active substance** is paracetamol. One tablet contains 500 mg paracetamol.

**The excipients** are: microcrystalline cellulose, sodium starch glycolate, purified talc, magnesium stearate, colloidal anhydrous silica.

### **Content of the pack**

Carton box with 20 or 60 tablets.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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