

## **Package Leaflet: Information for the user**

### **PARALIEF 500mg tablets**

#### **paracetamol**

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Paralief 500 mg Tablets are and what they are used for
2. What you need to know before you take Paralief 500 mg Tablets
3. How to take Paralief 500 mg Tablets
4. Possible side effects
5. How to store Paralief 500 mg Tablets
6. Contents of the pack and other Information

#### **1. What Paralief 500 mg Tablets are and what they are used for**

Paralief tablets contain the active ingredient paracetamol. Paracetamol belongs to a group of medicines known as non-narcotic analgesics, which are used to relieve pain and to lower temperature. Paralief Tablets are indicated for the relief of headaches, musculoskeletal disorders, period pain, toothache, colds and flu and the pain of osteoarthritis.

#### **2. What you need to know before you take Paralief 500 mg Tablets**

##### **Do not take Paralief 500 mg Tablets**

- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6). An allergic reaction can include a rash, itching or shortness of breath
- If you are under 6 years

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Paralief 500 mg Tablets

- if you have kidney problems
- if you have liver problems
- if you have liver disease caused by alcohol. You may be more sensitive to the toxic effects of paracetamol
- if you have a hereditary disease called Gilbert's syndrome
- if you have a high fever, signs of a secondary infection or if symptoms persist for more than a few days.
- if you are taking other medicines affecting liver function
- if you have Glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency)
- if you have haemolytic anaemia (abnormal breakdown of red blood cells)
- if you have glutathione deficiency
- if you are dehydrated or are suffering from chronic malnutrition
- if you weigh less than 50kg
- if you are elderly
- if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin.

Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

You may be more at risk of the side effects of paracetamol. Speak to your doctor or pharmacist if any of these apply to you.

Medicines containing paracetamol should only be used for a few days and not in high doses without advice from your doctor or dentist.

Prolonged use of paracetamol, especially in combination with other pain killing medicinal products, may cause kidney problems.

### **Other medicines and Paralief 500 mg Tablets**

You must not take **any other medicines that contain paracetamol** while you are taking this medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Other pain relieving medicines (e.g. morphine)
- Barbiturates used in the treatment of insomnia, epilepsy, or as an anaesthetic
- Drugs used to prevent clotting (e.g. warfarin and other coumarins)
- Zidovudine (AZT) used in HIV infections and AIDS
- Metoclopramide or domperidone used for nausea and vomiting
- Cholestyramine (used in high cholesterol)
- Propantheline used for irritable bowel syndrome or in the treatment of stomach ulcers
- Probenecid used in the treatment of gout.
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

### **Paralief 500 mg Tablets with food and alcohol**

There is no significant effect on absorption of paracetamol when taken with a meal.

There is an increased risk of side effects when alcohol is taken in combination with paracetamol.

### **Pregnancy and breast-feeding**

If necessary, Paralief 500 mg Tablets 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 or pharmacist if the pain and/or fever are not reduced or if you need to take the medicine more often.

### **Driving and using machines**

Paralief 500 mg tablets have no influence on the ability to drive and use machines.

## **3. How to take Paralief 500 mg Tablets**

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

The recommended dose is:

### **Adults, the elderly and young persons aged 16 and over**

The minimum effective dose should be used for the shortest time necessary to relieve symptoms.

Take one to two tablets three to four times daily with a drink of water. Do not take more than eight tablets in 24 hours.

The maximum daily dose should not exceed 60 mg / kg / day (up to four tablets in 24 hours) in the following situations:

- weight of less than 50 kg
- dehydration
- chronic malnutrition

Use in renal impairment:

In mild to moderate kidney impairment, the recommended dose is one tablet every 6 hours.

In severe kidney impairment, the recommended dose is one tablet every 8 hours.

Use in liver impairment:

In case of problems with your liver please consult your doctor. Your doctor may decide to reduce the dose.

In chronic alcoholics, a maximum of four tablets in 24 hours should not be exceeded.

**Use in children and adolescents**

**For children 6 to 9 years of age:**

Give half a tablet with a drink of water, every 4 to 6 hours as required. A maximum dose of two tablets daily should not be exceeded.

**For children 10 to 11 years of age:**

Give one tablet with a drink of water, every 4 to 6 hours as required. A maximum dose of four tablets daily should not be exceeded.

**For adolescents 12 to 15 years of age:**

Give one to one and a half tablets with a drink of water, every 4 to 6 hours as required. A maximum of six tablets daily should not be exceeded.

**Children under 6 years:** Not recommended.

**DO NOT EXCEED THE STATED DOSE.**

The tablets should be swallowed with a little water.

Consult your doctor if there is no improvement within 24 hours.

This product should only be used when clearly necessary.

Prolonged use without medical supervision may be harmful.

**If you take more Paralief tablets than you should**

If you accidentally take too many tablets, contact your nearest hospital casualty department or your doctor **IMMEDIATELY**.

**IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE, BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE.**

**If you forget to take Paralief tablets:**

If you forget to take a dose, take it as soon as you remember if required to relieve pain. Do not take two doses together.

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 following side effects may sometimes occur.

**If you have an allergic reaction to this medicine see your doctor straight away.**

An allergic reaction may include:

- skin rashes, flaking skin, boils, sore lips and mouth, swelling of the face, fever
- sudden wheezing, fluttering or tightness of the chest or collapse.

**If you get any of the following side effects stop taking this medicine and see your doctor as soon as possible:**

- difficulty breathing, sweating, nausea, drop in blood pressure

- bruising more easily, sore throat or other signs of infection (these may be signs of a blood disorder).
- serious skin reactions, very rare cases of which have been reported.

If paracetamol is taken for a long time, it may lead to liver and kidney problems.

Not Known (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

## **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:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store Paralief 500 mg Tablets**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture. Keep the blister in the outer carton in order to protect from light.

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 Paralief Tablets contain**

The active substance is paracetamol. Each tablet contains 500 mg paracetamol.

The other ingredients are maize starch, pregelatinised maize starch, magnesium stearate and colloidal anhydrous silica.

### **What Paralief 500 mg Tablets look like and contents of the pack**

White capsule-shaped tablet marked with the code 293 and partial breaklines on one side and the Clonmel logo on the reverse.

Pack sizes: 12 and 24 tablets in blisters.

Not all pack sizes may be marketed.

### **Marketing Authorisation holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### **Manufacturer**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Sofarimex, Av.das Indústrias, Alto do Colaride/Agualva, 2735-213 Cacém, Portugal

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

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