

Package leaflet: Information for the user

Paralief 500 mg soft capsules

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 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 in the treatment of fever and after 5 days in the treatment of pain.

What is in this leaflet

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

1. What Paralief is and what it is used for

Paralief belongs to the group of medicines, which have an analgesic and fever-reducing effect.

Paralief is used for the short-term treatment of mild to moderate pain such as:

- headache
- toothache
- muscle pain
- back pain (lumbago)
- fever and pain with flu and colds

You must talk to a doctor if you do not feel better or if you feel worse after 5 days (after 3 days in case of fever).

2. What you need to know before you take Paralief

DO NOT take Paralief

- 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 Paralief if you

- suffer from a liver or kidney disorder
- have moderate to severe kidney problems
- have mild to severe liver problems
- have Gilbert's syndrome
- have glucose-6-phosphate dehydrogenase deficiency
- have haemolytic anaemia
- are dehydrated
- have chronic malnutrition
- regular alcohol consumption
- are an asthmatic patient who is sensitive to acetylsalicylic acid

- have an infection that becomes serious and is accompanied by deep, rapid and difficult breathing, nausea and vomiting after taking paracetamol. Contact a doctor immediately if you experience these symptoms.

Consult your doctor if any of the above warnings applies to you or has applied to you in the past.

Do not take more medicine than recommended (see section 3.: How to take Paralief).

Simultaneous use of this medicine with other paracetamol-containing medicines, such as flu and cold medicines should be avoided as high doses can lead to liver damage. Do not use more than one medicine containing paracetamol without consulting your doctor.

During treatment with Paralief, tell your doctor straight away if:

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).

Children

Paralief is not suitable for children under 9 years of age.

Other medicines and Paralief

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

Contact your doctor or pharmacist before you use paracetamol in case you use one of the following medicines:

- **barbiturates** (sleeping pills and anaesthetics)
 - certain **antidepressants**
 - **probenecid** (an anti-jaundice medicine)
 - **chloramphenicol** (an antibiotic)
 - **metoclopramide** or **domperidone** (medicines to prevent nausea and vomiting)
 - **colestyramine** (an anticholinergic)
 - **warfarin** and **other coumarins** (anticoagulants)
 - **zidovudine** (a medicine used for the treatment of AIDS)
 - **salicylamide** (an analgesic)
 - **isoniazid** (a tuberculosis medicine)
 - **lamotrigine** (to treat epilepsy)
- flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Paracetamol can influence the test results of different laboratory tests.

Paralief with food, drink and alcohol

Do not drink alcohol whilst taking Paralief.

In case of chronic alcohol abuse, the dose of paracetamol should not be higher than 4 capsules (2,000 mg) a day. The long-term use of paracetamol in combination with alcohol is likely to cause liver damage.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

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

Breast-feeding

Although paracetamol is excreted in small quantities in breast milk, it does not have any adverse effect on children who are breast-fed. Paracetamol can be used at the recommended dose for a short time while breast-feeding.

Driving and using machines

As far as is known, paracetamol does not have any effect on the ability to drive or use machines.

Paralief contains sorbitol

This medicine contains 108 mg sorbitol in each capsule. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Paralief contains propylene glycol

This medicine contains 20 mg propylene glycol in each capsule.

3. How to take Paralief

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

Always use the lowest effective dose to relieve your symptoms.

If you take too much paracetamol, it can seriously damage your liver. Do not use this medicine if you are taking other medicines containing paracetamol to treat pain, fever, symptoms of a cold or flu, on medical prescription or otherwise do not exceed the indicated dosage.

Dosage

The effective daily dose may not exceed 60 mg/kg/day (up to 2,000 mg/day) in the following situations:

- adults who weigh less than 50 kg
- mild to moderate hepatic insufficiency, Gilbert's syndrome (familial non-haemolytic jaundice)
- dehydration
- chronic malnutrition

Use in adults and adolescents older than 15 years of age (> 55 kg body weight)

Take 1 or 2 capsules (500-1,000 mg) at a time, with a maximum of 6 capsules (3,000 mg) in 24 hours.

Use in children and adolescents under 15 years of age (<55 kg body weight)

Children weighing less than 30 kg (approx. below 9 years of age)

Do not give to children under 9 years. For children under 9 years, other formulations and dosage strengths are available which may be more appropriate.

Children and adolescents weighing 31 to 55 kg (approx. from 9 to 15 years of age)

- For children weighing 31 to 40 kg (approx. 9 to 12 years): take 1 capsule (500 mg) at a time, with a maximum of 3 to 4 capsules in 24 hours.
- For adolescents weighing 41 to 55 kg (approximately 12 to 15 years): take 1 capsule (500 mg) at a time, with a maximum of 4 to 6 capsules in 24 hours.

The lower frequency of administration is intended for the youngest children in the relevant age group. For children weighing less than 50 kg (approximately below 12 years of age) the daily dose should not be higher than 60 mg/kg body weight.

Instructions on use

- There must be at least 4 hours between two intakes.
- Do not use in combination with other paracetamol-containing products.
- Do not exceed the stated dose.

Method of administration

For oral use.

The capsules should be swallowed whole with sufficient water.

Duration of treatment

If your pain lasts for longer than 5 days or your fever lasts for longer than 3 days, these symptoms become worse or if other symptoms occur, stop the treatment and consult a doctor.

The use of high daily doses of paracetamol should be avoided for prolonged periods of time since it increases the risk of suffering adverse effects such as liver damage.

If pain and/or fever symptoms recur, treatment can be repeated based on the stated dosage regimen.

If you take more Paralief than you should

If you have taken too much of this medicine, immediately contact your doctor or pharmacist. When a higher dose than recommended is taken, nausea, vomiting and a lack of appetite can occur. Taking several times the maximum daily dose at once can cause very severe liver damage. A loss of consciousness does not usually occur, nevertheless, you should usually seek immediate medical help. If you do not act in time, the damage to your liver might be irreversible.

If you forget to take Paralief

Do not take a double dose to make up for a forgotten dose. Just continue with the recommended dosage schedule.

If you stop taking Paralief

The use of Paralief can be stopped suddenly without any consequences.

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 can occur:

Rare (may affect up to 1 in 1,000 people):

- blood abnormalities including agranulocytosis, thrombopenia, thrombocytopenic purpura, leukopenia and haemolytic anaemia
- allergies (excluding angioedema)
- abnormal liver function, liver failure, liver necrosis and jaundice
- itching (pruritus), rash, perspiration, purpura and nettle rash/hives (urticaria)
- overdose and intoxication
- depression, confusion and hallucinations
- tremor and headache
- blurred vision
- swelling of the feet, hands or other parts of the body (oedema)
- bleeding, gastric pain, diarrhoea, nausea, vomiting
- dizziness, fever and sleepiness

Very rare (may affect up to 1 in 10,000 people):

- reduction in the number of blood cells (pancytopenia)
- hypersensitivity reactions as a result of which treatment must be stopped, including angioedema, breathing difficulties, perspiration, nausea, hypotension, shock and anaphylaxis

- a feeling of tightness in the chest as a result of cramping respiratory muscles (bronchospasm) in people who are sensitive to acetylsalicylic acid and other NSAIDs (analgesics with anti-inflammatory and antipyretic activity)
- liver intoxication
- rash (exanthema)
- too low blood sugar level (hypoglycaemia)
- dark urine (sterile pyuria) and kidney reactions
- severe skin reactions

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

- severe skin rash which may include blistering or peeling of the skin (acute generalised exanthematous pustulosis, toxic epidermal necrolysis, drug-induced dermatosis and Stevens-Johnson syndrome)
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

After the long-term use of 6 to 8 capsules (3,000 to 4,000 mg of paracetamol) per day, liver damage is possible. This can also happen, if you take 12 capsules (6,000 mg of paracetamol) in one go.

If you experience a side effect which is not mentioned in this leaflet or which you consider to be serious, inform your doctor or pharmacist.

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Paralief

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 carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store in the original package in order to protect from moisture.

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 contains

- The active ingredient is paracetamol. Each capsule contains 500 mg of paracetamol.
- The other ingredients are: macrogol 400, propylene glycol (E 1520), silica, colloidal hydrated, purified water, gelatin, sorbitol liquid (E 420), titanium dioxide.

What Paralief looks like and contents of the pack

White opaque colour oval shape soft gelatin capsule containing off white to white colour suspension (approximately 19 mm length and 10 mm width).

Cardboard box with PVC/PVDC-Aluminium blisters containing 20 soft capsules.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

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

Manufacturer

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

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

Centrafarm Services B.V., Van de Reijstraat 31 E, 4814 NE Breda, The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands: Etos Paracetamol 500 mg liquid caps, zachte capsules

Ireland: Paralief 500 mg soft capsules

Portugal: PYRAMOL 500 mg cápsula mole

Slovakia: Parastad mäkké kapsuly

This leaflet was last revised in December 2024.