

Package leaflet: Information for the user

Paralief Extra Film-coated Tablets

Paracetamol 500 mg/Caffeine 65 mg

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, pharmacist or nurse have 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 your symptoms worsen or do not improve within 3 days for fever or 5 days for pain.

What is in this leaflet

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

1. What Paralief Extra is and what it is used for

The tablets contain two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

Paralief Extra are used for the symptomatic treatment of mild to moderate pain and/or fever.

This medicine is for use in adults, the elderly and children aged 12 years and over.

2. What you need to know before you take Paralief Extra

Do not take Paralief Extra:

- **If you are allergic** to paracetamol, caffeine or any of the other ingredients of this medicine (listed in Section 6).
- If you are **taking other medicines containing paracetamol**.
- If you are **under 12 years**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paralief Extra if you:

- have **liver** or **kidney problems**, including **alcoholic liver disease**.
- are underweight or malnourished.
- suffer from asthma and are sensitive to aspirin.
- have gout, hyperthyroidism or abnormal heart rhythm.

You may need to avoid using this product altogether or limit the amount of paracetamol that you take. A number of conditions including severe infection may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

Other precautions

Paralief Extra may affect the results of laboratory tests. If you have been asked to have blood, urine or other laboratory testing, remember to tell that you are taking Paralief Extra.

Children

Not recommended for children under 12 years of age.

Other medicines and Paralief Extra

Tell your doctor or pharmacist before taking these tablets if you are taking any other paracetamol-containing products or any prescribed medicines; particularly **metoclopramide** or **domperidone** (for nausea [feeling sick] or **vomiting** [being sick]) or **cholestyramine** (for **high cholesterol**).

Concomitant use with **blood thinning drugs (anticoagulants e.g. warfarin)** may lead to slight variations of INR values. If you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding. But you can still take **occasional** doses of Paralief Extra at the same time as anticoagulants.

Also tell your doctor if you are taking any of the following:

- some medicines used to treat infection (e.g. rifampicin, isoniazide, chloramphenicol, ciprofloxacin, enoxacin, or pipemidic acid)
- terbinafine (to treat fungal infections)
- zidovudine (to treat HIV)
- medicines to treat slow gastric emptying such as propantheline
- barbiturates and benzodiazepines (to treat anxiety and insomnia)
- lithium or fluvoxamine (to treat depression)
- disulfiram (to treat alcohol dependence)
- sympathomimetics (to raise low blood pressure or to treat nasal congestion)
- levothyroxine (to treat hypothyroidism)
- theophylline (to treat asthma)
- cimetidine (to treat heartburn and peptic ulcers)
- oral contraceptives
- nicotine used for smoking cessation
- epilepsy medication
- clozapine (to treat schizophrenia)
- medicines to treat gout
- 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 breastfeeding

This medicine is not recommended for use during pregnancy.

Use during breastfeeding should be avoided.

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.

Driving and using machines

Paralief Extra has no or negligible influence on the ability to drive and use machines.

Paralief Extra with food, drink and alcohol

Alcoholic beverages should be avoided while taking this medicine because alcohol use in combination with paracetamol may cause liver damage.

The use of caffeine containing products should be limited while taking these tablets (e.g. coffee, tea and some canned drinks) as excessive caffeine may cause nervousness, irritability, sleeplessness and occasionally rapid heartbeat.

3. How to take Paralief Extra

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

Adults, elderly and adolescents aged 16 years and over

Swallow 1 to 2 tablets with water up to 4 times daily as needed. Do not take more than 8 tablets in 24 hours.

Adolescents aged 12 – 15 years:

One tablet up to four times daily. The dose should not be repeated more frequently than every 4 hours. The daily dose of paracetamol should not exceed 2g/day.

The maximum daily dose of paracetamol should not exceed 2g/day (up to a maximum of 4 tablets per day) in the following situations, unless directed by a physician:

- Weight less than 50kg
- Liver failure or hepatic insufficiency
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

In patients with impaired kidney or liver function and patients with Gilbert Syndrome, the dose must be reduced or the dosing interval prolonged. Ask your doctor for advice.

- **Contains paracetamol.**
- **Do not take more frequently than every 4 hours.**
- **Do not give to children under 12 years.**
- **Do not take more than the recommended dose.**
- **If fever persists for more than 3 days or pain for more than 5 days gets worse or symptoms appear, stop taking this medicine and consult a doctor.**
- **Prolonged use except under medical supervision may be harmful.**
- **Avoid too much caffeine in drinks like coffee, tea, energy drinks and other caffeine containing products. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.**
- **Always use the lowest effective dose to relieve your symptoms.**

If your headache becomes persistent, **see your doctor.**

If you take more Paralief Extra than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop taking the medicine and tell your doctor if you experience:

- allergic reactions such as skin rash, or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face
- or have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product
- severe rash, peeling of the skin which may be accompanied by mouth ulcers

- unexpected bruising or bleeding
- changes in blood tests that measure the function of your liver

These reactions listed above are very rare (may affect up to 1 in 10,000 people).

The following other side effects may also occur. Tell your doctor if you get them:

- insomnia, restlessness, anxiety, irritability, headaches, upset stomach, palpitations, nervousness and dizziness (frequency of reaction is not known: cannot be estimated from the available data).

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. 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

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

5. How to store Paralief Extra

Keep out of the sight and reach of children.

Store below 30°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and blisters. 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 to protect the environment.

6. Contents of the pack and other information

What Paralief Extra contains

The active substances are Paracetamol 500 mg and Caffeine 65 mg.

The other ingredients are Pregelatinised Starch, Povidone K-30, Crospovidone Type A, Magnesium stearate, Hypromellose 2910 (E464), Talc, Titanium dioxide (E171) and Macrogol 400.

What Paralief Extra looks like and contents of the pack

Paralief Extra are capsule-shaped white film-coated tablets with a size of approximately 7.0 x 18.25 mm.

The tablets are available in blister pack sizes of 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 48 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation holder and Manufacturer

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

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

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|----------|-------------------------------------|
| Ireland: | Paralief Extra Film-coated Tablets |
| Iceland: | Paracaff 500/65 mg filmuhúðuð tafla |

This leaflet was last revised in March 2022.