

Package leaflet: Information for the user

Paralief Sinus Tablets

Paracetamol 500 mg / Pseudoephedrine Hydrochloride 30 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 or pharmacist 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 or 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.

The name of this medicine is Paralief Sinus Tablets.

What is in this leaflet

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

1. What Paralief Sinus Tablets are and what they are used for

Paralief Sinus Tablets relieves the symptoms of colds and flu including aches, pains, fever, nasal and sinus congestion.

The tablets contain paracetamol, an analgesic and antipyretic to relieve pain and fever, and pseudoephedrine, a decongestant to clear nasal congestion and blocked sinuses.

This medicine is for use in adults and adolescents aged 15 years and over

2. What you need to know before you take Paralief Sinus Tablets

Do not take Paralief Sinus Tablets:

- If you are allergic to paracetamol or pseudoephedrine or any of the other ingredients of this medicine (listed in section 6).
- If you have **high blood pressure** or **heart disease**
- If you are taking any other **paracetamol** containing products
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs)
- If you are taking tricyclic antidepressants.
- If you have **hyperthyroidism** (an excessive secretion of thyroid hormones).
- If you have **glaucoma (increased pressure in the eye)**.
- If you have **urinary retention** (difficulty passing water).
- If you have pheochromocytoma which is a tumour of the adrenal glands (glands near the kidneys) causing high blood pressure.
- If you are taking any other sympathomimetic drugs (stimulants or appetite suppressants and drugs to treat asthma and congestion).
- If you are taking beta blockers (medicines used to treat conditions such as angina, heart failure and high blood pressure).
- If you are taking the antibacterial agent furazolidine.
- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

If any of these apply to you, **get advice from a doctor or pharmacist without using Paralief Sinus Tablets.**

Warnings and precautions

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

- have kidney or liver problems (including Gilbert's Syndrome)
- have a deficiency of a certain enzyme called glucose-6-phosphatase
- have haemolytic anaemia (abnormal breakdown of red blood cells)
- in case of dehydration or chronic malnutrition
- weigh less than 50 kg
- have **diabetes**
- have **prostate problems** (difficulty with passing water or needing to pass water often)
- have a long term cough, asthma or emphysema
- have **alcohol dependence**
- have occlusive vascular problems e.g. Raynaud's Phenomenon
- **have psychosis**

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

During treatment with Paralief Sinus Tablets, 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).

If you develop a feverish generalised erythema associated with pustules, stop taking Paralief Sinus Tablets and contact your doctor or seek medical attention immediately. See section 4.

Sudden abdominal pain or rectal bleeding may occur with Paralief Sinus Tablets, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking Paralief Sinus Tablets and contact your doctor or seek medical attention immediately. See section 4.

Reduction of blood flow to your optic nerve may occur with Paralief Sinus Tablets. If you develop sudden loss of vision, stop taking Paralief Sinus Tablets and contact your doctor or seek medical attention immediately. See section 4.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Paralief Sinus Tablets immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

One of the active ingredients in Paralief Sinus Tablets, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Paralief Sinus Tablets than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

Children and adolescents

Do not give to children and adolescents under 15 years old.

Other medicines and Paralief Sinus Tablets

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

Do not take Paralief Sinus Tablets if you are taking:

- Or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs)
- Tricyclic antidepressants (used to treat mood disorder)
- Other sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma)
- Beta blockers (used for example to treat high blood pressure)
- If you are taking any other paracetamol containing products

Paralief Sinus Tablets and certain other medicines can affect each other and your doctor may need to adjust the doses that you are taking. It is especially important if you are taking any of the following medicines as well as Paralief Sinus Tablets

- Antihypertensives (drugs to treat high blood pressure such as guanethidine, methyldopa, alpha and beta blockers, debrisoquine, bretylium and betanidine)
- Sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat **congestion and asthma**)
- Cholestyramine (to **lower blood cholesterol**)
- Metoclopramide and domperidone (to treat **nausea and vomiting**)
- Anticoagulants (to **thin the blood** such as warfarin)
- Barbiturates (used to treat **anxiety** or help you **sleep**)
- Oral contraceptives ("**the pill**")
- Anticonvulsants (drugs used to treat **epilepsy**)
- Rifampicin and isoniazid (used to treat tuberculosis).
- Chloramphenicol (antibiotic drug) (not including topical chloramphenicol).
- Zidovudine (antiretroviral drug used to prevent and treat HIV/AIDS).
- Probenecid (treatment for gout)
- Halogenated anaesthetics (such as halothane and cyclopropane)
- Cardiac glycosides (medicines used to treat heart failure and irregular heartbeats).
- Linezolid (antibiotic used for the treatment of serious infections).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

If you are not sure about any of the medicines you are taking, show the pack to your pharmacist.

Pregnancy, breast-feeding and fertility

Paralief Sinus Tablets is not recommended in pregnancy.

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

There are no known effects on driving and using machines as a result of taking Paracetamol / Pseudoephedrine. If you are affected by dizziness while taking this medicine you are advised not to drive or operate machinery.

Paralief Sinus contains sodium

This medicine contains less than 1 mmol sodium (23mg) per Tablet, that is to say essentially 'sodium-free'.

3. How to take Paralief Sinus 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.

Check the table that follows to see how much medicine to take.

Age	Dose
Adults and adolescents aged 15 years and over.	1 to 2 tablets every 4 - 6 hours, two to three times a day

- Leave at least 4 hours between doses.
- Do not take more than 3 doses in 24 hours.
- Patients should seek medical advice if symptoms persist for more than 3 days or worsen.
- For oral use only.
- Do not exceed stated dose.
- Take with a glass of water.
- The dose may require adjustment in patients with kidney or liver problems and in frail, elderly patients.

The effective daily dose should not exceed 2 g / day of paracetamol in the following situations unless advised by a doctor:

- Weight less than 50 kg
- Liver impairment
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

If you take more Paralief Sinus Tablets than you should

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage.

If you forget to take Paralief Sinus Tablets

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose to make up for a forgotten dose.

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, and they are usually mild.

If you experience any of the following, stop using this medicine and talk to your doctor or seek medical attention immediately:

A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2) (Frequency 'Not known': frequency cannot be estimated from the available data).

Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) (Frequency Not known: frequency cannot be estimated from the available data).

Stop using Paralief Sinus Tablets immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting

- confusion
 - seizures
 - changes in vision
- A few people have had hallucinations, but this is rare. Occasionally people get skin rashes that are sometimes itchy.
 - A few men, especially those with prostate problems, may have trouble passing water.
 - There have been rare reports of blood disorders in people taking paracetamol, the symptoms of which include unusual tiredness, unexpected bruising or bleeding and getting more infections (such as colds) than normal.
 - Increased blood pressure and effects on the heart, such as a fast heartbeat.
 - Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with Paralief Sinus tablets, (Frequency not Known) See section 2.
 - Inflammation of the colon due to insufficient blood supply (ischaemic colitis) (Frequency Not known).
 - Reduced blood flow to the optic nerve (Ischaemic optic neuropathy) (Frequency Not known)

Long-term use

- People who use medicine containing paracetamol every day for a long time (several months or more) could get certain side-effects including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems.

Other effects which may occur include:

- Restlessness, having trouble getting to sleep or bad dreams.

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

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

5. How to store Paralief Sinus Tablets

This medicine does not require any special storage conditions.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. 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 Sinus Tablets contain

The active ingredients in Paralief Sinus Tablets are: 500 mg Paracetamol and 30 mg Pseudoephedrine hydrochloride per tablet.

Other ingredients are: Pregelatinised maize starch, crospovidone, povidone K30, stearic acid, microcrystalline cellulose, sodium starch glycolate Type A (see section 2), magnesium stearate.

What Paralief Sinus Tablets looks like and the contents of the pack

The tablets are white to off-white, capsule shaped tablets.

Paralief Sinus Tablets are available in blister packs of 4, 10, 12, 15, 18, 20, 24, 30 and 32 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Clonmel, Co. Tipperary, Ireland

Manufacturer

Chanelle Medical, Loughrea, Co. Galway, Ireland

JSC Grindeks, 53 Krustpils street, Riga, LV-1057, Latvia

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