

Package leaflet: Information for the user

Paralief Cold & Flu Hard Capsules

Paracetamol	300mg
Caffeine	25mg
Phenylephrine hydrochloride	5mg

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

1. What Paralief Cold & Flu is and what it is used for

Paralief Cold & Flu contains three drugs to help treat your symptoms (active ingredients):

- Paracetamol, which is an analgesic (pain killer) and antipyretic (it reduces body temperature when you have a fever)
- Phenylephrine, which is a type of drug known as a sympathomimetic. This works as a decongestant by unblocking the passages in and around your nose. This helps you to breathe more easily.
- Caffeine, which acts to further help the effectiveness of paracetamol.

Paralief Cold & Flu is used to relieve the symptoms of colds and influenza (flu) including fever, aches and pains, sore throat and nasal congestion.

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

2. What you need to know before you take Paralief Cold & Flu

DO NOT take Paralief Cold & Flu

- If you are **allergic** to paracetamol, caffeine, phenylephrine hydrochloride, or any of the other ingredients of this medicine (listed in section 6).
- If you have a rare hereditary disease known as **glucose-6-phosphate dehydrogenase (G6PD) deficiency**. G6PD deficiency is a shortage of an enzyme and can lead to anaemia (a shortage of red blood cells).
- **If you have a tumour of the adrenal glands** called a pheochromocytoma. The adrenal glands are triangle-shaped and located on top of your kidneys.
- If you have **severe kidney problems**
- If you have **high blood pressure**
- If you have a **thyroid gland that is too active**
- If you have **diabetes**

- If you have **heart disease**
- If you have **raised pressure in the eye (glaucoma)**
- If you are taking drugs known as **beta blockers**
- If you are taking drugs for depression known as **tricyclic antidepressants**
- If you are taking or have taken drugs for depression known as **monoamine oxidase inhibitors (MAOIs)** in the last two weeks

Warnings and precautions

Talk to your doctor or pharmacist before taking Paralief Cold & Flu

- If you have an **enlarged prostate gland**. Symptoms of an enlarged prostate gland include difficulty urinating, painful urination, or urinating more often.
- If you have **Raynaud's phenomenon** (discolouration of the fingers and toes caused by poor circulation)
- If you have heart or **circulation problems**
- If you have **liver or kidney problems** including alcoholic liver disease
- If you are **underweight** (less than 50 kg) or are malnourished
- If you use large quantities of alcohol regularly (**alcoholism**)
- If you suffer from severe **dehydration**
- If you are taking **medicines that affect your liver**
- if you are **elderly**
- if you have **glutathione deficiency** (a metabolic disorder which may lead to difficulty in breakdown of paracetamol)
- if you have an enzyme deficiency called **Glucose-6-phosphate dehydrogenase deficiency**
- if you have **haemolytic anaemia** (abnormal breakdown of red blood cells)

If any of the above applies to you, you may need to reduce the amount of Paralief Cold & Flu that you take or avoid taking this medicinal product altogether.

You should not use Paralief Cold & Flu if you are also using other sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma).

Do not take too much caffeine (e.g. coffee, tea and some canned drinks) when you are taking Paralief Cold & Flu.

Do not take any other medicines containing paracetamol. Taking too much paracetamol can lead to serious liver damage which can sometimes be fatal. You should take particular care if you have liver or kidney disease. You are more at risk of overdose if you are an alcoholic.

You should see your doctor if:

- you develop a high fever
- you develop signs of other infection such as feeling unwell, night sweats, tiredness, pain, or swelling
- your symptoms do not get better after three days

Other medicines and Paralief Cold & Flu

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines may affect or be affected by Paralief Cold & Flu.

You should not take Paralief Cold & Flu with any of the following medicines without first talking to your doctor:

- **Monoamine oxidase inhibitors (MAOIs)**, including moclobemide
- Sympathomimetic drugs (stimulants or appetite suppressants and drugs used to treat congestion and asthma)
- Beta blockers and other antihypertensive drugs (used to treat high blood pressure), including debrisoquine, guanethidine, reserpine, and methyl dopa

- Tricyclic antidepressants, for example amitriptyline, used to treat feeling sad (depression)
- Cardiac glycosides (drugs used to control heart rhythms or contractions) for example digoxin
- Ergot alkaloids (drugs used to treat migraine), for example ergotamine and methysergide
- Anticoagulants (drugs used to thin the blood, such as warfarin)
- Propantheline (used to treat gastrointestinal disorders, wetting (enuresis), and excessive sweating (hyperhidrosis))
- Pethidine and pentazocine (pain killers)
- Metoclopramide or domperidone (used to treat nausea and vomiting)
- Colestyramine (used to lower blood cholesterol)
- Carbamazepine, phenobarbital, phenytoin, and primidone (used to treat epilepsy)
- Rifampicin (an antibiotic)
- St John's wort (used to treat depression)
- 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

Do not take Paralief Cold & Flu with other products containing paracetamol.

Paralief Cold & Flu with drink and alcohol

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

Pregnancy and breast-feeding

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.

This product is not recommended if you are pregnant or while breast-feeding.

Driving and using machines

Take care when driving. Paralief Cold & Flu may affect your reactions, especially:

- at the start of treatment
- after increasing your dose
- when changing from a different medication
- if you also drink alcohol

Do not operate any tools or machines or drive if your reactions are affected.

Important information about some of the ingredients of Paralief Cold & Flu

- **Warning:**

Paralief Cold & Flu contains paracetamol and a drug to reduce congestion in the nasal passages (decongestant). Do not take with any other product for the relief of flu, colds or nasal congestion, or with other products containing paracetamol.

Paralief Cold & Flu contains sodium

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

3. How to take Paralief Cold & Flu

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

Always use the lowest effective dose for the shortest time necessary to relieve your symptoms.

The recommended dose is:

Adults (including the elderly)

Take 2 capsules up to 4 times a day as required. Do not take more than 8 capsules in 24 hours. Leave at least 4 hours between doses.

Children between 12 and 18 years of age

Take 2 capsules up to 3 times a day as required. Do not take more than 6 capsules in 24 hours. Leave at least 4 hours between doses.

Children under 12 years

Do not give Paralief Cold & Flu to children under 12 years old.

Special patient groups

Adults and elderly with special conditions

Do not take more than six capsules a day in the following situations, unless directed by your doctor:

- Weight less than 50 kg
- Use of large quantities of alcohol regularly (alcoholism)
- Dehydration
- Malnutrition

Use in kidney or liver impairment

If you have been diagnosed with kidney or liver problems, please consult your doctor or pharmacist. You may need to take a lower dose or increase the length of time between doses.

Do not take a higher dose than the recommended dose without first talking to your doctor.

Paralief Cold & Flu should be used during daytime only, as it contains caffeine, which may cause sleeplessness.

How to take Paralief Cold & Flu

The capsules should be taken by mouth.
Swallow the capsules whole with water. Do not chew.

For how long should you take Paralief Cold & Flu

If your symptoms do not get better after three days, talk to your doctor. Prolonged use, except under medical supervision may be harmful.

If you take more Paralief Cold & Flu than you should

Contact your doctor or nearest emergency department immediately for advice if:

- **You accidentally take too many capsules**
- **A child under 12 years of age takes any Paralief Cold & Flu**

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious, irreversible liver damage.

Take your medicine and this leaflet with you so that the medical staff know what you have taken.

You are at greater risk of overdose if:

- you are taking any of the following medicines for more than a few weeks:
 - carbamazepine, phenobarbital, phenytoin, and primidone (used to treat epilepsy)
 - rifampicin (an antibiotic)
 - St John's wort (used to treat depression)
- you regularly drink too much alcohol
- you have a shortage of a protein called glutathione. This can be due to:
 - an eating disorder such as lack or loss of appetite
 - starvation, or if you lose weight even when eating normally (a body wasting disease called cachexia)

- cystic fibrosis (a hereditary disease causing breathing difficulties)
- HIV infection (AIDS)

Symptoms of overdose in the first 24 hours are:

- Pale skin (pallor)
- Feeling sick (nausea)
- Being sick (vomiting)
- Lack of appetite (anorexia)
- Tummy pain (abdominal pain)

Other symptoms are:

- Problems with breaking down glucose
- Too much acid in the body (metabolic acidosis).

Severe overdose can be fatal and lead to:

- Liver failure
- Brain damage (encephalopathy)
- Bleeding (haemorrhage)
- Low blood sugar levels (hypoglycaemia)
- Swelling of the brain (cerebral oedema)
- Kidney failure with loin pain (acute tubular necrosis)
- Blood in the urine (haematuria)
- Protein in the urine (proteinuria)
- Irregular heartbeat (cardiac arrhythmia)
- Inflamed pancreas (pancreatitis)
- Pain in the upper part of the tummy (epigastric pain)
- Being sick (vomiting)
- Increased urine production (diuresis)
- Rapid heartbeat (tachycardia)
- Stimulation of the nervous system including:
 - difficulty sleeping (insomnia)
 - restlessness
 - excitement
 - feeling anxious (agitation)
 - feeling nervous and flustered (jitteriness)
 - uncontrolled shaking (tremors)
 - fits (convulsions)
- Other effects similar to those under section 4 “Possible Side Effects” in this leaflet
- High blood pressure (hypertension)
- Slow heartbeat (reflex bradycardia)
- Confusion
- Seeing or hearing things that are not there (hallucinations)

If you forget to take Paralief Cold & Flu

Do not take a double dose to make up for a forgotten capsule.

Make sure your next dose is taken at least four hours after your previous 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.

If you experience any of the following stop using the medicine and seek immediate help

- Allergic reactions:
 - swelling of the skin, of the face and lips, tongue and throat, or voice box (angioedema)
 - difficulty breathing (dyspnoea)
 - sweating
 - feeling sick (nausea)
 - low blood pressure (hypotension) leading to shock
 - severe allergic reaction (anaphylaxis)

If you experience any of the following, stop using the medicine and talk to your doctor

- Allergic skin reactions (cutaneous hypersensitivity reactions) including:
 - skin rashes
 - Stevens Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals)
 - Toxic Epidermal Necrolysis (severe blistering and peeling of the skin)
- Allergic reactions, for example: rash, hives (urticaria), skin inflammation (allergic dermatitis)
- Allergic (hypersensitivity) reactions. If you have had an allergic reaction with other sympathomimetic drugs (such as pseudoephedrine) before, you are more likely to have an allergic reaction (cross-sensitivity)

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

- Very rare cases of serious skin reactions have been reported
- Liver problems (hepatic dysfunction)

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

- Low numbers of blood cells called platelets or thrombocytes (thrombocytopenia)
- Low numbers of white blood cells called leukocytes (leukopenia)
- A severe lack of white blood cells (agranulocytosis)
- Low numbers of red and white blood cells (pancytopenia)
- Tiredness
- Headache
- Dizziness
- Difficulty sleeping (insomnia)
- Anxiety
- Nervousness
- Feeling irritated (irritability)
- Restlessness
- Feeling excited (excitability)
- Worsening of raised pressure in the eye (pre-existing narrow-angle glaucoma) (see also section 2, “DO NOT take Paralief Cold & Flu”)
- Dilated pupils (mydriasis)
- Sudden raised pressure in the eye (acute angle closure glaucoma)
- High blood pressure (hypertension)
- Feeling your heartbeat (palpitations)
- Rapid heartbeat (tachycardia)
- Narrowing of the upper airways (bronchospasm)
- Dry mouth
- Feeling sick (nausea)
- Being sick (vomiting)
- Runny stools (diarrhoea)
- Lack of appetite (anorexia)
- Kidney problems (renal dysfunction)
- Difficulty urinating (dysuria) or inability to urinate (urinary retention). This is more likely to occur if your bladder is blocked, for example if you have an enlarged prostate. See also section 2,

“Warnings and precautions.”

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRRA 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 Cold & Flu

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 and blister. The expiry date refers to the last day of that month.

Do not store above 25 °C.

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 Cold & Flu contains

The active substances are:

- paracetamol
- caffeine
- phenylephrine hydrochloride

Each capsule contains:

- 300 mg paracetamol
- 25 mg caffeine
- 5 mg phenylephrine hydrochloride

The other ingredients are:

- sodium laurylsulphate
- colloidal anhydrous silica
- magnesium stearate

The other ingredients in the capsule shell are:

- gelatin
- titanium dioxide (E 171)
- yellow iron oxide (E 172)

What Paralief Cold & Flu Capsules looks like and contents of the pack

Paralief Cold & Flu Capsules are hard capsules of size 1 with a white body and a yellow cap Filled with white to yellow powder.

Paralief Cold & Flu Capsules are available in:

- OPA/Alu/PVC–glassine paper/Alu/PVC/PVAC blister strips or
- PVC-PVDC / Aluminium blisters

Blister strips are packed into cardboard cartons.

Pack sizes are 10, 12, 20 and 24 capsules.

Not all pack sizes are marketed.

Marketing Authorisation Holder

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

Manufacturer

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

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

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

Spain	Grippostad con paracetamol/cafeína cápsulas duras
Ireland	Paralief Cold & Flu hard capsules, Paracetamol 300 mg Caffeine 25 mg Phenylephrine hydrochloride 5 mg
Romania	Grippostad Zi capsule

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