

## Package leaflet: Information for the user

### Paralief Hot Lemon Drink 600 mg Powder for Oral Solution in Sachet 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 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 Hot Lemon Drink is and what it is used for
2. What you need to know before you take Paralief Hot Lemon Drink
3. How to take Paralief Hot Lemon Drink
4. Possible side effects
5. How to store Paralief Hot Lemon Drink
6. Contents of the pack and other information

#### **1. What Paralief Hot Lemon Drink is and what it is used for**

CONTAINS PARACETAMOL

Paralief Hot Lemon Drink is a medicine used for relief of symptoms of influenza and feverish colds (incl. headache, aches and pains) menstrual pain and toothache.

For children aged 12 years or older, adolescents and adults.

#### **2. What you need to know before you take Paralief Hot Lemon Drink**

##### **DO NOT take Paralief Hot Lemon Drink**

- if you are allergic to paracetamol or any of the other ingredients of this medicine (listed in section 6)
- Do not take any other paracetamol-containing products.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Paralief Hot Lemon Drink if you:

- suffer from chronic alcoholism
- suffer from impaired liver function (liver inflammation, Gilbert's syndrome)
- have existing kidney damage
- are using other medicines that are known to affect the liver
- have a deficiency of a certain enzyme called glucose-6-phosphatedehydrogenase
- have haemolytic anaemia (abnormal breakdown of red blood cells)
- suffer from reduced glutathione levels
- are dehydrated or have impaired nutritional state e.g. caused by alcohol abuse, anorexia or wrong nutrition

**You must contact a doctor if your symptoms worsen or do not improve after 3 days, or if you develop a high fever.**

To avoid the risk of overdosing, it should be ensured that medicines taken at the same time as Paralief Hot Lemon Drink do not contain paracetamol.

### Prolonged use

You should not use Paralief Hot Lemon Drink over prolonged periods or at high doses without the advice of a doctor or dentist.

During prolonged, improper use of high-dose painkillers, headache can occur, which must not be treated by increased doses of the medicine.

In general, habitual use of painkillers may lead to permanent kidney damage with the risk of kidney failure (analgesic nephropathy), particularly if several painkilling drugs are combined.

### **Other medicines and Paralief Hot Lemon Drink**

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

Interactions are possible with:

- probenecid, a drug used in gout: If taken at the same time, the dose of Paralief Hot Lemon Drink should be lowered, as there may be a delay in the breakdown of paracetamol, the active substance in Paralief Hot Lemon Drink
- phenobarbital (sleeping medication), phenytoin and carbamazepine (used in epilepsy), rifampicin (used in tuberculosis), as well as other drugs that can damage the liver. There is a greater risk of liver damage if Paralief Hot Lemon Drink is taken at the same time
- metoclopramide and domperidone (used to treat nausea) can speed up the absorption and onset of action of paracetamol
- colestyramine (used to lower high blood fat levels) can reduce absorption of paracetamol, thereby making it less effective
- medicines that slow down gastric emptying, e.g. propantheline, can delay the absorption and onset of action of paracetamol
- zidovudine (used to treat HIV infections) - susceptibility to neutropenia (reduced number of white blood cells) is increased. Medical advice is therefore needed before taking Paralief Hot Lemon Drink at the same time as zidovudine
- medicines used to thin the blood such as warfarin and other coumarins. The effect of blood thinning drugs may be increased by regular use of Paralief Hot Lemon Drink over a longer period
- 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 kidney 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.

### Effects of taking Paralief Hot Lemon Drink on laboratory tests

Tests to determine uric acid and blood sugar levels may be affected.

Please remember that this information may also apply to recently used medications (which may still be in your body).

### **Paralief Hot Lemon Drink with alcohol**

Paralief Hot Lemon Drink must not be taken at the same time as alcohol.

### **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.

### Pregnancy

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

### Breast-feeding

Paracetamol passes into breast milk. It is not known to affect the baby adversely, so discontinuation of

breast-feeding is generally not required during short-term use.

### **Driving and using machines**

Paralief Hot Lemon Drink has no effect on the ability to drive and use machines. However, caution is always advised after taking any painkillers.

### **Paralief Hot Lemon Drink contains sucrose and aspartame (E951)**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Contains 3.8 g sucrose (sugar) per sachet. This should be taken into account in patients with diabetes mellitus.

This medicine contains 95 mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **3. How to take Paralief Hot Lemon Drink**

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.

#### Dosage

Unless otherwise prescribed by the doctor, the recommended dose is 1 sachet (600 mg paracetamol) taken as a single dose; maximum of 4 doses in 24 hours with at least 6 hours between doses.

#### **Do not exceed the stated dose - a single dose of 1 sachet at a time may not be exceeded.**

If other medicines containing paracetamol are taken at the same time, make sure that this won't exceed the maximum recommended daily dose of paracetamol. Please ask your doctor or pharmacist if the medicines you are taking contain the active ingredient paracetamol. He/she will inform you about the dosing and the best time to take such medicines while you are taking Paralief Hot Lemon Drink.

#### Patients with liver impairment and mild kidney impairment

Dose must be reduced by prolongation of dosing interval in patients with impaired liver or kidney function and Gilbert's syndrome.

#### Patients with severe kidney dysfunction

In cases of severe kidney dysfunction (creatinine clearance < 10 ml/min), there must be an interval of at least 8 hours between each dose.

#### Older people

No specific dose adjustment is required.

#### Use in adults with a low body weight

Paralief Hot Lemon Drink must not be used in patients weighing less than 40 kg as the dosage strength is not suitable for these patients. More appropriate dosage strengths and/or formulations of paracetamol (e.g. syrup or suppositories) are available for this patient group.

#### **Use in children and adolescents**

Paralief Hot Lemon Drink must not be used in children under 12 years of age. More appropriate dosage strengths and/or formulations of paracetamol (e.g. syrup or suppositories) are available for this patient group.

#### **Method of administration**

First, bring water to boil and let cool for about 10 minutes.

Empty the content of one sachet into a cup, top with the hot water and stir well. A slightly cloudy, colourless to light yellowish solution will be obtained.

Drink after sufficient cooling down to a drinkable temperature.

Dosing after meals may lead to a delayed onset of action.

### **Duration of treatment**

Do not take Paralief Hot Lemon Drink for more than 3 days without the advice of a doctor or dentist. A doctor should be consulted if symptoms persist for more than 3 days.

### **If you take more Paralief Hot Lemon Drink 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. In treating an overdose, the doctor will be guided by the symptoms and will take all appropriate courses of action.

In the event of overdose with Paralief Hot Lemon Drink, the following symptoms can occur:

- nausea
- vomiting
- loss of appetite
- paleness
- stomach ache
- sweating
- drowsiness
- malaise (general feeling of being unwell)

Liver damage and even hepatic coma, heart muscle damage and pancreatitis can occur in the event of severe overdose.

### **If you forget to take Paralief Hot Lemon Drink**

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

### **If you stop taking Paralief Hot Lemon Drink**

If Paralief Hot Lemon Drink has been used correctly, there are no special considerations.

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.

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

- slight increase in liver enzymes (serum transaminases)

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

- changes in the blood count such as reduction in blood platelets (thrombocytopenia) or a pronounced reduction in certain white blood cells (agranulocytosis)
- allergic reactions, from simple skin rash or nettle rash (urticaria) to a shock reaction
- airway constriction (analgesic-induced asthma) can be triggered in sensitive patients
- very rare cases of serious skin reactions have been reported

In the event of an allergic shock reaction, seek immediate help from the nearest available doctor.

### **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:

HPRAs 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 Hot Lemon Drink**

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 outer carton and sachet 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 Hot Lemon Drink contains**

The active substance is paracetamol.

Each sachet contains 600 mg paracetamol.

The other ingredients are:

ascorbic acid, aspartame (E951), citric acid, ethylcellulose, colloidal anhydrous silica, sucrose, lemon flavouring (consisting of citral, citronella oil, coriander seed oil, gum arabic and lime oil distilled).

### **What Paralief Hot Lemon Drink looks like and contents of the pack**

Powder for oral solution in sachet, and is white to slightly yellow with the smell of lemon.

Paralief Hot Lemon Drink is available in packs of 5 and 10 sachets.

### **Marketing Authorisation Holder and Manufacturer**

#### 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:**

UK (NI): Care Cold and Flu Remedy 600 mg powder for oral solution

CZ: Paracetamol STADA 600 mg prášek pro perorální roztok v sáčku

IE: Paralief Hot Lemon Drink 600 mg powder for oral solution in sachet

SK: Grippostad horúci nápoj

**This leaflet was last revised in March 2022.**