PAROL 500 mg Tablet

Taken orally · ATC: N02BE01 · Active substance: Paracetamol 500 mg

Orally | Analgesic | Antipyretic | Paracetamol 500 mg | Age ≥ 6 years

COMPOSITION

Active substance: 500 mg paracetamol per tablet

Excipients: Microcrystalline cellulose, povidone K-30, corn starch, stearic acid

Pack sizes: Blister packs of 20 and 30 tablets

Read this leaflet carefully before you start using this medicine

Keep this leaflet. You may need to read it again.

If you have further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Do not pass it on to others.

If you go to a doctor or hospital during treatment, tell them you are using this medicine.

Follow the instructions in this leaflet exactly. Do not use a higher or lower dose than recommended.

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What PAROL is and what it is used for

PAROL is a medicine containing 500 mg paracetamol per tablet. It acts as a pain reliever (analgesic) and fever reducer (antipyretic).

PAROL is available in blister packs of 20 and 30 tablets.

Indications

INDICATION 1

Mild to moderate pain

Symptomatic relief of mild and moderate pain (not curative treatment of the underlying condition)

INDICATION 2

Fever

Symptomatic relief of fever (not curative treatment of the underlying condition)

What you need to know before you use PAROL

Do NOT use PAROL if you:

Contraindications

Are allergic (hypersensitive) to paracetamol or any other ingredient of this medicine

Have severe liver or kidney failure

Warnings and precautions – Use PAROL with care if you:

Talk to your doctor or pharmacist before using PAROL

Have anaemia, lung disease, or impaired liver or kidney function – use only under medical supervision.

Notice skin redness, rash or any skin reaction – use with caution.

Are taking any other medicine containing paracetamol – do not use PAROL at the same time. Combined use may cause an overdose. Do not use together with other analgesics, antipyretics, cold and flu remedies or sleep aids that contain paracetamol.

Experience skin redness, rash or a skin reaction at the first or any subsequent dose of paracetamol – you must not use this medicine or any other paracetamol-containing product again.

Drink alcohol – do not take more than 2 grams of paracetamol (4 PAROL tablets) per day.

Are underweight, anorexic or malnourished.

Have Gilbert's syndrome (a hereditary condition characterised by elevated liver enzymes and transient jaundice).

Have glucose-6-phosphate dehydrogenase (G6PD) enzyme deficiency – haemolysis (destruction of red blood cells) may rarely occur.

If new symptoms appear or if the pain and/or fever do not decrease within 3–5 days, stop taking paracetamol and consult your doctor.

PAROL causes serious liver toxicity when taken in a single high dose (acute). When taken in high daily doses over a long period (chronic use) in adults, it may cause liver damage. It should be used with caution in patients with alcoholic liver disease. In people who drink alcohol, the daily paracetamol dose must not exceed 2,000 mg due to the risk of liver toxicity (hepatotoxicity).

In patients with glutathione deficiency, such as those with sepsis, the use of paracetamol may increase the risk of metabolic acidosis.

If you have a serious infection, this may also increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

Deep, rapid and laboured breathing

Nausea and vomiting

Loss of appetite

If any of these warnings have applied to you at any time in the past, please consult your doctor.

PAROL with food and drink

When used together with alcohol or foods, medicines or other products containing alcohol, the risk of harmful effects on the liver may increase.

Food may reduce the absorption of paracetamol from the intestine.

Pregnancy

> **Pregnancy**
>
> Ask your doctor or pharmacist before taking this medicine. No harmful effects related to the use of PAROL during pregnancy have been reported. However, it should still be used during this period only on the advice of a physician. If you find out that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

> **Breast-feeding**
>
> Ask your doctor or pharmacist before taking this medicine. Taking PAROL at therapeutic doses by a breast-feeding mother does not pose a risk to the infant. Paracetamol passes into breast milk in small amounts. Breast-feeding mothers may use this medicine during this period on the advice of a physician.

Driving and using machines

> **Driving and using machines**
>
> PAROL is not expected to have any effect on the ability to drive or use machines. However, paracetamol may cause dizziness or drowsiness in some patients. You should be careful when performing tasks that require you to stay alert while using PAROL.

Other medicines and PAROL

The effect of PAROL may change when used together with certain medicines. Please tell your doctor if you are taking any of the following medicines:

Medicines that delay gastric emptying (e.g. propantheline)

Medicines that accelerate gastric emptying (e.g. metoclopramide)

Medicines that induce liver enzymes (e.g. some sleeping medicines, and medicines used for epilepsy such as phenytoin, phenobarbital, carbamazepine)

Antibiotics: chloramphenicol, rifampicin

Warfarin and coumarin-derivative anticoagulants (medicines that prevent blood clotting)

Zidovudine (a medicine used in the treatment and prevention of HIV infection/AIDS in children and adults)

Domperidone (used in the treatment of nausea and vomiting)

Medicines containing St. John's Wort (Hypericum perforatum)

Medicines containing colestyramine (used in the treatment of high cholesterol)

Medicines containing tropisetron and granisetron (used to prevent nausea and vomiting in patients receiving radiotherapy and/or chemotherapy)

Other analgesics (pain killers)

Alcohol

Antidepressants (some medicines used in the treatment of depression)

If you are currently using or have recently used any prescription or non-prescription medicines, please inform your doctor or pharmacist.

How to use PAROL

Dosage and frequency of administration

PAROL is suitable for adults and children over 6 years of age.

Adults and children over 12 years	1–2 tablets; may be repeated every 4 hours if necessary. No more than 4 doses in 24 hours.	4,000 mg
Children aged 6–12 years	½–1 tablet every 4–6 hours	10–15 mg/kg in divided doses, up to 60 mg/kg

Always use the lowest effective dose to relieve symptoms. Do not exceed the stated dose. If you do, consult a doctor immediately.

Route and method of administration

For oral use. Swallow with a glass of water.

Use in different age groups

Children

Do not give to children under 6 years of age without a doctor's recommendation. In children aged 6–11 years, do not use for more than 3 days without consulting a doctor.

Elderly

The normal adult dose is appropriate for healthy, mobile elderly patients. However, in frail and immobile elderly patients, the dose and frequency should be reduced.

Renal/hepatic impairment

Use with caution in patients with mild to moderate hepatic or renal impairment.

If you have the impression that the effect of PAROL is too strong or too weak, talk to your doctor or pharmacist.

If you use more PAROL than you should

Overdose – seek medical help immediately

The main symptoms of overdose are pallor, loss of appetite, nausea and vomiting, although in some cases no symptoms may appear for several hours. Therefore, in case of overdose or accidental ingestion, contact your doctor or go to a hospital emergency department immediately. Taking a high dose in a short period of time (acute overdose) may lead to liver toxicity. Paracetamol overdose may result in liver failure that can progress to liver transplantation or death. Acute pancreatitis may also be observed together with liver toxicity and hepatic dysfunction. The harm of overdose is greater in patients with alcoholic liver disease. In people who drink alcohol, the daily paracetamol dose must not exceed 2,000 mg due to the risk of hepatotoxicity. Paracetamol overdose must be treated immediately.

If you forget to take PAROL

Missed dose

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

Effects when treatment with PAROL is stopped

Use your medicine for the duration advised by your doctor. No adverse effects are expected when treatment is stopped.

Possible side effects

Like all medicines, PAROL may cause side effects in people who are sensitive to its ingredients. The unwanted side effects of paracetamol are generally mild. Harmful effects are likely when more than 10 grams (20 PAROL tablets) of paracetamol are taken.

Stop using PAROL and contact a doctor or go to the nearest hospital emergency department IMMEDIATELY if any of the following occur:

- Swelling of the hands, feet, face and lips, or swelling especially of the throat causing difficulty breathing (anaphylactic shock)
- Allergic symptoms
- Asthma and asthma-like symptoms causing breathing difficulty in the lungs (bronchospasm)
- If you have experienced difficulty breathing when using aspirin or similar non-steroidal anti-inflammatory drugs and you experience similar symptoms with this medicine
- Unexpected bruising and bleeding

These are very serious side effects. If you experience these, you may have a serious allergy to PAROL. You may need emergency medical intervention or hospitalisation.

Side effects are classified in the following categories:

Very common: may affect at least 1 in 10 patients

Common: may affect fewer than 1 in 10 but more than 1 in 100 patients

Uncommon: may affect fewer than 1 in 100 but more than 1 in 1,000 patients

Rare: may affect fewer than 1 in 1,000 patients

Very rare: may affect fewer than 1 in 10,000 patients

Unknown: cannot be estimated from the available data

Common

Drowsiness (somnolence)

Headache

Dizziness

Upper respiratory tract infection symptoms

Nausea

Vomiting

Sensory disturbances such as numbness, tingling and burning sensation

Intestinal gas (flatulence)

Abdominal pain

Constipation

Indigestion (dyspepsia)

Uncommon

Kidney damage (papillary necrosis) that may lead to kidney failure with prolonged use

Gastrointestinal bleeding

Rare

Decrease in white blood cell count (leucopenia), decrease in blood cells (pancytopenia), anaemia, presence of methaemoglobin in the blood (methaemoglobinaemia), abnormally low white blood cell count (neutropenia), bleeding of capillaries into the skin (thrombocytopenic purpura) – these side effects are not in a cause-and-effect relationship with paracetamol

Nausea, vomiting, diarrhoea, abdominal pain

Sudden and potentially fatal serious allergic reaction (anaphylaxis)

Skin rash, itching, eczema, allergic oedema, swelling of the face, tongue and throat (angioedema), widespread pustular eruptions (acute generalised exanthematous pustulosis), hypersensitivity reaction causing lace-like redness on the hands, face and feet (erythema multiforme)

Stevens-Johnson syndrome (a serious condition in which the skin and mucous membranes react severely to a medicine or infection)

Toxic epidermal necrolysis (Lyell's syndrome) (a skin disease that may develop due to medicines and various infections)

Very rare

Sudden and frequent decrease in blood cell count (agranulocytosis)

Decrease in platelet count (thrombocytopenia)

Allergic reaction symptoms

Bronchospasm in patients who are sensitive to aspirin or similar non-steroidal anti-inflammatory drugs

Liver dysfunction

Unknown

Central nervous system stimulation, dizziness, brain inflammation (encephalopathy), insomnia, tremor

Positive allergy test

Immune thrombocytopenia (the body's immune system recognises platelets as harmful and destroys them)

If you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

TÜFAM – Turkish Pharmacovigilance Centre

If you experience any side effect, whether or not it is mentioned in this leaflet, please talk to your doctor, pharmacist or nurse. You can also report side effects directly to the Turkish Pharmacovigilance Centre (TÜFAM) by clicking the "Drug Side Effect Reporting" icon on the website **www.titck.gov.tr** or by calling the side effect reporting line at **0 800 314 00 08**. By reporting side effects, you can help provide more information on the safety of the medicine you are using.

How to store PAROL

Keep PAROL out of the sight and reach of children.

Store below 25°C at room temperature in its original packaging.

Use in accordance with the expiry date.

Expiry date

Do not use PAROL after the expiry date shown on the packaging.

Disposal

Do not dispose of expired or unused medicines in the rubbish! Hand them in to the collection system designated by the Ministry of Environment and Urbanisation.

Marketing Authorisation Holder

ATABAY KİMYA SAN. VE TİC. A.Ş.
Acıbadem, Köftüncü Sokak No: 1
34718 Kadıköy / İSTANBUL

Manufacturer

ATABAY İLAÇ FABRİKASI A.Ş.
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This patient information leaflet was approved on …./…./…..