



PACKAGE LEAFLET

PIROFEN 250 mg / 5 ml Oral Suspension

Taken through mouth.

Active Substance: Each 5 ml suspension contains 250 mg paracetamol.

Excipients: Sorbitol liquid (non-crystalline) (E420), sucrose, glycerol, methyl parahydroxybenzoate (E218), polysorbate 80, xantham gum, Avicell RC (microcrystalline cellulose/sodium carboxymethyl cellulose), sucralose, banana flavor, quinoline yellow, sunset yellow (E110), purified water.

Read all of this PACKAGE LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

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1. WHAT PIROFEN IS AND WHAT IT IS USED FOR

PIROFEN is a medicine that relieves pain and reduces fever, containing 250 mg paracetamol in each measuring spoon (5 ml) in the form of suspension (solution, solid-liquid mixture).

PIROFEN is presented in a honey-colored glass bottle containing 150 mL suspension.

PIROFEN is used for the symptomatic (not curative for the disease, only reliever for the symptoms) treatment of mild to moderate pain and fever.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PIROFEN

DO NOT take PIROFEN

- If you are hypersensitive (allergic) to paracetamol or any other ingredients of this medicine,
- If you have severe liver or kidney disease.

TAKE SPECIAL CARE with PIROFEN

- If you have anemia.
- If you have lung disease.
- If you have liver or kidney dysfunction.
- If you are taking another medicine containing paracetamol.
- If you or your child has been told that you have an intolerance to some sugars.



- If you are taking medicines that slow the rate of gastric emptying such as propantheline; medicines used for nausea and vomiting such as metoclopramide and domperidone; an antibiotic called chloramphenicol; azidothymidine used to treat AIDS; warfarin or coumarin derivatives that prevent blood clotting (anticoagulant).
- If you are taking certain medicines that slow down the functioning of central nervous system (hypnotics); medicines used to treat epilepsy (antiepileptic drugs – glutethimide, phenobarbital, phenytoin, carbamazepine, etc.); an antibiotic called rifampicin.
- If you are taking medicines that contain St. John's Wort (*Hypericum perforatum*).
- If you are taking medicines containing cholestyramine used to treat high cholesterol.
- If you are taking medicines containing tropisetron and granisetron to prevent nausea and vomiting in patients receiving radiotherapy and/or chemotherapy.
- If redness, rash or a reaction occurs on the skin.
- If you have Gilbert's syndrome, a hereditary disease characterized by elevated liver enzymes and transient jaundice.
- Hemolysis (destruction of red blood cells) may rarely occur in patients with deficiency of the glucose-6-phosphate dehydrogenase enzyme, which is effective in blood sugar metabolism.

Stop using paracetamol for your child and consult a doctor if new symptoms occur within 3-5 days or if pain and/or fever do not subside.

PIROFEN causes serious liver toxicity (poisoning) when taken at acute (short-term) high doses. In adults, it may cause liver damage when taken at chronic (long-term and repeatedly) daily doses.

Do not use this medicine if you are taking another paracetamol-containing medicine, including those obtained without a prescription, in order to relieve pain, fever, cold or flu symptoms or in order for you to sleep.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Consult your doctor before use if the following situations occur:

- If you have mild to moderate liver or kidney problems
- If you are underweight or malnourished
- If you regularly drink alcohol

You may need to avoid using this product completely or limit the amount of paracetamol that you have been taking.

Consult your doctor before use if the following situations occur:

- If you have a severe infection
- If you have severe nutritional deficiency
- If you are extremely underweight
- If you are a chronic heavy alcohol user (this may increase the risk of metabolic acidosis)

Symptoms of metabolic acidosis include:

- Deep, rapid and difficult breathing
- Nausea and vomiting
- Loss of appetite

If you are experiencing a combination of these symptoms, contact your doctor immediately.

If your symptoms do not improve, please consult your doctor.



Using PIROFEN with food and drink

The risk of harmful effects on the liver may increase when used with alcohol or alcohol-containing foods and beverages. Due to the risk of liver poisoning (hepatotoxicity) in people who consume alcohol, the daily dose of paracetamol should not exceed 2000 milligrams.

Foods may reduce the intestinal absorption of paracetamol.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

No harmful effects have been reported regarding the safety of PIROFEN use during pregnancy. However, during this period, it must still be used upon the recommendation of a physician.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

Taking PIROFEN at therapeutic doses by a breastfeeding mother does not pose a risk to the baby. Paracetamol passes into breast milk but only slightly. Breastfeeding mothers can use this medicine during this period upon the advice of a physician.

Driving and using machines

Dizziness or somnolence may occur in some patients due to paracetamol use. Patients using paracetamol should be careful during activities that require alertness.

Important information on some of the excipients in PIROFEN

If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicinal product due to sorbitol (E420) contained in PIROFEN. When used at the maximum daily dose, the amount of sorbitol you ingest may exceed 10 grams, which means you may experience a mild laxative effect.

If you have been told by a doctor that you or your child is intolerant (weak) against some sugars, contact the doctor before taking this medicinal product since PIROFEN contains sucrose.

This medicine may cause allergic reactions (possibly delayed) due to the content of methyl parahydroxybenzoate (E218).

PIROFEN may cause allergic reactions because it contains sunset yellow (E110) as a coloring agent.

Concomitant use with other drugs

The effect of PIROFEN may be altered when taken with certain medicines. Please inform your physician if your child is using any of the following medicines:

- Medicines that delay gastric emptying (e.g. propantheline used to treat gastrointestinal-biliary spasm, etc.)
- Medicines that accelerate gastric emptying (e.g. metoclopramide used to treat nausea and vomiting)
- Medicines that stimulate liver enzymes (e.g. some sleeping pills, some epilepsy medicines such as glutethimide, phenobarbital, phenytoin or carbamazepine, and rifampicin to treat infections)
- Chloramphenicol, an antibiotic



- Warfarin and coumarin derivative anticoagulants (medicines that prevent blood clotting)
- Zidovudine (a medicine used to treat and prevent HIV infections [AIDS] in children and adults)
- Domperidone (used to treat nausea and vomiting)
- Medicines containing St. John's Wort (*Hypericum perforatum*)
- Medicines containing cholestyramine (used to treat high cholesterol)
- Medicines containing tropisetron and granisetron (used to prevent nausea and vomiting in patients receiving radiotherapy and/or chemotherapy)
- Other pain-relieving medicines

You can use this medicine while taking oral contraceptives (birth control pills), but it may not work very well on your pain or fever.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

3. HOW TO USE PIROFEN

Instructions for proper use and dose/frequency of administration

Do not use more than the dose suggested by your doctor.

Use it at the lowest dose and for the shortest duration needed to relieve your symptoms.

Do not use PIROFEN more frequently than once every 4 hours.

Each 5 mL suspension contains 250 mg paracetamol.

PIROFEN is for use by individuals over 6 years of age.

Use every 6 hours, with each dose being 10-15 mg per kg of body weight. If your child weighs over 30 kg, use a maximum of 500 mg (10 mL, i.e. 2 measuring spoons) per dose.

Do not use more than 60 mg per kg of body weight in total in one day. If your child weighs over 30 kg, do not exceed a total of 2 grams (40 mL, i.e. 8 measuring spoons) per day.

Do not use for more than 3 consecutive days without consulting your doctor.

Since liver toxicity (poisoning) may occur in people who drink alcohol, the daily dose of paracetamol should not exceed 2000 milligrams.

Route and method of administration

Taken by mouth.

The thick consistency of PIROFEN prevents the medicine from spilling from the measuring spoon and makes it easier to apply.

Before each use, shake the bottle well.

PIROFEN is used without dilution.



Different age groups

Use in children

PIROFEN is for use by individuals over 6 years of age.

Use in the elderly

The normal adult dose is appropriate in healthy, active elderly patients, but dosage strength and frequency should be reduced in frail and inactive patients.

Special use conditions

Kidney failure

It should not be used in patients with severe kidney failure. It should be used with caution in patients with mild or moderate kidney failure.

Liver failure

It should not be used in patients with severe liver failure. It should be used with caution in patients with mild or moderate liver failure.

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

If you have taken more PIROFEN than you should

In case of overdose, the main symptoms are paleness, loss of appetite, nausea and vomiting; however, in some cases, symptoms may not appear for hours. Therefore, in case of overdose or accidental intake of the medicine, immediately inform your doctor or go to a hospital right away. It may cause liver damage when taken at high doses in a short period of time. If you have taken more PIROFEN than you should, seek medical help immediately due to the risk of liver failure, even if you have not experienced any symptoms.

If you have used more PIROFEN than you should, talk to a doctor or pharmacist.

If you have forgotten to take PIROFEN

Do not apply a double dose to compensate the missed dose.

Effects that may occur when treatment with PIROFEN is terminated

Take this medicine for the duration prescribed by your doctor. As long as it is taken as prescribed by the doctor, no negative effects are expected.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PIROFEN may cause side effects in people who are sensitive to its ingredients.

Side effects are classified as shown in the following categories:

Very common	: may occur in at least 1 in 10 patients.
Common	: may occur in less than 1 in 10 patients, but more than 1 in 100 patients.
Uncommon	: may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients.
Rare	: may occur in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
Very rare	: may occur in less than 1 in 10,000 patients.
Not known	: frequency cannot be estimated from the available data.



If any of the following happens, stop using PIROFEN and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Skin rash, itching, eczema, allergic (associated with hypersensitivity) edema, swelling of the face, tongue or especially the throat leading to shortness of breath (anaphylactic shock), widespread blistering rashes (acute generalized exanthematous pustulosis), symptoms resembling a scald appearance on the skin (toxic epidermal necrolysis), a type of hypersensitivity reaction (erythema multiforme) that produces lace-like rashes on the face, hands and feet.

These are all very serious side effects.

If you have any of these, it means you are seriously allergic to PIROFEN.

You may need emergency medical attention or hospitalization.

Very common

- Liver enzymes (ALT) exceeding the upper limit

Common

- Infection (microbial disease that causes inflammation)
- Headache
- Dizziness
- Somnolence
- Numbness (paresthesia)
- Upper respiratory tract infection
- Nausea
- Diarrhea
- Indigestion, digestive disorder (dyspepsia)
- Bloating (flatulence) due to gas in the stomach and intestines
- Stomachache
- Constipation
- Vomiting
- Liver enzymes (ALT) being 1.5 times the upper limit
- Edema in the face
- Post-extraction bleeding (bleeding after tooth extraction)

Uncommon

- Balance disorder
- Bleeding in the stomach and intestines (gastrointestinal bleeding)
- Peripheral edema (edema in areas such as hands and ankles)
- Post-tonsillectomy bleeding (bleeding after tonsil surgery)

Rare

- Skin rash
- Hives (urticaria)
- Itching
- Widespread blistering rashes (acute generalized exanthematous pustulosis)
- Signs resembling a scald appearance on the skin (toxic epidermal necrolysis)
- A hypersensitivity reaction causing lace-like rashes on the face, hands and feet (erythema multiforme)
- Allergic edema
- Swelling of the face, tongue and throat (angioedema)
- Appearance of spots (redness) and shaped lesions (eruption) on the skin, with or without fever



- Painful, red or purplish rashes and fluid-filled blisters that spread to the skin, usually starting with flu-like symptoms and eventually causing the upper layer of the skin to die and fall off (Stevens-Johnson syndrome).

Very rare

- Agranulocytosis (a dangerous leukopenia [reduction in the number of white blood cells] that can develop suddenly and frequently in the body)
- Thrombocytopenia (decrease in the number of platelets [blood cells involved in coagulation])
- Purpura (pinhead-shaped red bruises)
- Fever
- Asthenia (chronic fatigue)
- Bronchospasm (asthma-like symptoms in the lungs causing shortness of breath)
- Anaphylactic shock (swelling of the hands, feet, face and lips, or especially the throat, leading to shortness of breath)
- Positive allergy test
- Impaired liver function (hepatic dysfunction)
- Immune thrombocytopenia

Not known

- Harmful (nephrotoxic) effects of paracetamol, the active substance of PIROFEN, on the kidney following the doses used in treatment are not common. Kidney damage (papillary necrosis) has been reported with long-term administration.

See your doctor immediately if you have the following symptoms: feeling unusually tired, unexpected bruising or bleeding, and having more infections (such as a cold). These are very rare side effects in patients taking paracetamol.

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

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE PIROFEN

Keep PIROFEN out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

Shake the bottle vigorously before each use.

PIROFEN is used undiluted.

Use it in accordance with the expiry date.

Do not use PIROFEN after the expiry date, which is stated on the package.

Do not use PIROFEN if you notice any defects in the product and/or on its package.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. 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.



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Manufacturer:

DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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