

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Panadol, film-coated tablets, 500 mg

Composition: each film-coated tablet contains 500 mg paracetamol.

For information about inactive ingredients in the medicine see section 6 – “Additional information”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist. This medicine is dispensed without need for a doctor's prescription and is intended for adults and children from the age of 6 years and above. You should take this medicine according to the instructions in section 3 in this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if the fever persists for more than 3 days or if the symptoms worsen or do not resolve within 5 days despite use of the medicine.

1. What is the medicine intended for?

The medicine is intended to reduce fever and relieve pain. For short-term treatment of headache, muscle and skeletal pain, menstrual pain and toothache.

Therapeutic class: analgesic and antipyretic.

2. Before using the medicine:

Do not use this medicine if:

- There is a known sensitivity to paracetamol or to any of the ingredients of the medicine (listed in section 6)

Special warnings regarding the use of the medicine

- If you have developed skin side effects in the past as a result of taking medicines containing paracetamol, do not take medicines containing paracetamol, so that they do not cause severe skin side effects again.
- The medicine contains paracetamol which may cause liver damage when given at a higher dosage than recommended or for a prolonged period or when consuming alcoholic beverages or taking additional medicines which affect liver function during the course of treatment.
- Do not use this medicine frequently without consulting the doctor.
- Do not take other medicines for fever reduction and pain relief or cold medicines without consulting a doctor or a pharmacist, to prevent paracetamol overdose or poisoning.
- Do not take other medicines that contain paracetamol.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.

Tell the doctor before starting treatment if you suffer or have suffered in the past from:

- Sensitivity to any food or medicine
- Liver disease or impaired liver function
- Impaired kidney function
- Alcoholism
- Jaundice

Tell the doctor before starting treatment if:

- You are pregnant or breastfeeding

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Medicines for prevention of blood clots such as warfarin
- Medicines that stimulate the production of enzymes in the liver (for example: rifampicin, barbiturates)
- Medicines for epilepsy – phenytoin, carbamazepine
- Non-steroidal anti-inflammatory drugs
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Chloramphenicol (an antibiotic)
- Probenecid (for treatment of gout)
- Cholestyramine (for reduction of excess blood lipids)
- Flucloxacillin (an antibiotic), due to a serious risk of blood and fluid disorders (high anion gap metabolic acidosis), a condition that requires urgent treatment and may happen especially in cases of severe kidney impairment, sepsis (a condition in which bacteria and their toxins are present in the blood, leading to organ damage), malnutrition, chronic alcoholism and in cases in which the maximum daily dosage of paracetamol is used.

Using paracetamol and alcohol consumption

Do not consume alcohol during treatment with paracetamol due to increased risk of liver damage.

Pregnancy and breastfeeding

Pregnancy: if you are pregnant or breastfeeding, consult a doctor before you start using the medicine. Take the lowest dose that is effective for relieving your pain and/or reducing your fever, for the shortest duration possible. Consult the doctor if there is no reduction in pain or in fever or if you need to take the medicine more often.

Breastfeeding: small amounts of paracetamol pass into breastmilk. Consult a doctor before use.

Driving and operating machinery

Paracetamol does not affect the ability to drive or operate machinery.

Use in children

This medicine is intended for adults and children above 6 years of age, see section 3.

Parents must report to the treating doctor all side effects and any additional medicine given to the child.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The generally accepted dosage when no other instruction from the doctor is given:

Adults and children 12 years of age and above:

1-2 tablets every 4-6 hours, as needed.

Do not exceed a dosage of 8 tablets a day.

Children 9-12 years of age:

1/2-1 tablet every 4-6 hours, as needed.

Do not exceed a dosage of 4 tablets a day (2 grams per day).

Children 6-9 years of age:

1/2 tablet every 4-6 hours, as needed.

Do not exceed a dosage of 3 tablets a day (1.5 grams per day).

Do not give a tablet to children below 6 years of age.

- **Do not exceed the recommended dose.**

- **Refer to the doctor if the fever persists for more than 3 days or if the symptoms do not resolve within 5 days despite use of the medicine.**

Method of use:

Do not chew or crush! The tablets may be halved at the score line. The medicine should be swallowed with some water.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor!

Even if you feel well, immediate treatment is essential, **due to the risk of developing severe liver damage.** Side effects can be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, flatulence, increased sweating, pain or tenderness in the upper abdomen. These side effects may not reflect the severity of liver damage.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, use of Panadol may cause side effects, such as dizziness, in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. Side effects may be more severe in the elderly.

Serious side effects:

Stop the treatment and contact the doctor immediately:

- If acute allergic reactions appear, such as rash and itching, swelling of the extremities and/or swelling of the face, lips, tongue or throat which can cause breathing or swallowing difficulties
- If acute skin diseases appear (in rare cases) whose signs can be: redness, rash, blisters, widespread skin damage (acute skin side effects may appear even if you had no problems in the past taking preparations containing the active ingredient paracetamol)
- If skin side effects appear
- If signs of changes in the blood system occur, such as: bleeding, easily bruising, persistent fatigue, developing inflammations more easily (for example, sore throat) as a result of a severe decrease in the number of white blood cells
- If there is a shortness of breath (rare)
- If breathing problems appear. They are more likely to happen if you have experienced breathing problems in the past while taking other painkillers such as ibuprofen and aspirin
- If any of the following effects occur: nausea, sudden weight loss, loss of appetite, yellowing of the eyes and the skin.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor
- Do not use this medicine after the expiry date (exp.date) appearing on the package. The expiry date refers to the last day of that month
- Store below 25°C.

6. Additional information

- In addition to the active ingredient, the medicine also contains:
Pregelatinised starch, Maize starch, Talc, Stearic acid, Povidone (K25), Hypromellose, Potassium sorbate, Triacetin and Carnauba wax.
- What does the medicine look like and what are the contents of the package? Panadol tablets are white, film-coated and have flat edges, with a triangular logo debossed on one side and a score line on the other side.
Panadol tablets are manufactured in packs of 8, 10, 12, 20 or 24 tablets. Not all package sizes may be marketed.
- Marketing authorization holder: Haleon CH Israel Ltd., P.O. box 3256, Petach Tikva.
- Manufacturer: Haleon Ireland Dungarvan Ltd., Knockbrack, Dungarvan, County Waterford X35 RY76, Ireland.
- This leaflet was reviewed and approved by the Ministry of Health in June 2012 and updated in accordance with the Ministry of Health guidelines in September 2024.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 122-37-30225
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