Patient package insert according to Pharmacists' Regulations (Preparations) – 1986
This medicine can be sold without a physician's prescription

Dexamol®, Caplets, 500mg

Each caplet contains Paracetamol 500mg

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine is administered without a doctor's prescription and is intended for adults and children aged 6 years and older. Take this medicine according to the instructions in section 3 "How to use the medicine?" in this leaflet. Consult the pharmacist if you need additional information.
Refer to a doctor if the fever persists for more than 3 days or if the symptoms worsen or do not pass within 5 days despite use of the medicine.

1. What is the medicine intended for?

The medicine is intended for the relief of pain and fever of different etiologies such as headache, toothache, colds, influenza, rheumatic pain and menstrual pain.

Therapeutic group:
Analgesic and antipyretic.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (paracetamol), or to any of the other ingredients this medicine contains (see 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 preparations containing paracetamol, do not take preparations containing paracetamol, so that severe skin effects will not recur.
- The preparation contains paracetamol, which may cause liver damage when:
  - Given at a dosage higher than recommended or for a prolonged period.
  - Alcoholic beverages are consumed during the course of treatment.
  - Other medicines which affect liver function are taken.
- Do not use this medicine frequently without consulting a doctor.
- Do not take other antipyretics and analgesics or cold medicines without consulting a doctor or pharmacist to prevent paracetamol overdose or poisoning.
- Do not take other medicines from the **Dexamol** family and/or other paracetamol containing preparations.
- Avoid taking a high dosage (within the recommended limit) of this medicine when fasting.

Before starting treatment, tell the doctor if you suffer or have suffered in the past from:

- Sensitivity to any food or medicine
- A liver disease or impaired liver function
- Impaired kidney function
- Alcoholism
- Jaundice
- If you are pregnant or breastfeeding

During treatment with this medicine, tell your doctor immediately if:
You have serious illness, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood stream leading to organ damage), malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and

body fluids abnormality) has been reported in patients in these situations when paracetamol was taken at regular doses for a prolonged period or when paracetamol was taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, nausea and vomiting.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- Anticoagulants, such as warfarin.
- Preparations which stimulate liver enzyme activity (e.g., rifampicin, barbiturates).
- Antiepileptics – phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory drugs.
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems).
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).
- Cholestyramine (to reduce excessive blood fats).
- Flucloxacillin (antibiotic), due to a serious risk of blood and body fluids abnormality (called metabolic acidosis) which requires urgent treatment (see section 2).

Use of the medicine and alcohol consumption
Do not consume alcohol during the course of treatment with paracetamol due to increased risk of liver damage.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding consult the doctor before starting treatment with the medicine.
Pregnancy:
Take the lowest dose that is effective for you in relieving pain and/or lowering fever, for the shortest possible time. Consult the doctor if there is no relief of pain or fever or if you need to take the medicine more often.
Breastfeeding:
Small amounts of paracetamol pass into breast milk. Consult the doctor before taking the medicine.

Driving and using machines
Paracetamol does not affect the ability to drive or operate machinery.

Use in children
This medicine is intended for adults and children over the age of 6 years, see section 3.
Parents must report to the attending doctor any side effects and any additional medicine being given to the child.

Important information about some of the ingredients of the medicine
This medicine contains sunset yellow FCF aluminum lake (E110), which may cause allergic reactions.
This medicine contains less than 1 mmol sodium (23 mg) per caplet, that is to say essentially "sodium-free".

3. How to use the medicine?
Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
Unless otherwise instructed by the doctor, the usual recommended dosage is:
Adults and children aged 12 years and over:
1-2 caplets every 4-6 hours, as needed. Do not exceed a dosage of 8 caplets per day.
Children aged 6-9 years: ½ caplet every 4-6 hours, as needed. Do not exceed a dosage of 3 caplets per day (1.5 grams per day).
Children aged 9-12 years: ½ - 1 caplet every 4-6 hours, as needed. Do not exceed a dosage of 4 caplets per day (2 grams per day).
Do not give a caplet to children under 6 years of age.
Do not exceed the recommended dose.

Refer to a doctor if the fever persists for more than 3 days or if the symptoms worsen or do not pass within 5 days despite use of the medicine.

Method of administration:
Swallow the caplet with a small amount of water. The caplet can be halved. There is no information regarding chewing or crushing the caplet.

If you have accidentally taken a higher dosage
If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring 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 could be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, flatulence, increased sweating, pain or tenderness in the upper abdomen and they may not reflect the severity of the liver damage.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine.
Wear glasses if you need them.
If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. <u>Side effects</u>

Like any medicine, the use of **Dexamol** may cause side effects such as dizziness in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Side effects may be more serious in elderly people.

Serious side effects:
Stop taking this medicine and refer to a doctor immediately with the occurrence of:

- Acute allergic reactions including rash and itching, swelling of the face, lips, tongue, throat, which may cause difficulty in breathing or swallowing, swelling of the limbs.
- In rare cases, acute skin diseases whose signs can be: redness, rash, blisters, widespread skin damage. Acute skin side effects may occur even if you have taken preparations containing the active ingredient paracetamol in the past with no problem. If skin side effects occur, stop treatment and refer to the doctor immediately.
- Signs of changes in the blood system such as: bleeding, bruising easily, persistent tiredness, development of inflammations more easily (e.g. sore throats) as a result of a severe reduction in the white blood cell count.
- Shortness of breath (rare).
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- A serious condition called metabolic acidosis, that can make the blood more acidic, in patients with severe illness using this medicine (see section 2). The frequency of this side effect is not known (frequency cannot be estimated from the available data).

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

<u>Reporting side effects</u>
Side effects can be reported to the Ministry of Health by clicking the link
"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

5. <u>How to store the medicine?</u>

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**: Do not store above 25°C. In a bottle package, the medicine can be used after opening until the expiry date stated on the package.

6. Additional information

In addition to the active ingredients, the medicine also contains:
Povidone, hypromellose, titanium dioxide (E171), croscarmellose sodium, magnesium stearate, macrogol, quinoline yellow aluminum lake (E104), sunset yellow FCF aluminum lake (E110), carnauba wax

What the medicine looks like and what the package contains:
An oblong yellow caplet with a score line on both sides.
Approved package sizes:
Blister package: 8, 10, 16, 20, 32, 50, 56, 64, 100, 1000 caplets.
Bottle package: 50 caplets.
Not all package sizes may be marketed.
Revised in June 2025 according to MOH guidelines.
Drug registration number at the national drug registry of the Ministry of Health:
039-64-25921-00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel