

This medicine can be sold without a physician's prescription

Dexamol®, caplets, 500 mg

Each caplet contains paracetamol 500 mg
Inactive ingredients and allergens in the medicine – see section 6
"Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. Ask 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 the medicine in accordance with the instructions in section 3 "How to use this medicine" in this leaflet. Consult a pharmacist if you need further 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 relief of pain and to lower 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 overdose or paracetamol 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.

Tell the doctor before commencing treatment if you are suffering 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

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 production of liver enzymes (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).

Use of this 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

Pregnancy:
If you are pregnant or breastfeeding consult a doctor before commencing use of the medicine. 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 the breast milk. Consult the doctor.

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 this medicine

This medicine contains sunset yellow FCF aluminum lake (E110), which may cause allergic reactions. This medicine contains less than 1 millimole (23 mg) sodium per caplet, which means it is essentially "sodium free".

3. How to use this medicine

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

In the absence of other instruction from 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 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 do not pass within 5 days, despite use of the medicine.

Method of administration:

Swallow the medicine with a small amount of water. It is allowed to halve the caplets. There is no information regarding chewing or crushing.

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, excessive sweating, pain or sensitivity 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 each time 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. Side effects

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 the treatment and refer to a doctor immediately with the appearance of:

- Acute allergic reactions such as rash and itching, swelling of the face, lips, tongue, and 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 injury. Acute skin side effects may appear even if you have taken preparations containing the active ingredient paracetamol in the past with no problem. If skin side effects appear, stop treatment and refer to the doctor immediately.
- Signs of changes in the blood system such as: bleeding, bruising easily, development of inflammations more easily as a result of a severe reduction in the white blood cell count.
- Shortness of breath (rare).

If a side effect appears, 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.

Reporting side effects

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי בעקב טיפול תרופתי" that can be found on the home

page of the Ministry of Health (www.health.gov.il)

directing to the online form of adverse events reporting or via the following link:
<https://sideeffects.health.gov.il>

5. How to store the medicine

- 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 פגות) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store over 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 ingredient, this 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 (tray) package: 8, 10, 16, 20, 32, 50, 56, 64, 100, 1000 caplets.
Bottle package: 50 caplets.
Not all package sizes may be marketed.

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Drug registration number at the national drug registry of the Ministry of Health:
039-64-25921-00

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Manufacturer and registration holder:

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