

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold without a physician's prescription

DEXAMOL PLUS[®], CAPLETS

Each caplet contains Paracetamol 500 mg and Caffeine 50 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 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 12 years and older.

Take the medicine in accordance with the instructions in section 3 "How should you use the medicine?" in this leaflet. Consult the 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 3 days despite use of the medicine.

1. What is the medicine intended for?

Dexamol plus is intended for relief of pain and fever of different etiologies such as headache, toothache, colds, influenza, rheumatic pain and dysmenorrhoea.

Therapeutic group:

Paracetamol – Analgesic and antipyretic.
Caffeine – xanthine derivative, helps relieve pain.

2. Before using the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients (paracetamol, caffeine), or to any of the other ingredients this medicine contains (see section 6).
- If you are not sure, consult the doctor, pharmacist or nurse before taking the medicine.

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.

Tell the doctor before starting 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
- You drink a lot of caffeinated drinks e.g. tea and coffee

• If you are pregnant or breastfeeding
If you are not sure if any of the above apply to you, consult the doctor, pharmacist or nurse before using the medicine.

Drug interactions

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

Do not take any other medicines which contain paracetamol while taking Dexamol plus.

Especially tell the doctor or pharmacist if you are taking:

- Domperidone or metoclopramide (for treatment of nausea, vomiting and other digestive problems), may increase the pain relief effect of paracetamol.
- Cholestyramine (to reduce excessive blood fats), may reduce the pain relief effect of paracetamol.
- Warfarin or other coumarins (for thinning the blood) - if you take warfarin you can take occasional doses of **Dexamol plus**, but consult the doctor first before you take it on a regular basis.
- Isoniazid (for tuberculosis), may increase the effect of caffeine.
- Meprobamate (for reducing anxiety, tension and muscular spasms), may increase the effect of caffeine
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- Preparations which stimulate production of liver enzymes (e.g., rifampicin, barbiturates).
- Antiepileptics – phenytoin, carbamazepine.
- Non-steroidal anti-inflammatory drugs.
- Chloramphenicol (antibiotic).
- Probenecid (for treatment of gout).

If you are not sure if any of the above apply to you, consult the doctor, pharmacist or nurse before using the medicine.

Use of the medicine and alcohol consumption
Do not consume alcohol during treatment with the medicine.

Use of the medicine and food

As this medicine contains caffeine you should avoid drinking too many caffeine-containing drinks such as tea or coffee during treatment with the medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult the doctor or pharmacist before taking the medicine.

If necessary, the medicine can be used during pregnancy. Take the lowest dose that is effective for you in relieving pain and/or lowering fever, for the shortest time possible. Consult the doctor if there is no relief of pain or fever or if you need to take the medicine more often.

The caffeine in this medicine may affect your child.

Use in children

This medicine is intended for adults and children over the age of 12 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 FD&C yellow No. 6 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 should you 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.

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 3 days, despite use of the medicine.

Method of administration:

Swallow the medicine with water. If necessary, the caplet can be split in half for immediate use, to ease swallowing. The two halves must be swallowed together immediately after splitting. 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, 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 plus** 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 occurrence of:

- Acute allergic reactions such as rash and itching, swelling of the face, lips, tongue, throat, and neck, 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, development of inflammations more easily as a result of a severe reduction in the white blood cell count.
- Shortness of breath (rare).

Tell the doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- Nausea
- Headache
- Insomnia
- Skin rash

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.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי בקרב טיפול הרפואי" 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. 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 תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, the medicine also contains:

Povidone, croscarmellose sodium, hypromellose, magnesium stearate, iron oxide yellow (E172), titanium dioxide (E171), macrogol 400, iron oxide red (E172), FD&C yellow No. 6 aluminum lake (E110), iron oxide black (E172), carnauba wax

What the medicine looks like and what the package contains:

Brown caplet with a score line on both sides.
Approved package sizes: 10, 20, 30, 32, 50 caplets. Not all package sizes may be marketed. Revised in August 2022 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:
042-81-25950-00

Manufacturer and registration holder:
Dexcel[®] Ltd.

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