DEXAMOL®, Caplets

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

This medicine is dispensed without a physician's prescription.

Composition: Each caplet contains:
Paracetamol 500 mg.

For the list of inactive ingredients in the preparation – see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine is dispensed without a physician's prescription and is intended for adults and children above the age of 6 only; under this age the dosage forms intended for children should be used. You should use it correctly. Consult the physician or pharmacist if you need further information.

Refer to a physician if the fever persists for more than 3 days or if the symptoms of the illness worsen or do not improve within 3 days despite use of the medicine or in any situation in which new symptoms appear.

1. What is the medicine intended for?

Dexamol is intended to relieve pain and reduce fever caused by different factors, such as headache, toothache, cold, influenza, rheumatic pain and menstrual pain.

Therapeutic group:
Analgesic and anti-pyretic.

2. Before using this medicine

☒ Do not use the medicine if:

You are sensitive to paracetamol or to any of the other ingredients contained in the medicine.

❗ Special warnings regarding use of the medicine:

- **Before treatment with Dexamol, tell the physician if:**
  - You suffer or have suffered in the past from alcoholism, jaundice, impaired liver function or impaired kidney/urinary tract function.
  - You are sensitive to any type of food or medicine.
  - You suffer from arthritis and need to take painkillers every day.
- Do not use this medicine frequently without consulting a physician.
- Avoid taking a high dosage (even within the recommended limit) of this medicine while fasting.
- The preparation contains paracetamol which may cause damage to the liver in the following cases: when administered at a dosage higher than the recommended one or for a prolonged period, when consuming alcoholic beverages during the treatment period, or when taking additional medicines that affect the function of the liver.
- Do not take additional medicines for fever reduction and pain relief or cold medicines without consulting the physician or pharmacist - in order to prevent overdose or paracetamol poisoning.
- Do not take other medicines from the "Dexamol" family and/or other preparations containing paracetamol.
- 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.

❗ If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and food supplements, tell the physician or pharmacist. In particular, inform the physician or pharmacist if you are taking:

- Anticoagulants (e.g., warfarin).
- Medicines which stimulate liver enzyme activity, such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures and psychiatric problems), rifampicin (antibiotic), probenecid (for treatment of gout).
- Aspirin or other salicylates, other analgesics or anti-pyretics and non-steroidal anti-inflammatory drugs.
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other stomach problems) and cholestyramine (for reducing excessive blood lipids).
- Do not take this medicine together with other paracetamol-containing products (if you are unsure whether a medicine that you are taking contains paracetamol, consult the physician or pharmacist).

❗ Use of Dexamol and alcohol consumption
Do not drink alcoholic beverages during the course of treatment with this medicine due to the increased risk of liver damage.

❗ Pregnancy and breastfeeding
If you are pregnant or breastfeeding, consult a physician before commencing treatment.

❗ Use in children
This medicine is intended for adults and children above the age of 6, see section 3. Parents should report to the attending physician about any side effects and any additional medicine being given to the child.

3. How should you use the medicine?

Check with the physician or pharmacist if you are unsure.

Unless otherwise directed by the physician, the usual **dosage** is generally:
Adults and children aged 12 years and above: 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).
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).
Do not give this caplet to children under the age of 6 years.
Do not exceed the dosage recommended by the physician or pharmacist.
Swallow the medicine with water. It is permitted to halve or crush.

If you have accidentally taken too high a dosage or if a child has accidentally swallowed the medicine, refer immediately to a physician or proceed to a hospital emergency room, and bring the package of the medicine with you! Do not induce vomiting unless explicitly instructed to do so by the physician! Even if you feel well, immediate treatment is essential, due to the risk of developing severe liver damage.

Side effects such as diarrhea, excessive sweating, decreased appetite, nausea or vomiting, spasms or abdominal pain, flatulence, pain or sensitivity in the upper abdomen may occur and it is possible that these do not reflect the the liver damage.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

4. Side effects

As with any medicine, use of **Dexamol** may cause side effects, such as dizziness in some users. Do not be alarmed by the list of side effects. It is possible that you may not suffer from any of them. The side effects may be more severe in the elderly.

Serious side effects:
Stop treatment and refer to a physician immediately if the following occur:

- Signs of allergy such as: rash, itching of skin occasionally accompanied by swelling of the face, lips, tongue, throat which may cause difficulty breathing/ shortness of breath, swelling of the limbs.
- Paracetamol can, in rare cases, cause the appearance of severe skin diseases, whose signs can be: redness, rash, blisters, mouth sores, peeling skin, widespread skin damage.
  Severe skin side effects may appear even if you have taken preparations containing the active ingredient paracetamol in the past with no problem.
- Signs of changes in the blood system, e.g., tendency of bleeding, unexplained bruises, development of inflammations more easily.
- Nausea, sudden weight loss, decreased appetite and yellowing of skin and eyes.
- Side effects that stem from an overdose (see section "If you have accidentally taken too high a dosage").

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, you must consult with the physician.

5. How should the medicine be stored?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/ or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician!

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage Conditions:
Store at a temperature below 25°C.
Store in the original packaging.

6. Further information

In addition to the active ingredient, the medicine also contains:
Povidone, Croscarmellose sodium, Magnesium stearate.
Coating: Hypromellose, Macrogol, Titanium dioxide, Carnauba wax.
Pigments: E-104, E-110
Each caplet contains 0.3 mg of sodium.

What the medicine looks like and what are the contents of the package:
An elongated yellow caplet with a score line on both sides.
The approved package sizes: 8, 16 caplets for the medicine packaged in blister packs.
Not all package sizes may be marketed.
Manufacturer and license holder:
Dexcel Ltd., 1 Dexcel St., Or-Akiva 3060000, Israel.

This leaflet was checked and approved by the Ministry of Health in 11/2013.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 039 64 25921 00

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