

This medicine can be sold without a physician's prescription.

## DEXAMOL COLD® NIGHT CARE, CAPLETS

Each caplet contains:

Paracetamol 500 mg  
Pseudoephedrine HCl 25 mg  
Dextromethorphan Hydrobromide 10 mg  
Chlorpheniramine maleate 2 mg

For list of excipients, please see section 6.

**Read this entire leaflet carefully before you start taking this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.

This medicine is intended for adults and children over 12 years of age. Only under the age refer to the physician. Use it in the correct manner. Consult the physician or the pharmacist if you need additional information.

Refer to the physician if the fever lasts for more than 3 days or if the symptoms of the illness get worse. Do not mix this medicine with alcohol, the use of the medicine or in any situation, where new symptoms appear.

### 1. What is the medicine used for?

Symptomatic relief of cold, cough and nasal congestion accompanied by fever and pain, for treatment at night.

#### Therapeutic group:

- Paracetamol: pain reliever and fever reducer.
- Pseudoephedrine HCl: sympathomimetic amine which relieves runny nose, nasal and ear congestion, accompanying a cold and/or sinusitis.
- Dextromethorphan Hydrobromide: suppresses cough accompanying a cold.
- Chlorpheniramine maleate: an antihistamine that dries mucus.

### 2. Before using the medicine

#### Do not use the medicine if:

- You are pregnant or breastfeeding.
- You are hypersensitive (allergic) to the active ingredients (paracetamol, pseudoephedrine, dextromethorphan or chlorpheniramine), other antihistamines or any other decongestants, or to any of the ingredients of this medicine.
- You are treated concomitantly with medicines of the monoamine oxidase inhibitors (MAOIs) group (e.g. for the treatment of depression) or within 14 days of stopping treatment with them: if you are treated with medicines of the following groups: SSRIs (serotonin selective reuptake inhibitors); decongestants; additional medicines that contain antihistamine, other cough and cold medicines; beta-blockers (e.g. for the treatment of heart problems or hypertension).
- Do not use this medicine for the relief of chronic cough.
- Do not use this medicine concomitantly with other paracetamol containing medicines. (If you are not sure whether the medicine that you are taking contains paracetamol, consult a physician or pharmacist).
- You suffer from the following diseases or conditions: severe liver disease, heart or vascular disease, severe liver or

kidney disease, overactive thyroid gland, increased intracranial pressure (glaucoma), prostate gland enlargement, cold accompanied by excessive phlegm or that lasts for long term, difficulty breathing, asthma, lung disease or diabetes.

#### Special warnings regarding the use of product medicine:

##### • Before taking DexamolCold Night Care tell your physician if:

- You suffer or have suffered in the past from impaired function of the respiratory system (e.g. asthma, chronic bronchitis, cough with excessive phlegm or that is long lasting e.g. cough caused by the enlargement of the prostate gland, bronchiectasis), the heart and/or blood vessels, the liver (including alcoholic liver disease), the kidney (e.g. a tumour of the prostate, prostatic hyperplasia, the urinary tract, the digestion system (e.g. ulcer), the thyroid gland or the nervous system).
- You suffer or have suffered in the past from hypertension, coronary arterial disease, increased intracranial pressure (glaucoma), difficulty urinating, enlargement of the prostate gland, alcoholism, jaundice, diabetes, epilepsy or increased restlessness.
- You are over the age of 60, as patients at this age may be sensitive to decongestive medicines.
- You are sensitive to any food or medicine.
- You suffer from arthritis and have to take pain relievers every day.
- Do not use this medicine frequently without consulting a physician.
- Avoid taking a high dosage (even if the recommended limit) of this medicine while fasting.
- This medicine contains paracetamol that may cause damage to the kidney and liver in the following cases: when administered at a dosage higher than recommended or taken for a prolonged period, when consuming alcoholic beverages during the treatment period or when taking additional medicines that affect liver function.
- Do not take additional medicines for fever (including analgesics) or other cold medicines without consulting a physician or pharmacist – in order to prevent paracetamol overdose/toxicity.
- Do not take additional medicines of the "Dexamol" group and/or additional paracetamol containing medicines.
- If you have developed dermal side effects (e.g. in the past resulting from taking medicines containing paracetamol, do not take products containing paracetamol to avoid recurrence of severe skin manifestations.
- If you are about to undergo laboratory tests, you should inform the physician of taking this medicine, as treatment with this medicine may affect the test results.

**If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, tell the physician or pharmacist.** Especially inform the physician or pharmacist if you are taking:

- medicines affecting the central nervous system (e.g. sedatives, hypnotics, for Parkinson's disease, for convulsions (epilepsy),

antiallergics (such as antihistamines that cause drowsiness), anesthetics for surgeries and narcotic pain relievers).

- Anticoagulants (e.g. warfarin), antidepressants (e.g. medicines of the tricyclic antidepressants group), and medicines of the treatment of anxiety.
- Methyldopa and other antihypertensive medicines and medicines for the treatment of heart problems (e.g. alpha blockers, amiodarone, cocaine or other).
- Medicines that increase liver enzyme activity such as barbiturates, phenylion or carbamazepine (used mainly for epilepsy, seizures, psychiatric problems), antibiotics such as rifampicin, chloramphenicol or linezolid, lopinavir (anti-viral), probenecid (for the treatment of gout).
- Aspirin or other salicylates, additional pain relief or fever reducing medicines, and non-steroidal anti-inflammatory drugs, medicines for the treatment of rheumatoid arthritis, medicines that may cause dry mouth, anticholinergic medicines or medicines that have an anticholinergic activity (such as stomach medicines).
- Metoclopramide or domperidone (for the treatment of nausea, vomiting and other stomach problems), cholestyramine (for the treatment of the bile cholesterol level), oral contraceptives, oxytocin (for induction of labor and cessation of excessive bleeding during birth).
- Do not use this medicine if you are concomitantly treated with medicines of the following groups: monoamine oxidase inhibitors (MAOIs), SSRI selective serotonin reuptake inhibitors, decongestants, additional medicines that contain antihistamine, other cough and cold medicines, beta blockers and other medicines containing paracetamol – see also section "Do not use the medicine if".

#### Use of this medicine and food

Take this medicine with food in order to reduce stomach problems.

#### Use of this medicine and alcohol consumption

Do not drink alcoholic beverages during the period of treatment with this medicine due to the increased risk of liver damage.

#### Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or breastfeeding.

#### Use in children

This medicine is intended for adults and children over the age of 12 only. Parents should report to the physician about any side effects and any additional medicine given to the child.

#### Driving and use of machinery

Use of the medicine may cause drowsiness, dizziness, impaired alertness and cause blurred vision. In such cases, do not drive a vehicle, operate dangerous machinery or be involved with any activity that requires alertness. Children should be warned against riding a bicycle or playing near roads etc.

#### 3. How to use this medicine

Check with a physician or pharmacist if you are not sure.

Unless otherwise instructed by the physician, the recommended dosage is:

Adults and children over 12 years of age: 1-2 caplets before bedtime.

In concomitant use with DexamolCold Day Care, replace a dose of DexamolCold Day

Care with a dose of DexamolCold Night Care, and do not take it as a supplement to the above maximum recommended dosage of DexamolCold Night Care.

#### Do not exceed the recommended dose by the physician or pharmacist.

Swallow the medicine with water, it can be halved. There is no information regarding crushing.

**If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a physician or to the nearest hospital room, and bring the package of the medicine with you! Do not induce vomiting unless explicitly instructed to do so by a physician even if you feel well.** Immediate treatment is essential, because of the risk of developing severe liver damage. Do not drive if you have taken an overdose.

Side effects may occur such as: diarrhea, excessive sweating, poor appetite, nausea (or vomiting), abdominal cramps or pain, swelling, pain or tenderness in the upper abdomen, acute inflammation of the pancreas and they may not reflect the damage to the liver. In addition adverse reactions may appear such as: blurred vision, confusion, difficulty urinating, slow breathing and excessive nervousness.

**If you forgot to take this medicine,** take the next dose as scheduled.

Do not take a double dose to compensate for the forgotten dose.

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

If you have any further questions regarding the use of this medicine, consult a physician or pharmacist.

#### 4. Side effects

Like all medicines, the use of DexamolCold Night Care may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them. The side effects may be more serious in the elderly.

#### Serious side effects:

**Stop use of this medicine and refer to the physician immediately if you have the following appear:**

- Signs of allergy such as: rash, itching skin, wheezing often accompanied by swelling of the face, lips, tongue, throat which may cause breathing difficulties/ shortness of breath, swelling of the limbs.
- Impaired liver function including liver inflammation (hepatitis) and jaundice (manifested as yellowing of the skin and eyes).
- Paracetamol can in rare cases cause the appearance of acute skin diseases that may have signs such as: redness, rash, blisters, mouth ulcers, peeling skin, extensive skin damage.
- Acute skin side effects may also occur if in the past you have taken medicines containing the active ingredient paracetamol without any problem.

- Dry mouth, that may cause an increase in craves (it is recommended to use artificial saliva and keep oral hygiene), vomiting, diarrhea, stomach pain, indigestion, lack of coordination, confusion, agitation, feeling anxiety, restlessness or paranoia, sleep disturbances, dizziness, hallucinations, difficulty urinating especially in men suffering from a prostate problem, kidney damage (with prolonged use), irregular heart rate or changes in heart rate, palpitations or "lightness" in the chest.
- Extreme fatigue, tendency to hemorrhages, bleeding and unusually high tendency of contracting infections, these symptoms may indicate systemic disorders (decrease in the number of blood cells, such as anemia, thrombocytopenia, pancytopenia, agranulocytosis, leucopenia or neutropenia).
- Nausea, sudden loss of weight, poor appetite.
- Cough that lasts for more than 7 days, comes back or is accompanied by fever, rash or persistent headache.
- Side effects resulting from overdose (see section "If you have accidentally taken a higher dosage").
- Collapse.

#### Additional side effects:

Feeling tired, drowsiness, concentration difficulties, blurred vision, headache, feeling generally unwell, feeling stressed or over excitement, tremor, ringing in the ears, heartburn, nausea, increase in the viscosity of the phlegm (increased coughing, phlegm), increased sun sensitivity, sensitivity to light, muscle weakness, cramps, depression, low mood, bad dreams, hypotension (may cause you to feel faint), hyperactivity (especially in children).

If a side effect appears, if any of the side effects worsens, or if you suffer from side effect not mentioned in this leaflet, consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "בידור מרחב" or "בידור מרחב" that can be found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of adverse events reporting or via the following link: <http://il.sphdada/getsequence/getsequence.aspx?unittype=AdverseEffectMedication.gov.il>

#### 5. How to store the medicine?

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe 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 physician. Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month. Store at a temperature below 25°C. Store in the original package.

#### 6. Additional information

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

Povidone, Croscarmellose sodium, Hypromellose, Magnesium stearate, Titanium dioxide E171, Macrogol, Erythrosine aluminum lake

E-127, Silica colloidal anhydrous, Indigo carmine aluminum lake, E-132, Quinoline yellow aluminum lake, E-104, Carnauba wax, Brilliant blue FCF aluminum lake, 1333.

**What the medicine looks like and what does the package contains:**  
Elongated pink caplet with a score line on both sides.

Each package contains 10, 16, 20, 50 or 100 caplets in blisters.

Not all package sizes may be marketed.

**Drug registration number at the national medicines registry of the Ministry of Health: 053-66-26462-00**

This leaflet was checked and approved by the Ministry of Health in March 2016

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**Manufacturer and registration holder:**

**Dexcel® Ltd**

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