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

Dexamol cold® night care, Caplets

Each caplet contains: Paracetamol 500mg, Pseudoephedrine hydrochloride 25mg, Dextromethorphan hydrobromide 10mg and Chlorpheniramine maleate 2mg.

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 over 12 years.
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 improve after 5 days despite use of the medicine or in any case in which new symptoms occur.

1. What is the medicine intended for?

The medicine is intended for the symptomatic relief of cold, cough and nasal congestion accompanied by fever and pain, for treatment at night.

Therapeutic group:
Paracetamol – analgesic and antipyretic.
Pseudoephedrine – relieves nasal congestion.
Dextromethorphan – cough suppressant.
Chlorpheniramine – antihistamine.

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, chlorpheniramine), to other antihistamine or any other decongestants, or to any of the other ingredients this medicine contains (see section 6).
- You are taking or have taken in the last 14 days, medicines from the Monoamine Oxidase Inhibitors (MAOIs) group (for depression) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- You are taking or have taken in the last two weeks, medicines from the Selective Serotonin Reuptake Inhibitors (SSRIs) group (for depression or anxiety).
- You are taking or have taken in the last two weeks other medicines for depression, psychiatric or emotional conditions or medicines for Parkinson's disease.
- You are taking other decongestants, additional cough and cold medicines.
- You are taking medicines from the beta-blockers group (used to treat heart problems, high blood pressure).
- You suffer from heart disease or high blood pressure.
- You have diabetes.
- You are a child under the age of 12 years.
- You are taking other preparations containing paracetamol (if you are not sure whether the medicine that you are taking contains paracetamol, consult the doctor or pharmacist).
- You suffer from overactive thyroid gland.
- You suffer from increased pressure in the eye (glaucoma).
- You suffer from severe kidney disease.
- You suffer from Phaeochromocytoma (a rare tumor in the adrenal gland which affects blood pressure and heart rate).

- You are taking medicines that stimulate or suppress appetite or medicines for asthma (sympathomimetic medicines).

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.
- You must inform the doctor if you are about to undergo laboratory tests, since the treatment with this medicine may affect the test results.
- 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.
- If you are sensitive to any food or medicine, you must inform the doctor before taking this medicine.
- Taking this medicine regularly for a long period of time can lead to addiction. Take this medicine as described in this leaflet.

Before the treatment with Dexamol cold night care, tell the doctor if you suffer or have suffered in the past from:
- Disease or impaired function of the heart and/or blood vessels (such as: coronary artery disease – blocked arteries or veins)
- Disease or impairment in the respiratory system, such as: asthma or if you are suffering from an asthma attack, bronchitis, cough for a long time, cough accompanied by fever, rash or persistent headache or any other lung problem
- Liver disease or impaired liver function
- Impaired kidney function
- Difficulty passing urine or enlarged prostate (causes frequent urination)
- Impaired thyroid function
- Impaired prostate function
- You are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs
- You have recently suffered from withdrawal symptoms such as: agitation, anxiety, sweating or shaking, when you have stopped taking alcohol or drugs.
- Epilepsy
- Jaundice

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 tell the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:
- Anticholinergics (to treat cramps and spasms such as atropine)
- Medicines from the Selective Serotonin Reuptake Inhibitors (SSRIs) group (for depression or anxiety) or if you have taken them within the last two weeks (see in section 2, "Do not use the medicine if")
- Anticoagulants especially warfarin
- Antidepressants (including MAOIs, RIMAs – see in section 2, "Do not use the medicine if") or if you have taken them within the last two weeks
- Tricyclic antidepressants
- Medicines for depression, psychiatric or emotional conditions or Parkinson's disease or if you have taken them within the last two weeks (see in section 2, "Do not use the medicine if")

- Moclobemide – antidepressant
- Other antihistamines, including those in cough and cold medicines (e.g. other medicines for nasal congestion, see in section 2, "Do not use the medicine if") that make you sleepy
- Antihypertensives (to treat high blood pressure) such as: guanethidine, methyldopa, adrenergic neuron blockers, debrisoquine, bretylium and betanidine or other antihypertensives (e.g., beta-blockers – see in section 2, "Do not use the medicine if")
- Preparations which stimulate liver enzyme activity (e.g., barbiturates)
- Antiepileptics – phenytoin, carbamazepine
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Chloramphenicol or rifampicin (antibiotic)
- Probenecid (for treatment of gout)
- Cholestyramine (to reduce excessive blood fats)
- Non-steroidal anti-inflammatory drugs
- Medicines for anxiety and sleeping pills
- Oral contraceptives
- Ergot alkaloids – for the treatment of migraines, such as: ergotamine or methysergide
- Cardiac glycosides (medicines used to treat heart rhythm disorders or heart failure such as digoxin)
- Medicines to treat heart problems such as quinidine and amiodarone
- Oxytocin (medicine to help contractions during childbirth)
- Terbinafine for the treatment of fungal infections
- Cinacalcet for the treatment of secondary hyperparathyroidism (overactive parathyroid gland)
- Methadone for the treatment of severe pain

Inform the doctor or pharmacist if you are taking 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

If you are taking **Dexamol cold night care** with antidepressants or antipsychotics, you may experience mental status changes (such as: agitation, hallucinations, coma) and other symptoms such as: body temperature above 38°C, increased heart rate, unstable blood pressure, exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (nausea, vomiting, diarrhea).

Use of the medicine and food
The medicine should be taken after a meal.

Use of the medicine and alcohol consumption
During treatment with this medicine, do not consume alcohol due to the increased risk of liver damage.

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

Driving and using machines
Do not drive or operate dangerous machinery while using this medicine because this medicine may impair alertness, you may feel drowsy, dizzy or have blurred vision. As for children, they should be warned about riding a bicycle or playing near roads etc.

Use in children
This medicine is intended for children over 12 years, see section 3.
Parents must inform the attending doctor of any side effects and any other medicine being given to the child.

Important information about some of the ingredients of the medicine

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 over 12 years:
1-2 caplets before bedtime.
Patients over 60 years: consult the doctor before using this medicine, as they may be sensitive to preparations of this kind.
Upon concomitant use of **Dexamol cold day care** do not exceed a total daily dosage of 8 caplets (upon concomitant use of **Dexamol cold day care**, replace a dose of **Dexamol cold day care** with a dose of **Dexamol cold night care** and do not take it as a supplement to the maximum dosage recommended above for **Dexamol cold night care**).
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 improve after 5 days despite use of the medicine, or in any case in which new symptoms occur.

Method of administration:
Swallow the caplet with 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.
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. They may not reflect the severity of the liver damage. Muscle contractions, agitation, confusion, somnolence, impaired alertness (consciousness), rapid and involuntary eye movements, heart problems (rapid heart rate), coordination problems, severe mental disorder with hallucinations, hyperexcitability.

If you forgot to take this medicine, take the next dose when needed, provided that the last dose was taken at least 4 hours before taking the current dose. Do not take a double dose.

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 cold night care** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects:
Stop taking this medicine and refer to a doctor immediately with the occurrence of:
- Acute allergic reactions including skin rash such as hives (may include blistering and peeling of the skin) and itching, swelling of the face, lips, mouth, tongue, throat, which may cause difficulty in breathing or swallowing, swelling of the limbs
- Paracetamol may, in rare cases, cause 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
- Stomach upset
- Dizziness, drowsiness, confusion

- Hallucinations (rare) (hearing or seeing things that do not exist, irrational thoughts and feelings)
- Problem passing urine, especially in men with a prostate problem
- Signs of changes in the blood system such as: unexplained tiredness, bleeding, anemia, bruises, development of infections more easily
- Irregular heartbeat, chest tightness
- Sudden severe headache, nausea, vomiting, confusion, fits, visual disturbances
- Sudden and severe abdominal pain or rectal bleeding due to inflammation of the colon as a result of insufficient blood supply (Ischaemic colitis)
- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders, arms) or a heart attack
- Stroke (weakness of the face, arms or legs or speech problems)
- A sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalised Exanthematous Pustulosis - AGEP) which may occur during the first two days of treatment with this medicine
- Sudden loss of vision
- Liver problems including jaundice (yellowing of the skin and eyes)
- Lack of coordination
- Confusion among the elderly

Additional side effects:
Very common side effects (effects that occur in more than 1 in 10 users):
- Headache

Common side effects (effects that occur in 1-10 out of 100 users):
- Difficulty sleeping, nervousness, dizziness
- Dry mouth or nausea

Side effects with unknown frequency (effects for which a frequency has not yet been determined):
- Anxiety, restlessness, irritability, feeling jittery or feelings of extreme happiness
- Sleep disturbances
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)
- Drowsiness
- High blood pressure
- Abdominal pain, diarrhea, vomiting
- Pain when passing urine
- Tingling or numbness of the hands or feet
- Tremor
- Reduced blood flow to the optic nerve may cause sudden loss of vision (Ischaemic optic neuropathy)
- Dependence and addiction - when you stop taking the medicine you may experience drug withdrawal symptoms, which include: restlessness, difficulty sleeping, irritability, anxiety, palpitations, high blood pressure, nausea and vomiting, diarrhea, shaking, sweating
- Fatigue
- Dry mouth, loss of appetite, heartburn
- Nightmares, depression, low blood pressure, rash, sensitivity to light, nausea, increased viscosity of sputum (may cause cough or phlegm)
- Ringing in the ears, blurred vision, inability to concentrate, malaise, muscle weakness, muscle twitching, hyperactivity in children, blood disorders such as anemia
- Low blood count, hepatitis (severe abdominal pain, nausea, vomiting, loss of appetite)

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. 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, titanium dioxide (E171), macrogol 400, erythrosine aluminum lake (E127), silica colloidal anhydrous, indigo carmine aluminum lake (E132), quinoline yellow aluminum lake (E104), brilliant blue FCF aluminum lake (E133), carnauba wax

What the medicine looks like and what the package contains:
A pink caplet with a score line on both sides.
Approved package sizes: 10, 16, 20, 50 caplets. Not all package sizes may be marketed.
Revised in March 2023 according to MOH guidelines.
Drug registration number at the national drug registry of the Ministry of Health:
053-66-26462-00

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