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

Dexamol cold® day care, Caplets

Each caplet contains: Paracetamol 325mg, Guaifenesin 200mg, Pseudoephedrine hydrochloride 25mg, Dextromethorphan hydrobromide 10mg.

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.
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.
This medicine is intended for adults and children from the age of 12 years and above.

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 day.

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

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredients (paracetamol, guaifenesin, pseudoephedrine, dextromethorphan), to 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 (to treat 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 a very high blood pressure (severe hypertension) or from hypertension that is not controlled by medications, from heart or blood vessel disease or a history of stroke.
- You have diabetes.
- You are a child under 12 years of age.
- 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 have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- 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 to treat asthma (sympathomimetic medicines).

- You have a chest infection, worsening asthma or severe respiratory problems.

Special warnings regarding the use of the medicine

- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using **Dexamol cold day care** immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Side effects" for symptoms).
- 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.
- 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.
  Possible signs of addiction to this medicine:
  - You need to take the medicine for a longer period of time than recommended
  - You feel the need to use a higher dose than the recommended dose
  - You are using the medicine for reasons other than prescribed
  - You feel unwell when you stop taking the medicine, and you feel better when you take the medicine again

  If you notice any of these signs, it is important that you talk to your doctor or pharmacist.

Before the treatment with Dexamol cold day 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, persistent cough, cough accompanied by fever, rash or persistent headache
- 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
- Jaundice

During treatment with this medicine, tell your doctor immediately if:

You have serious illness, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood stream leading to organ damage), malnutrition, chronic alcoholism or if you are also taking flucloxacillin (antibiotic). A serious condition called metabolic acidosis (a blood and body fluid abnormality) has been reported in patients in these situations when paracetamol was taken at regular doses for a prolonged period or when paracetamol was taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, nausea and vomiting.

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 spasms and cramps 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
- Medicines for lowering blood pressure, such as: guanethidine, methyldopa, adrenergic neuron blockers, debrisoquine, bretylium and betanidine or other medicines for lowering blood pressure (such as: beta blockers – see in section 2, "Do not use the medicine if", alpha blockers or vasodilators) and medicines for the heart (such as: amiodarone, quinidine)
- Preparations which stimulate liver enzyme activity (such as: phenytoin [for convulsions], barbiturates)
- Anticonvulsant medicines (for the treatment of epilepsy), such as: phenytoin, carbamazepine
- Metoclopramide or domperidone (for treatment of nausea, vomiting and other digestive problems)
- Chloramphenicol or rifampicin (antibiotics)
- Probenecid (for treatment of gout)
- Cholestyramine (to reduce excessive blood fats)
- Non-steroidal anti-inflammatory drugs
- Oral contraceptives
- Cardiac glycosides (medicines used to treat heart rhythm disorders or heart failure such as digoxin)
- Ergot alkaloids – for the treatment of migraines, such as: ergotamine or methysergide
- 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
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (metabolic acidosis) that must have urgent treatment (see in section 2)

If you are taking **Dexamol cold day 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 can be taken with or without food.

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

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

Driving and using machines
The medicine may make you feel tired and dizzy; therefore, the medicine may affect your ability to drive or use tools or machinery.
Do not drive or operate machinery until you know how the medicine affects you.
As for children, they should be warned about riding a bicycle or playing near roads etc.

Additional information
The active ingredient pseudoephedrine has potential for abuse. An increased dose may be toxic. Prolonged use may lead to taking a higher dose than recommended in order to achieve the desired effect, resulting in an increased risk of overdose. Do not exceed the recommended dose and duration of treatment (see section 3).

Important information about some of the ingredients of the medicine
This medicine contains Ponceau 4R aluminum lake (E124), 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 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 above 12 years of age: 1-2 caplets, every 4-6 hours, up to 4 times a day.
Do not exceed a total daily dosage of 8 caplets.
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 night care** do not exceed a total daily dosage of 8 caplets (upon concomitant use of **Dexamol cold night 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 day care**).
Wait at least 4 hours before taking your next dose.
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 and 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 accompanied by hallucinations, tendency to become overexcited.

If you forgot to take this medicine, take the next dose as 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 <u>each time</u> 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 day 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 using the medicine immediately and seek urgent medical attention:
If you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- Severe headache with a sudden onset
- Feeling sick
- Vomiting
- Confusion
- Seizures
- Changes in vision

Stop taking the 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, rapid heart rate
- 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, bruises, development of infections more easily
- Irregular heartbeat
- 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

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):

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

- 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 which may cause 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
- A serious condition that can make the blood more acidic (called metabolic acidosis), in patients with severe illness using this medicine (see in section 2)

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 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:
Croscarmellose sodium, talc, povidone, hypromellose, magnesium stearate, titanium dioxide (E171), methylcellulose, silica colloidal anhydrous, macrogol 400, brilliant blue FCF aluminum lake (E133), ponceau 4R aluminum lake (E124), quinoline yellow aluminum lake (E104), carnauba wax

What the medicine looks like and what the package contains:
A blue caplet with a score line on both sides.
Approved package sizes: 10, 16, 20, 30, 48, 50 caplets. Not all package sizes may be marketed.
Revised in August 2025 according to MOH guidelines.
Drug registration number at the national drug registry of the Ministry of Health:
057-04-26978-00

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