

DEXAMOL® COLD DAY CARE, CAPLETS

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

This medicine can be sold without a physician's prescription

Each caplet contains:

Paracetamol	325 mg
Guaifenesin	200 mg
Pseudoephedrine HCl	25 mg
Dextromethorphan Hydrobromide	10 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, ask your physician or pharmacist.

This medicine is intended for use in adults and children over 12 years of age only. Under this age, refer to your physician. Use in the correct manner. Consult your pharmacist if you need additional information.

Refer to your physician if the fever lasts for more than 3 days or if the symptoms of your illness get worse or do not improve within 3 days despite 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, day care medicine.

Therapeutic group:

- Paracetamol - pain reliever and fever reducer.
- Guaifenesin - expectorant that helps release phlegm and secretions accumulated in the respiratory tract due to cold.
- Pseudoephedrine Hydrochloride - sympathomimetic amine which relieves runny nose, nasal and ear congestion, accompanying a cold and/or sinusitis.
- Dextromethorphan Hydrobromide - suppresses coughing that accompanies a cold.

2. Before you take the medicine:

Do not use the medicine if:

- You are pregnant or breastfeeding.
- You are under 12 years old.
- You are hypersensitive to the active ingredients (paracetamol, pseudoephedrine, guaifenesin or dextromethorphan) or to any of the other ingredients of this medicine or to other decongestants.
- You are treated concomitantly with medicines of the following groups: monoamine oxidase inhibitors (MAOIs) (e.g. for the treatment of depression) or within 14 days of stopping treatment with them; SSRIs (serotonin selective reuptake inhibitors); decongestants, 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 your physician or pharmacist).
- If you suffer from the following diseases or conditions: hypertension, heart or vascular disease, severe liver or kidney disease, overactive thyroid gland, increased intraocular pressure (glaucoma), prostate gland problems, a cough accompanied by excessive phlegm or that lasts long, difficulty breathing, lung disease or diabetes.

Special warnings regarding the use of this medicine:

- Before taking Dexamol Cold Day Care tell your physician if:
 - you suffer or have suffered in the past from impaired function of the respiratory system (e.g. asthma, long lasting cough with excessive phlegm, chronic bronchitis, or cough accompanied with fever, rash or lasting headache), the heart and/or blood vessels, the liver, the kidney (e.g. a tumour of the pheochromocytoma type) or urinary tract, the thyroid gland, the nervous system.
 - you suffer or have suffered in the past from hypertension, coronary arterial disease, increased intraocular pressure (glaucoma), epilepsy, alcoholism, jaundice (including a disease caused by alcohol consumption), enlarged prostate gland, problems with urinating, diabetes or increased restlessness.
 - you suffer from fever, rash or permanent headache.
 - 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 your physician.
- Avoid taking a high dosage (even if at 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 for an extended 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 reduction and relief of pain, or other cold medicines, without consulting your 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 in the past resulting from taking products containing paracetamol, do not take products containing paracetamol to avoid severe skin manifestations from recurring.
- If you are about to take a urine test, you should inform your physician regarding taking this medicine, as treatment with this medicine may affect the test results. You should also inform your physician if you have recently finished treatment with this medicine.

Please tell your physician or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.

Especially inform your physician or pharmacist if you are taking:

- medicines affecting the central nervous system (e.g. appetite suppressants, medicines used to treat congestion or asthma), antiallergics or medicines that cause sleepiness, mental health medicines such as: antidepressants, for example: of the tricyclic group (tricyclic antidepressants), sedatives and hypnotics.
- anticoagulants (warfarin)
- methyldopa and other antihypertensive medicines and medicines used to treat heart problems (such as: alpha blockers, amiodarone, digoxin or quinidine); medicines that increase liver enzyme activity such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures, psychiatric problems); additional medicines for the treatment of convulsions or Parkinson's disease; rifampicin (antibiotic), probenecid (for the treatment of gout).
- aspirin or other salicylates, additional pain relieving or fever reducing medicines, non-steroidal anti-inflammatory drugs or medicines for arthritis, medicines for the treatment of migraines (Ergot alkaloids).
- metoclopramide or domperidone (for the treatment of nausea, vomiting and other stomach problems); cholestyramine (for reduction of the blood cholesterol level), medicines that may cause dryness of the mouth, oral contraceptives, oxytocin (for induction of labor and cessation of excessive bleeding after birth).
- do not take this medicine with other paracetamol-containing medicines, monoamine oxidase inhibitors (MAOIs),

SSRIs (selective serotonin reuptake inhibitors), decongestants, other cough and cold medicines, beta blockers - see also section "Do not use the medicine if".

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, see Section 3.

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 impair alertness and therefore requires caution when driving a vehicle, operating dangerous machinery, and 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 your 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 every 4-6 hours, up to 4 times a day.

In concomitant use with 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 above maximum recommended dosage of **Dexamol Cold Day Care**.

Wait at least 4 hours between one dose and the next.

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

Swallow the medicine with water, it may be halved or crushed.

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

Side effects may occur such as diarrhea, excessive sweating, poor appetite, nausea or vomiting, stomach 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, urinating difficulties, slow breathing, excessive nervousness,

drowsiness.

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.

4. Side effects:

Like all medicines, **Dexamol Cold Day Care** can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects. You may not suffer from any of them. The side effects in the elderly may be more serious.

Stop use of this medicine and refer to your physician immediately if the following appear:

- signs of allergy such as: rash, itching skin often accompanied by swelling of the face, lips, tongue, throat that may cause breathing difficulties/shortness of breath, swelling of the limbs.
- lack of appetite, dryness of the mouth that may cause an increase in caries (it is recommended to use artificial saliva and keep oral hygiene), nervousness, drowsiness, anxiety, agitation, paranoia, confusion or over excitement, sleep disturbances, dizziness, indigestion, hallucinations, difficulty urinating especially in men suffering from a prostate problem, kidney damage (with prolonged use), irregular heart rate, palpitations, hypertension.
- paracetamol can in rare cases cause the appearance of acute skin diseases that may have signs such as: redness, rash, blisters, mouth ulcers, skin peeling, extensive skin damage.
- Acute skin side effects may occur even if in the past you have taken medicines containing the active ingredient paracetamol without a problem.
- extreme fatigue, tendency to hemorrhages, bleeding and unusually high tendency of contracting infections - these symptoms may indicate blood system disorders (decrease in the number of blood cells), such as anemia, thrombocytopenia, pancytopenia, agranulocytosis, leukopenia or neutropenia.
- nausea, sudden loss of weight, poor appetite and yellowing of the skin and eyes.
- cough or nasal congestion that lasts for

more than 7 days, recurs or is accompanied by fever, rash, weight loss, shortness of breath, chest pain or persistent headache.

- side effects resulting from overdose (see section "If you accidentally took a higher dosage").

Additional side effects:

Headache, nausea, vomiting, diarrhea, bad dreams, ringing in the ears, tension, tremor.

If any of the side effects gets worse, or if you suffer side effects not mentioned in the leaflet, consult your physician.

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 your 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, this medicine also contains:

Croscarmellose sodium, talc, povidone, hypromellose, magnesium stearate, titanium dioxide, silica colloidal anhydrous, methylcellulose, macrogol, carnauba wax, pigments: E-133, E-124, E-104.

Each caplet contains approximately 3 mg of Sodium.

What the medicine looks like and contents of the package:

Light blue caplet with a score line on both sides. Each package contains 10, 16, 20, 30, 48, 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: 057 04 26978 00

This leaflet was checked and approved by the Ministry of Health in 03/2014.

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Manufacturer and registration holder **Dexcel® Ltd**

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