

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

DEXAMOL SINUS® NIGHT CARE, CAPLETS

Each caplet contains:

Paracetamol	500 mg
Pseudoephedrine HCl	25 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 6 years of age only. Under this 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 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 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.
- 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 or chlorpheniramine), other antihistamines or any other decongestants, or to any of the ingredients of this medicine.
- You are treated concomitantly with medicines from the following groups: monoamine oxidase inhibitors (MAOIs) (e.g. for the treatment of depression) or within 14 days of stopping treatment with them; decongestants; additional medicines that contain antihistamine including other cough and cold medicines; beta-blockers (usually for the treatment of heart problems or hypertension).
- 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: severe hypertension, heart or vascular disease, severe liver or kidney disease, overactive thyroid gland, increased intraocular pressure (glaucoma), asthma or diabetes.

Special warnings regarding the use of this medicine:

• Before taking DexamolSinus Night Care tell your physician if:

- You suffer or have suffered in the past from impaired function of the heart and/or blood vessels, the liver, the kidney (e.g. a tumour of the pheochromocytoma type) or urinary tract, the digestive system (e.g. ulcer), the thyroid gland.
- You suffer or have suffered in the past from increased intraocular pressure (glaucoma), difficulty urinating, enlargement of the prostate gland, breathing problem (such as emphysema, asthma, bronchitis, bronchiectasis), diabetes, hypertension, increased restlessness, epilepsy, jaundice and alcoholism.
- You are over the age of 60, as patients at this age may be sensitive to medicines of this type.
- 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 at the recommended limit) of this medicine while fasting.
- This medicine contains paracetamol that may cause damage to the 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 reduction and relief of pain, 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 in the past resulting from taking products 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. appetite suppressants, medicines used to treat congestion or asthma, sedatives, hypnotics, for Parkinson's disease, for convulsions (epilepsy), antiarrhythmics (such as antiarrhythmics that cause drowsiness), anesthetics for surgeries and narcotic pain relievers).
- Anticoagulants (e.g. warfarin).
- Medicines for the treatment of depression (e.g. medicines of the tricyclic antidepressants group) or medicines for the treatment of anxiety.
- Methyldopa and other antihypertensive medicines and medicines for the treatment of heart problems (e.g. alpha blockers, digoxin). Cough and cold medicines, medicines that may cause dryness of the mouth, anticholinergics or medicines with an anticholinergic activity (such as medicine for stomach cramps).
- Medicines that increase liver enzyme activity such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures, psychiatric problems); antibiotics such as rifampicin, chloramphenicol, 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 migraines (Ergot alkaloids).
- Metoclopramide or domperidone (for the treatment of nausea, vomiting and other stomach problems), cholestyramine (for reduction of the blood cholesterol level), oral contraceptives, oxytocin (for induction of labor and cessation of excessive bleeding after birth).
- Monoamine oxidase inhibitors (MAOIs), decongestants, additional medicines that contain antihistamine, beta blockers and other medicines containing paracetamol - 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 6 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 cause drowsiness, dizziness, impair 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.

Important information about some of the ingredients of this medicine

The medicine contains FD&C Yellow no. 6 aluminum lake E-110 which may cause allergic reactions.

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.

Children 10-12 years of age: 1 caplet before bedtime.

Children 6-9 years of age: ½ caplet before bedtime.

In concomitant use with DexamolSinus Day Care, replace a dose of DexamolSinus Day Care with a dose of DexamolSinus Night Care, and do not take it as a supplement to the above maximum recommended dosage of DexamolSinus 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 a hospital emergency 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, acute inflammation of the pancreas, abdominal cramps or pain, swelling, pain or tenderness in the upper abdomen and they may not reflect the damage to the liver.

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 DexamolSinus 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 the following appear:

- Signs of allergy such as: rash, itching skin, 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.
- Nausea, sudden loss of weight, poor appetite.
- Lack of coordination, confusion (especially in the elderly), dizziness, nervousness, restlessness, anxiety or paranoia, sleep disturbances, hallucinations, difficulty urinating especially in men suffering from a prostate problem, changes in heart rate, palpitations or chest tightness.

- 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, leucopenia or neutropenia.

• Side effects resulting from overdose (see section "If you have accidentally taken a higher dosage").

- Collapse.

Additional side effects:

Drowsiness, concentrating difficulty, dry mouth that may cause an increase in caries (it is recommended to use artificial saliva and keep oral hygiene), blurred vision, headache, generally unwell, tension, over excitement, tremor, ringing in the ears; heartburn, nausea, vomiting, diarrhea, abdominal pain, indigestion, loss of appetite; increase in sputum viscosity (increased

cough, phlegm), increased sensitivity to sunlight, muscle weakness, cramps, depression, low mood, bad dreams, decreased blood pressure (can cause faintness) or hypertension, 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 <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?form1Type=AdversEffectMedic@moh.gov.il> that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?form1Type=AdversEffectMedic@moh.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.

Do not store above 25°C. Store in the original package.

6. Additional information

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

Povidone, Hypromellose, Croscarmellose sodium, Magnesium stearate, Titanium dioxide E171, Macrogol, FD&C Yellow no. 6 aluminum lake E-110, Quinoline yellow aluminum lake E-104, Silica colloidal anhydrous, Carnauba wax.

What the medicine looks like and what does the package contains:

Orange elongated 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: 053-65-26686-00

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

Dexamol Sinus Night Care PIL PB0616-04

Manufacturer and registration holder: **Dexcel® Ltd**

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