

DEXAMOLCOLD® NIGHT CARE

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

Carefully read the entire package insert before using this medication.

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

List of inactive ingredients: Povidone, croscarmellose sodium (approx. 1 mg sodium), magnesium stearate, silica colloidal anhydrous, hypromellose, titanium dioxide, macrogol, camauba wax pigments: E-127, E-132, E-104, E-133

Therapeutic action: Dexamolcold night care contains four active ingredients: Paracetamol is an analgesic and an antipyretic. Pseudoephedrine hydrochloride is a sympathomimetic amine which relieves runny nose, nasal and ear congestion, accompanying cold and/or sinusitis. Dextromethorphan hydrobromide suppresses cough accompanying cold. Chlorpheniramine maleate is an antihistamine that dries mucus.

Indications: This medicine is intended for the symptomatic relief of cold, cough and nasal congestion accompanied by fever and pain. Night care medicine

When should this medicine not be used?

Do not use this medicine if you are pregnant or breastfeeding. Do not use this medicine if you are aware of any hypersensitivity to one of its ingredients. Do not use this medicine if you are taking monoamine oxidase inhibitors (MAOI) (for the treatment of depression, for instance) or within 14 days of stopping treatment with MAOIs. Do not use this medicine for the relief of chronic cough.

Do not use this medicine without consulting your physician before commencing treatment: if you suffer, or have suffered in the past, from impaired function of the respiratory system (e.g. asthma, cough that occurs with too much phlegm, chronic bronchitis), the heart and/or vascular system, hypertension, coronary arterial disease, increased intraocular pressure (glaucoma), the liver, the kidney/urinary tract, alcoholism, jaundice, the thyroid, the nervous system, enlargement of the prostate gland, trouble urinating, diabetes.

How will this medicine influence your daily schedule?

Use of this medicine may impair alertness. It is therefore advisable to take special care when driving, operating dangerous machinery or when engaging in any other activity which requires alertness. Children should be cautioned against bicycle riding or playing near traffic, etc.

Do not drink wine or other alcoholic beverages during the period of treatment with this medicine.

Warnings: Paracetamol may cause damage in the liver in the following cases: when administered at a dosage higher than the recommended one, when administered for extended periods, when consuming alcoholic beverages during the treatment period, when taking additional medicines that affect the function of the liver. Do not use this medicine frequently without consulting your physician (also see below - "Dosage"). If you are aware of any sensitivities to foods or drugs inform your physician before taking this medicine.

Patients above the age of 60 years should notify their physician before taking this medicine as they might be sensitive to decongestive drugs.

Avoid exceeding the recommended dosage while fasting. Do not take additional medicines for reduction of fever and relief of pain, or other cold medicines, without consulting your physician or pharmacist in order to avoid paracetamol overdose/toxicity.

Drug interactions: If you are taking other medicines concurrently, or have just completed treatment with another medicine inform your physician in order to prevent hazards or inefficacy arising from drug interactions, especially in regard to: drugs affecting the central nervous system (e.g. appetite suppressants, tranquilizers, sedatives and hypnotics, for Parkinson's disease, epilepsy, anti-allergics, surgical anaesthetics and narcotic analgesics); anticoagulants; antidepressants; antihypertensives and drugs for the heart; drugs that increase liver enzyme

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דקסמולקולד® לטיפול בלילה

נشرة طبية للمستهلك بموجب انظمة الصيدلة (مستحضرات) 1986

الرائي النشرة يامعان حتى نهايتها قبل استعمالك للدواء

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דקסמולקולד® לטיפול בלילה

עלון לצרכן לפי תקנות הרוקחים (תכשירים) התשמ"ו - 1986

יש לקרוא בעיון את העלון עד סופו לפני השימוש בתרופה.

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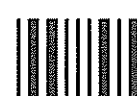
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המשך מעבר לדף



דקסמולקולד® לטיפול בילדה

דקסמולקולד® للعلاج في الليل

DEXAMOLCOLD® NIGHT CARE

Continued

activity such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures, psychiatric problems); rifampicin (antibiotic); aspirin or other salicylates, other analgesics or antipyretics, other cough and cold preparations; anticonvulsants; anticholinergic drugs or drugs with anticholinergic activity (e.g. drugs for the treatment of abdominal spasm); non-steroidal anti-inflammatory drugs or antirheumatic drugs; metoclopramide or domperidone (used to treat nausea, vomiting and other stomach problems); cholestyramine (used to treat high blood lipid levels).

Do not take this medicine with any other paracetamol-containing products. Do not use this medicine if you are under treatment with medicines of the MAOI group (for the treatment of depression, for instance) or within 14 days of stopping treatment with MAOI (see above).

Side effects: In addition to the desired effect of the medicine, some side effects may appear during treatment, such as: dryness of the mouth, drowsiness, excitability (especially in children), thickening of mucus, hypotension. These side effects usually disappear within a short time following a period of adjustment to the medicine.

Side effects requiring special attention: Nervousness, insomnia, dizziness, signs of allergy (such as: rash, skin irritation) (rare); discontinue treatment and contact your physician. Irregular heartbeat, shortness of breath (rare); discontinue treatment and contact your physician immediately!

Trouble urinating (rare): continue treatment and contact your physician immediately! **Side effects that are generally caused by overdose and requiring special attention:** Diarrhea, increased sweating, loss of appetite, nausea or vomiting, stomach cramps or pain, swelling, pain or tenderness in the upper abdomen. Discontinue treatment and contact your physician! If you experience side effects not mentioned in this insert, or if you feel any change in your general health, contact your physician immediately.

Side effects and drug interactions in children: Parents should report to the physician any side effect and also any additional medicine taken by the child! See above mentioned special side effects and drug interactions.

Dosage: Unless otherwise prescribed by the physician, the recommended dosage is: Adults and children over 12 years of age: 1-2 caplets before bedtime. Children aged 6-9 years: 1/2 caplet before bedtime. Children aged 9-12 years: 1/2-1 caplet before bedtime.

This medicine is usually not intended for children and infants under the age of 6 years. Consult your physician in the following cases: if fever lasts for more than 3 days or gets worse; if the pain gets worse or lasts for more than 5 days; if cough lasts for more than 7 days, comes back or occurs with fever, rash or persistent headache; if the painful area is red or swollen; if the sore throat is very painful, lasts for more than 2 days, or is accompanied by fever, headache, skin rash, nausea and/or vomiting; or in any case that new symptoms occur.

Directions for use: Can be halved, can be crushed. This medicine should be taken with water. This medicine should be taken with meals in order to reduce gastric problems.

Avoid poisoning! This medicine, and any other medicine should be kept in a closed place out of the reach of children and/or infants to avoid poisoning. If you took an overdose, or if a child accidentally swallowed this medicine, proceed immediately to a hospital emergency room and bring the medicine package with you even if you feel well, because of the risk of liver damage. Do not induce vomiting without explicit instructions from a physician! Medicines should not be taken in the dark! Check the label and the dose every time you take this medicine. Wear glasses if you need them.

Storage: Store in a cool and dry place. Even if kept in their recommended storage conditions, drugs retain their potency for a limited period only. Please note the expiry date of this medicine. If in doubt, consult with the dispensing pharmacist. Do not store different medicines in the same container.

Registration number of the drug: 053 66 26462 00.

The format of this leaflet was determined by the Ministry of Health (MOH) and its content was checked and approved by the MOH.

תתם

מן فصילה המכודרת); משכב תחיר הדם; משכב האיכות הנפשי; מخفضات ضغط הדם ואדوية القلب; الادوية المنشطة لفعالية الخشائر في الكبد كالباربيטورات. فينيטوين أو كاربامازיפין (المستعملة بشكل خاص لعلاج مرض الصرع للتشنجات. المضطربات العظمية); ريفامپيسين (مضاد حيوي); أسبرين أو الساليسيلات الأخرى. أدوية إضافية ذات فعالية مسكنة للألام أو مخفضة للسخونة. مضادات أخرى للسعال وتزلات البرد; مضادات التشنج; أدوية مضادة للإلزام الكوليول أو ذات نشاط مضاد للإلزام الكوليول (كالمسحخرات المضادة للتشنجات في البطن); مضادات الالتهابات الالسترويدية أو مضادات التهابات المفاصل; ميتوكلوپرامید أو دومپریدون (لعلاج الغثيان التقيؤات والإضطرابات المعوية الأخرى). كولیستریپین (لتخفيض زيادة الدهون في الدم) لا يجوز تناول هذا الدواء. بالإضافة مع مستحضرات أخرى حاوية على الباراسیتامول.

لا يجوز استعمال هذا الدواء. بشكل متزامن إذا كنت تتعاطى /ين بأدوية من فصيلة مثبطات سونوانجین اوكسيداز (المستعملة مثلاً للإكتئاب النفسي) أو خلال 14 يوماً منذ التوقف عن العلاج بها (انظر /ي أعلاه).

الأعراض الجانبية: إضافة إلى التأثيرات الطبية المرغوبة للدواء. فقد تظهر أثناء فترة استعماله بعض الأعراض الجانبية كجفاف الفم نغاس. زيادة الإفرازات (خاصة لدى الأطفال). إزدیاد لزوجة البلغم. إنخفاض في ضغط الدم. تخثني هذه الأعراض عادة خلال فترة قصيرة بعد أن يعتاد الجسم على الدواء.

الأعراض التي تقتضي اهتماماً خاصاً: قلة النوم، دوام، إشارات التحسس (كإحمرار الحكة في الجلد) (نادرًا). توقف /ي عن العلاج وراجع /ي الطبيب. عدم إنتظام خفقات القلب. قسر في التنفس (نادرًا). توقف /ي عن العلاج وراجع /ي الطبيب حالاً! إضطرابات في التبول (نادرًا). إستمرو /ي في العلاج وراجع /ي الطبيب حالاً!

الأعراض الجانبية الناتجة عن الإفراط عادة في الجرعات التوائبة والتي تقتضي اهتماماً خاصاً: إسهال، زيادة التعرق إنحطاط في الشهية للطعام، غثيان أو تقيؤات، تشنجات أو ألآم في البطن، إنتفاخ، ألم أو حساسية في القسم العلوي من البطن. يجب التوقف عن العلاج ومراجعة الطبيب؛ أما إذا ظهرت لديك أعراض جانبية لم تذكر في هذه النشرة. أو إذا لمرا أي تغيير على شعورك العام نتيجة لاستعمالك لهذا الدواء. عليك عندئذ مراجعة الطبيب حالاً!

الأعراض الجانبية والفتعلات بين الأدوية عند الأطفال: على الوالدين إبلاغ الطبيب المعالج عن كل تأثير جانبي يبدو لدى الطفل وعن أي دواء آخر يتناوله وراجع /ي القدرات المتعلقة بالأعراض الجانبية والفتعلات الخاصة بين الأدوية المذكورة أعلاه.

الجرعة الدوائية: الجرعة الدوائية الاعتيادية في حالة عدم وجود تعليمات أخرى من الطبيب هي للكبار والأطفال ما فوق عمر 12 سنة: حبيولة - حبيولتين قبل النوم.

للأطفال من عمر 6 - 9 سنوات: نصف حبيولة قبل النوم. للأطفال من عمر 9 - 12 سنة: نصف حبيولة - حبيولة واحدة قبل النوم.

هذا الدواء غير مخصص للإستعمال عادة لدى الأطفال والرضع دون عمر 6 سنين.

يجب مراجعة الطبيب في الحالات التالية: إذا إستمرت السخونة لفترة تزيد عن 3 أيام أو إذا تفاقمت؛ إذا اشتدت الآلام أو إذا إستمرت الآلام لفترة تزيد عن 7 أيام؛ إذا إستمر السعال لفترة أكثر من 7 أيام؛ إذا عاد السعال أو واقفت سخونة. طلع أو صداع مستمر؛ إذا كانت المنطقة المؤلمة تنفخة أو مدمرة؛ إذا كانت الآلم الشجرة شديدة لم تختف خلال بوسن أو إذا واقفتها سخونة. صداع، طلع جلدي، غثيان و/أو تقيؤات؛ في كل حالة تظهر فيها أعراض جديدة.

إرشادات الإستعمال: بالإمكان شطو/ سحق الحبيولة. يبلع الدواء مع الماء. يجب تناول الدواء مع وجبة من الطعام من أجل تقليل الإضطرابات في المعدة.

تحذير/ي التسمم! يجب حفظ هذا الدواء وكمن دواء، في مكان مغلق بعيداً عن متناول أيدي الأطفال و/أو الرضع. وذلك لتفادي إصابتهم بالتسمم. إذا أفرقت في تناول الجرعة الدوائية أو إذا بلع الطفل/ة حلاً من هذا الدواء. عليك التوجه إلى المستشفى حالاً مصطحباً/ة عبوة الدواء، حتى ولو كنت تشعر /ين بحسنة جيدة. نظراً لوجود خطورة لإصابة الكبد.

لا تستعمل/ي التقيؤ بدون تعليمات صريحة من الطبيب. لا تتناول /ي الدواء في الغمعة يجب تشخيص طابع الدواء والتأكد من الجرعة الدوائية في كل مرة تتناول /ين فيها دواء. ضع /ي النظارات الطبية إذا لزم الأمر ذلك.

التخزين: في مكان بارد وجاف. تبقى الأدوية صالحة للتناول محدودة فقط حتى ولو نكث في علبتها الأصلية وتم حفظها بوجبة تعليمات التخزين. الرجاء ملاحظة تاريخ إنتهائها. صلاحية المستحضر الدوائية على العبوة. في حالة الشك؛ عليك إستشارة الصيدلي الذي صرف لك هذا الدواء. لا يجوز تخزين أدوية مختلفة في نفس العبوة رقم بسجل الدواء: 053 66 26462 00

أقرت وزارة الصحة صيغة هذه النشرة ومحتواها فحص ورخص من قبلها.

