תאריך אפריל 2025

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לצרכן ולרופא של התכשיר

אקמול צינון ושפעת לילה קפליות

Acamol Tsinun and Shapaat Night, Caplets

Contains: Paracetamol 500mg, Pseudoephedrine hydrochloride 30 mg,
Dextromethorphan hydrobromide 15mg, Chlorpheniramine maleate 2 mg

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<u>התוויה כפי שאושרה בתעודת הרישום:</u>

- For the relief of cold, cough and nasal congestion associated with fever and pain, for night care.

עדכונים בעלון לצרכן

<u>בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):</u>

2. <u>לפני השימוש בתרופה</u>

אין להשתמש בתרופה זו:

[...]

אם יש לך זיהום בחזה, החמרה באסתמה או בעיות נשימה חמורות.

אזהרות מיוחדות הנוגעות לשימוש בתרופה

[...]

סימנים אפשריים להתמכרות לתרופה זו:
- יש צורך לקחת את התרופה למשך זמן ממושך יותר מהמומלץ
- אתה חש צורך להשתמש במינון גבוה מהמינון המומלץ
- אתה משתמש בתרופה שלא בהתאם להתוויות

- כאשר אתה מפסיק לקחת את התרופה אתה מרגיש לא טוב, ואתה מרגיש טוב יותר לאחר שאתה לוקח את התרופה שוב
אם אתה מבחין באחד מהסימנים הללו, חשוב שתדבר עם הרופא המטפל או עם רוקח.

עדכונים בעלון לרופא

בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק,ירוק הזזת מיקום):

4.3 Contraindications

[...]

Patients with, or at risk of developing, respiratory failure (e.g. those with chronic obstructive airways disease or pneumonia, or during an asthma attack or an exacerbation of asthma).

4.4 Special warnings and precautions for use

[...]

Patients suffering from chronic cough as occurs with smoking, asthma or patients suffering from an acute asthma attack, chronic bronchitis, and emphysema, or where cough is accompanied by excessive secretions should be advised to consult a Healthcare Professional before use.

[...]

Medical advice should be sought before taking **dextromethorphan** in patients with: severe renal impairment.

Concomitant use of other cough and cold medicines should be avoided.

Concomitant use of alcohol should be avoided.

[...]

4.5 Interaction with other medicinal products and other forms of interaction

[...]

Do not use if you are now taking a prescription a selective serotonin reuptake inhibitor (SSRI), tricyclic antidepressants (TCAs) or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the medication

4.6 Fertility, pregnancy and lactation

Pracetamol and Pseudoephedrine

There are no adequate and well-controlled clinical studies in pregnant or breast-feeding women for the combination of paracetamol and pseudoephedrine.

This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or breastfeeding infant.

Pregnancy

The safety of **pseudoephedrine** in pregnancy has not been established.

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, **paracetamol** can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

~~Although **dextromethorphan** has been in widespread use for many years without apparent ill-consequence, there are no specific data on its use during pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment against any possible hazards.~~

There is no adequate data from the use of **chlorphenamine maleate** in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essentially by a physician.

Breastfeeding

Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast-fed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60 mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. Data from a study of lactating mothers taking 60 mg pseudoephedrine every 6 hours suggests that from 2.2 to 6.7% of the maximum daily dose (240 mg) may be available to the infant from a breastfeeding mother.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding. A pharmacokinetic study of paracetamol in 12 nursing mothers revealed that less than 1% of a 650 mg oral dose of paracetamol appeared in the breast milk. Similar findings have been reported in other studies, therefore maternal ingestion of therapeutic doses of paracetamol does not appear to present a risk to the infant.

~~It is not known whether **dextromethorphan** or its metabolites are excreted in human milk.~~

Chlorphenamine maleate and other antihistamine may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

Fertility

No studies have been conducted in animals to determine whether pseudoephedrine has the potential to impair fertility. There is no information of the effect of this medicine on fertility.

Dextromethorphan

Fertility

There are no relevant clinical data available regarding effects on fertility from patients taking dextromethorphan. Studies in rats have demonstrated a lack of adverse effect on fertility (see section 5.3). Therefore, no adverse effects on human fertility are expected at therapeutically relevant doses.

Pregnancy

There are no relevant clinical data available regarding effects on pregnancy from patients taking dextromethorphan. Animal studies do not indicate embryofetal toxicity (see section 5.3). Dextromethorphan should not be used during pregnancy without medical advice.

Breastfeeding

Avoid the use of the product during lactation, unless the benefits to the mother outweigh the risks to the infant. If used, the lowest effective dose and shortest duration of treatment should be considered.

Dextromethorphan is excreted in breast milk in minor quantities. There is a lack of data available on the effect of infant exposure through breast milk.

4.8 Undesirable effects

Dextromethorphan

The following adverse events have been observed in clinical trials with dextromethorphan.

Gastrointestinal Disorders:

Gastrointestinal upset, nausea, vomiting, abdominal discomfort

Nervous System Disorders:

Dizziness, drowsiness, mental confusion

Adverse reactions identified during post-marketing use are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown.

Immune System Disorders:

Hypersensitivity

Psychiatric Disorders:

Frequency unknown: Drug dependence (see section 4.4)

Skin and Subcutaneous Disorders

Allergic reactions (e.g. rash, urticaria, angioedema)

General Disorders and Administration Site Conditions:

Frequency unknown: drug withdrawal syndrome

5.3 Preclinical safety data

[...]

Dextromethorphan

Non-clinical safety data on dextromethorphan obtained from the literature and in-house have not revealed findings which are of relevance to the recommended dosage and use of the product.

Reproductive and developmental toxicity

No adverse effects on male and female fertility or postnatal development were observed rats following oral administration of up to 50 mg/kg/day dextromethorphan. No effects on embryofetal development were observed in both rats and rabbits following oral administration of up to 50 mg/kg/day dextromethorphan during pregnancy. A 50 mg/kg/day dose in rats and rabbits is approximately 5- and 11-times the maximum human equivalent therapeutic dose (based on the body weight of 12-year-old child of 40 kg), respectively.

העלונים נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

https://israeldrugs.health.gov.il, וניתן לקבלו מודפס ע"י פניה לחברת טבע.