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Making Health Affordable™

דצמבר 2021

רופא ה, רוקח/ת נכבד/ה,
חברת אינובמד בע"מ מודיעה על עדכון העלון לרופא של התכשיר:
פאריקלציטול אינובמד 5 מק"ג/מ"ל
PARICALCITOL INOVAMED 5 MCG/ML
SOLUTION FOR INJECTION

עדכונים בעלון לרופא

התוויה כפי שמאושרת בתעודת הרישום:

Paricalcitol is indicated in adults for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure who are undergoing haemodialysis.

ברצוננו להודיע על עדכון העלון לרופא של התכשיר הנ"ל בפירוט שלהלן כוללים העדכונים העיקריים בלבד (תוספות מסומנות באדום – החמרה והסרות מידע כטקסט מחוק) כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע (כחול), ועדכוני נוסח שאינם מהווים החמרה.

4.4 Special warnings and precautions for use

[...]

Warning for excipients

This medicinal product contains 20% v/v of ethanol (alcohol). Each dose may contain up to 1.3g ethanol. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

A dose of 40 micrograms of this medicine administered to an adult weighing 70 kg would result in exposure to approximately 18 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 3 mg/100 ml.

For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml.

4.5 Interaction with other medicinal products and other forms of interaction

[...]

Specific interaction studies were not performed with paricalcitol injection. Digitalis toxicity is potentiated by hypercalcaemia of any cause, so caution should be applied when digitalis is prescribed concomitantly with paricalcitol (see Section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy:

There are no adequate data from the use of paricalcitol in pregnant women. There are no or limited amount of data from the use of paricalcitol in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown. Paricalcitol Inovamed 5 mcg/ml should not be used in pregnancy unless clearly necessary. **is not recommended during pregnancy and in women of childbearing potential not using contraception**

Breast-feeding

It is unknown whether paricalcitol/metabolites are excreted in human milk. Available pharmacodynamic/toxicological data in animals have shown excretion of paricalcitol/metabolites in milk (for details see 5.3).

Animal studies have shown excretion of paricalcitol or its metabolites in breast milk, in small amounts.

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A risk to the newborns/infants cannot be excluded

A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with paricalcitol should be made taking into account the benefit of breast-feeding to the child and the benefit of paricalcitol therapy to the woman.

Fertility

Animal studies have shown no effect of paricalcitol on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

~~Paricalcitol may have minor influence on the ability to drive and use machines. Dizziness may occur following administration of paricalcitol (see section 4.8).~~

Dizziness may occur following administration of paricalcitol, which may have a minor influence on the ability to drive and use machines (see section 4.8).

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות <http://www.health.gov.il> וניתן לקבלו מודפס ע"י פניה לחברת אינובמד בע"מ.

בברכה
ד"ר עמליה לוי
רוקחת ממונה
אינובמד בע"מ