

יוני 2023

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

אטופוסיד טבע

Etoposide Teva

Contains: Etoposide 20mg/ml

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Hodgkin's disease.
Malignant (non-Hodgkin's) Lymphomas, especially of the Histiocytic variety.
Acute Non-Lymphocytic leukemia.
Management of refractory testicular tumors and of small cell lung cancer.

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

4.4 Special warnings and precautions for use

Excipients

Ethanol

This product contains 30 vol % ethanol (alcohol).

Adults

A dose of 120 mg/m² of this medicine administered to an adult weighing 70 kg would result in exposure to 37.2 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 6.2 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.

The amount of alcohol in this medicine is not likely to have an effect in adults.

The amount of alcohol in this medicine may alter the effects of other medicines (see section 4.5).

To be taken into account in pregnant women. To be taken into account in patients who are addicted to alcohol.

Paediatric population

A dose of 150 mg/m² of this medicine administered to a child weighing 17 kg would result in exposure to 75.5 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 12.6 mg/100 ml.

The amount of alcohol in this medicine may alter the effects of other medicines (see section 4.5).

The alcohol in this preparation is likely to affect children weighing <17 kg. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities. To be taken into account in children with epilepsy or liver disease.



Because this medicine is usually given slowly over 30-60 minutes, the effects of alcohol may be reduced.

4.5 Interaction with other medicinal products and other forms of interaction

Paediatric population

Interaction studies have only been performed in adults.

Because this medicinal product contains ethanol interactions might occur with other medicinal products. Therefore, if other medicinal products are co-administered, it should be checked whether there are interactions with ethanol for these.

Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

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