

Atriance 5mg/ml, Solution for infusion : הנדון

התכשיר שבנדון רשום בישראל להתוויות הבאות:

Atriance 5 mg/ml is indicated for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens.

המרכיב הפעיל: Nelarabine 5 mg/ml

ברצוננו להודיעכם על עידכון העלון לרופא של התכשיר בנדון:

(מידע שהתווסף מודגש בקו תחתון, מידע שנמחק – מסומן בקו-חוצה, החמרות-מודגשות בצהוב)

- עדכון פרק 4.6 Fertility, pregnancy and lactation

4.6 Fertility, pregnancy and lactation**Contraception in males and females**

Both sexually active men and women should use effective methods of contraception during treatment with nelarabine. Men with partners who are pregnant or could become pregnant should use condoms during treatment with nelarabine and for at least three months following cessation of treatment.

Pregnancy

There are no adequate or limited amount of data from the use of nelarabine in pregnant women.

Studies in animals have shown reproductive toxicity including malformations (see section 5.3). The potential risk in humans is unknown, however, exposure during pregnancy will likely lead to anomalies and malformations of the foetus.

Nelarabine should not be used during pregnancy unless clearly necessary. If a patient becomes pregnant during treatment with nelarabine, they should be informed of the possible risk to the foetus.

Breast-feeding

It is unknown whether nelarabine or its metabolites are excreted in human breast milk. The excretion of nelarabine in milk has not been studied in animals. However, because of the potential for serious adverse reactions in infants, breastfeeding should be discontinued. A risk to the newborn/infant cannot be excluded. Breast-feeding should be discontinued during treatment with Atriance.

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• עדכון פרק 4.7 Effects on ability to drive and use machines

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~~No studies on the effects on the ability to drive and use machines have been performed.~~
~~Atriance has major influence on the ability to drive and use machines.~~

Patients treated with nelarabine are potentially at risk of suffering from somnolence during and for several days after treatment. Patients must be cautioned that somnolence can affect performance of skilled tasks, such as driving.

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• עדכון פרק 4.8 Undesirable effects

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Nervous system disorders

There have been reports of events associated with demyelination and ascending peripheral neuropathies similar in appearance to Guillain-Barré syndrome.

~~One Two subject in the paediatric group patients had a fatal neurological events of status epilepticus.~~

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העלון לרופא כולל שינויי עריכה / שינויים נוספים שאינם החמרות.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פניה לבעל הרישום

בברכה,

עדי אלוש
רוקחת ממונה