

יוני 2023

רופא /ה, רוקח/ת נכבד/ה

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

וינקריסטין טבע

Vincristine Teva

Contains: VINCRISTINE SULFATE 1mg/ml

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Vincristine may be used either as sole agent or in combination therapy in the treatment of acute leukaemia.

Malignant lymphomas including Hodgkin's disease lymphosarcoma and reticulum cell sarcoma, neuroblastoma, Wilms' tumour, rhabdomyosarcoma .

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

Hepatic impairment

Hepatic dysfunction may increase the circulating concentrations and the plasma half-life of vincristine with an increase in its adverse effects **because vincristine is predominantly metabolised in the liver.**

Vincristine should not be given to patients receiving radiotherapy if the radiation field includes the liver.

Hepatic and renal functions, blood cell count and neurological functions should be assessed before starting therapy and during treatment, and before each course of treatment. If there are signs of bone marrow depression, the next dose should only be given after careful assessment of the clinical picture. The same applies to the occurrence of neurological symptoms, as severe neuropathies may develop if treatment is continued.

4.5 Interaction with other medicinal products and other forms of interaction

Nifedipine

Care should be taken regarding the possible interaction between vincristine sulfate and calcium channel blockers, especially nifedipine. Concomitant administration of vincristine sulfate and nifedipine may cause a decrease in plasma clearance of vincristine sulfate with a risk of increased toxicity.

Asparaginase/ isoniazid and other neurotoxic medicinal products

[...]

neurotoxic medicinal products, such as ciclosporin and isoniazid should **not** be administered **concomitantly**.

4.7 Effects on ability to drive and use machines

~~There are no data available about the effect of this product on the ability to drive and use machines.~~ Due to the (neurological **and gastrointestinal**) side effects ~~the possibility that this medicinal product may affect the ability to drive and use machines.~~ **should be taken into account.**

4.8 Undesirable effects

Side effects may be pronounced in patients with hepatic impairment due to reduced metabolism and delayed biliary excretion.

4.9 Overdose

Symptoms

The main clinical symptoms of overdose are abdominal pain, neurotoxic effects such as areflexia, sensory and motor disturbances, somnolence, thrombocytopenia, leukopenia, and paralytic ileus.

Management

- Administration of an anti-convulsive agent **for at least 1 week after overdose** ~~to prevent seizures~~

העלון לצרכן ולרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

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