



נובמבר 2022

Depalept Chrono 500mg

חומר פעיל:

VALPROIC ACID 145 MG
VALPROIC ACID (AS SODIUM) 333 MG

ההתוויה המאושרת:

Treatment of generalized or partial epilepsy secondary epilepsy and mixed forms of epilepsy.
Bipolar disorders:
Treatment and/or prevention of acute manic episodes in the context of bipolar disorders.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלונים לרופא ולצרכן.

העדכונים העיקריים הינם:

בעלון לרופא:

4.4 Special warnings and precautions for use

Damage to the liver and/or pancreas

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Liver function should be monitored again where necessary if there are changes in concomitant medication (dose increase or new addition) known to have an effect on the liver (see also section 4.5 on the risk of liver damage from salicylates, other anticonvulsants including cannabidiol).

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4.5 Interaction with other medicinal products and other forms of interaction

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Other interactions

Risk of liver damage

The concomitant use of salicylates should be avoided in children under 12 years due to the risk of liver toxicity (see section 4.4).

Concomitant use of valproate and multiple anticonvulsant therapy increases the risk of liver damage, especially in young children (see section 4.4).

Concomitant administration of cannabidiol increases the incidence of elevated transaminases. In patients of all ages receiving concomitantly cannabidiol at doses of 10 to 25 mg/kg and valproate, clinical trials have reported ALT increases greater than 3 times the upper limit of normal in 19% of patients. Appropriate liver monitoring should be exercised when valproate is used concomitantly with other anticonvulsants with potential hepatotoxicity, including cannabidiol, and dose reductions or discontinuation should be considered in case of significant anomalies of liver parameters (see section 4.4).

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4.6 Fertility, pregnancy and lactation

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Teratogenicity and developmental effects

Pregnancy Exposure Risk related to valproate

Both valproate monotherapy and valproate polytherapy are frequently associated with abnormal pregnancy outcomes. Available data show an increased risk of severe-major congenital malformations and neurodevelopmental disorders with valproate, both when used as monotherapy and as part of combination therapy, compared to the unexposed population.

Valproate was shown to cross the placental barrier both in animal species and in humans (see section 5.2).

Teratogenic effects have been demonstrated in mice, rats and rabbits (see section 5.3).

Congenital malformations

A meta-analysis (including registries and cohort studies) showed that approximately 11% of children of epileptic women exposed to valproate monotherapy during pregnancy suffer from major congenital malformations. This value is higher than the risk of major malformations for the general population (about 3 %).

-The risk of severe-major congenital malformations in children following *in utero* exposure is greater in the case of anti-epileptic combination therapy with valproate than anti-epileptic combination therapy without valproate.

בעלון לצרכן:

2. לפני השימוש בתרופה

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אינטראקציות / תגובות בין תרופתיות

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אינטראקציות אחרות

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- תרופות אחרות הפוגעות במטבוליזם של הכבד. כגון קנאבידיאול (המשמשת לטיפול באפילפסיה ובמחלות אחרות), עלולות להגביר את הסיכון לפגיעה בכבד,

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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום - סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700.

להלן הקישור לאתר משרד הבריאות: <https://israeldrugs.health.gov.il/#!/byDrug>

בברכה,

חברת סאנופי אוונטיס ישראל בע"מ