



אפריל 2024

Depalept Chrono 500mg

חומר פעיל:

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

ההתוויה המאושרת:

Epilepsy:

Treatment of generalized or partial epilepsy secondary epilepsy and mixed forms of epilepsy.

Bipolar disorders:

Treatment of manic episode bipolar disorder when lithium is contraindicated or not tolerated. The continuation of treatment after manic episode could be considered in patients who have responded to valproic acid for acute mania.

חברת סאנופי ישראל מבקשת להודיע על עדכון העלון לרופא.

העדכונים העיקריים הם:

4.6 Fertility, pregnancy and lactation

Pregnancy

Treatment of epilepsy

- ~~Valproate is contraindicated as treatment for bipolar disorder~~ during pregnancy. ~~Valproate is contraindicated as treatment for epilepsy during pregnancy,~~ unless there is no suitable alternative ~~to treat epilepsy~~ treatment.
- ~~Valproate is contraindicated for use~~ in women of childbearing potential, unless the conditions of the pregnancy prevention program are fulfilled (see sections 4.3 and 4.4).

Treatment of Bipolar disorder

- ~~Valproate is contraindicated during pregnancy.~~
- ~~Valproate is contraindicated in women of childbearing potential, unless the conditions of the pregnancy prevention programme are fulfilled (see sections 4.3 and 4.4).~~

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5.3. Preclinical safety data

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In ~~repeat~~repeated-dose toxicity studies, testicular degeneration/atrophy or spermatogenesis abnormalities and a decrease in testes weight were reported in adult rats and dogs after oral administration at doses of ~~400~~ ~~1250~~ mg/kg/day and 150 mg/kg/day, respectively with associated



NOAELs (no observed adverse effect levels) for testis findings of 270 mg/kg/day in adult rats and 90 mg/kg/day in adult dogs.

The safety margin comparisons based on extrapolated AUC (area under the curve) in rats and dogs indicate that there may be no safety margin.

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: <https://www.gov.il/he/service/israeli-drug-index>

בברכה,

חברת סאנופי ישראל בע"מ