אפריל 2019

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון: **CONTROLOC® I.V. 40 mg/Vial**
קונטרולוק™ I.V. 40 מ"ג/בקבוקון (ויאל)

חברת טקדה ישראל בע"מ מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון, התעדכן באפריל 2019.

העדכון מופיע במכתב זה, מטה.

למידע נוסף, יש לעיין בעלון לרופא המעודכן אשר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

=https://www.old.health.gov.il/units/pharmacy/trufot/PerutTrufa.asp?Reg_Number=129 41 30772 00&safa

כמו כן, ניתן לקבלו מודפס על-ידי פנייה לבעל הרישום:

טקדה ישראל בע"מ, רח' אפעל 25, פתח-תקווה, טל': 03-3733140.

ההתוויה המאושרת לתכשיר בישראל:

Controloc I.V. is indicated for the treatment of duodenal ulcer, gastric ulcer, moderate and severe forms of reflux oesophagitis, Zollinger Ellison Syndrome.

מרכיב פעיל: Pantoprazole (as sodium) 40 mg/Vial

בברכה,

יהב ורדי
רוקחת ממונה
טקדה ישראל בע"מ

IL/PANV/0319/0002

העדכון בעלון לרופא הינו (טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן כטקסט אדום עם קו חוצה):

5.3 Preclinical Safety Data

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A slight increase of neoplastic changes of the thyroid was observed in the group of rats receiving the highest dose (200 mg/kg). The occurrence of these neoplasms is associated with the pantoprazole-induced changes in the breakdown of thyroxine in the rat liver. As the therapeutic dose in man is low, no harmful effects to the thyroid glands are expected.

In a peri-postnatal rat reproduction study designed to assess bone development ~~In animal reproduction studies,~~ signs of offspring toxicity (mortality, lower mean body weight, lower mean body weight gain and reduced bone growth) ~~slight fetotoxicity~~ were observed at exposures (Cmax) approximately 2x the human clinical exposure. By the end of the recovery phase, bone parameters were similar across groups and body weights were also trending toward reversibility after a drug-free recovery period. The increased mortality has only been reported in pre-weaning rat pups (up to 21 days age) which is estimated to correspond to infants up to the age of 2 years old. The relevance of this finding to the paediatric population is unclear. A previous peri-postnatal study in rats at slightly lower doses found no adverse effects at 3 mg/kg compared with a low dose of 5 mg/kg in this study ~~doses above 5 mg/kg~~.

Investigations revealed no evidence of impaired fertility or teratogenic effects.

Penetration of the placenta was investigated in the rat and was found to increase with advanced gestation. As a result, concentration of pantoprazole in the foetus is increased shortly before birth.

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