אפריל 2019

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

הנדון: **CONTROLOC® 20mg and 40mg tablets**
קונטרולוק™ 20 מ"ג ו-40 מ"ג טבליות

חברת טקדה ישראל בע"מ מבקשת להודיעכם כי העלון לרופא של התכשירים 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=116 36 29745 00&safa=

https://www.old.health.gov.il/units/pharmacy/trufot/PerutTrufa.asp?Reg_Number=104 40 28684 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® 20 mg

For the treatment of reflux oesophagitis and associated symptoms (e.g. hearburn acid regurgitation pain on swallowing).

For long-term management and prevention of relapse in reflux oesophagitis.

Prevention of gastroduodenal ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAIDs treatment.

Controloc® 40 mg

Short term treatment of acute duodenal ulcer.

Acute gastric ulcer.

Moderate and severe reflux esophagitis.

Eradication of Helicobacter pylori in combination with clarithromycin and amoxycillin or clarithromycin and metronidazole or amoxycillin and metronidazole in cases of duodenal ulcer and gastric ulcer with the objective of reducing of duodenal and gastric ulcers caused by this microorganism.

Zollinger-Ellison-Syndrome.

מרכיב פעיל: Controloc® 20 mg - Pantoprazole 20 mg
Controloc® 40 mg - Pantoprazole 40 mg

בברכה,

יהב ורדי
רוקחת ממונה
טקדה ישראל בע"מ

IL/PANV/0319/0001

Takeda Israel Ltd.
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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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