יוני 2024

רופא /ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון <u>לרופא</u> של התכשיר:

Spironolactone Teva 100 mg ספירונולקטון טבע 100 מ"ג

Each Tablet Contains: Spironolactone 100 mg

עדכונים בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

~~Edematous conditions:~~
Congestive heart failure, cirrhotic ~~of the liver accompanied by edema and/or~~ ascites, ~~nephrotic syndrome. Essential hypertention. Primary hyperaldostronism. Hypokalemia.~~

ברצוננו להודיע שהעלון לצרכן עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות משמעותיות מסומנות <u>באדום</u> והסרות בקו חוצה):

4.6 Fertility, pregnancy and lactation

Pregnancy
~~Spironolactone or its metabolites may cross the placental barrier. With spironolactone, feminisation has been observed in male rat foetuses. The use of Spironolactone Teva in pregnant women requires that the anticipated benefit be weighed against the possible hazards to the mother and foetus~~
There are limited data from the use of spironolactone in pregnant women. Studies in animals have shown reproductive toxicity associated with the anti-androgenic effect of spironolactone (see Section 5.3).
Diuretics can lead to reduced perfusion of the placenta and thus to impairment of intrauterine growth and are therefore not recommended for the standard therapy for hypertension and oedema during pregnancy.
Spironolactone should not be used during pregnancy, unless the potential benefit justifies the potential risk.

Breast-feeding
Canrenone (a major and active) metabolite of spironolactone, is excreted in human milk. There is insufficient information on the effects of spironolactone in newborns/infants.
Spironolactone should not be used during breast-feeding. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from spironolactone therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility
Spironolactone administered to female mice reduced fertility (see Section 5.3).

טבע ישראל בע"מ
www.tevapharm ורחוב התאנה 1, פארק התעשיות חמ"ן ת.ד. 975, שוהם 60850 וטל. 03-6864653 ופקס.03-6864944

5.3 Preclinical safety data

Spironolactone has been shown to produce tumours in rats when administered at high doses over a long period of time. The significance of these findings with respect to clinical use is not ~~certain~~ known. Nonclinical data reveal no evidence of teratogenicity, but embryo-fetal toxicity has been seen in rabbits, and an anti-androgenic effect in rat offspring has raised concern about possible adverse effects on male genital development. Endocrine disrupting effects have also been observed in female rodents at clinically relevant exposures. In adult rats, spironolactone was found to increase the length of the estrous cycle, and in female offspring exposed late in pregnancy, endocrine dysfunction persisting to adulthood was observed. In mice spironolactone inhibited ovulation and implantation, thereby decreasing fertility. The clinical relevance of these findings is unknown.

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