נובמבר 2024

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון:
Yaz Plus
Film coated tablets
Drospirenone 3 mg
Ethinylestradiol 0.02 mg
Levomefolate calcium 0.451 mg

אנו מבקשים להודיעכם שהעלונים לרופא של התכשיר עודכנו.

ההתוויות המאושרות לתכשיר:

- Oral contraception.
- Treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of birth control.
- Treatment of moderate acne vulgaris in women at least 14 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche.
- In women who choose to use an oral contraceptive as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while taking the product or shortly after discontinuing the product.

בהודעה זו כלולים העידכונים המהותיים בלבד. בפירוט שלהלן מופיע, מתוך כל פרק ששונה בעלונים, רק המידע שהתעדכן. תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת ~~בקו חוצה~~.

העידכונים בעלון לרופא:

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There is ~~little or~~ no ~~increased risk of birth defects~~ use for contraception in pregnancy; therefore, Yaz plus should be discontinued ~~women who inadvertently use COCs~~ during ~~early~~ pregnancy. Epidemiologic studies and meta-analyses have not found an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following exposure to ~~low dose COCs prior to~~ CHC's (Combined hormonal contraceptives) before conception or during early pregnancy. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively

~~The administration of COCs to induce withdrawal bleeding should not be used as a test for pregnancy. COCs should not be used during pregnancy to treat threatened or habitual abortion.~~

~~Women who do not breastfeed may start COCs no earlier than four weeks postpartum.~~

~~***8.3 Nursing Mothers***~~

~~When possible, advise the nursing mother to use other forms of contraception until she has weaned her child. Estrogen-containing COCs can reduce milk production in breastfeeding mothers. This is less likely to occur once breastfeeding is well-established; however, it can occur at any time in some women. Small amounts of oral contraceptive steroids and/or metabolites are present in breast milk.~~

~~After oral administration of 3 mg DRSP/0.03 mg EE tablets (Yasmin), about 0.02% of the DRSP dose was excreted into the breast milk of postpartum women within 24 hours. This results in a maximal daily dose of about 0.003 mg DRSP in an infant.~~

~~Studies to date indicate there is no adverse effect of folate on nursing infants.~~

Data

Human Data

A retrospective database study of women in Norway, that included 44,734 pregnancies of which 368 were women who inadvertently took drospirenone/ethinyl estradiol during the first trimester of a pregnancy, found there were no adverse effects on pre-term birth, small for gestational age, or birth weight Z-scores.

Post-marketing adverse event data on the use of Yaz Plus in pregnant women suggest that frequencies of miscarriage and congenital anomalies were not higher than the estimated background risk in the general population.

8.2 Lactation

Risk Summary

DRSP is present in human milk. After a single oral administration of 3 mg DRSP/0.03 mg EE tablets, DRSP concentration in breast milk over the 24-h period ranged from 1.4 to 7.0 ng/mL, with a mean ± standard deviation value of 3.7 ± 1.9 ng/mL. The estimated mean infant dose was 0.003 mg/day, which is about 0.1% of maternal dose (see Data). There is limited information on the effects of Yaz Plus on the breast-fed infant. CHCs can reduce milk production in breast-feeding females. This reduction can occur at any time but is less likely to occur once breast-feeding is well-established. When possible, advise the nursing female to use other methods of contraception until she discontinues breast-feeding. *[See also Dosage and Administration (2.2)]*. Increase in folate concentration in milk is not expected (see Data).

The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for Yaz Plus and any potential adverse effects on the breast-fed child from Yaz Plus or from the underlying maternal condition.

Data

Human Data

An open-label study evaluated the degree of DRSP transfer into milk within 72 hours following a single oral administration of 3 mg DRSP/0.03 mg EE tablets to 6 healthy lactating women who were 1 week to 3 months post-partum. DRSP was present in breast milk with a mean C_{max} of 13.5 ng/mL, while the mean C_{max} in serum of lactating women was 30.8 ng/mL. The DRSP concentration in breast milk over the 24-hour period following dosing ranged from 1.4 to 7.0 ng/mL, with a mean ± standard deviation value of 3.7 ± 1.9 ng/mL. Based on single dose data, the maximal daily infant dose of DRSP was calculated to be 0.003 mg/day, which represented a mean of 0.1% of the maternal dose.

A study in approximately 60 lactating women demonstrated no significant differences in folate concentrations in milk between women who received 416mcg/day [6S]-5-methyltetrahydrofolate or 400 mcg/day folic acid and women who received placebo over a 16 week period. Studies to date indicate there is no adverse effect of folate on nursing infants.

העלונים לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug
ניתן לקבלם מודפסים ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700.

בברכה,
באייר ישראל