

הודעה על החמרה (מידע בטיחות)

(מעודכן 05.2013)

אשר – 5.16

תאריך 19.5.2016

שם תכשיר באנגלית Mercilon

מספר הרישום 103 11 26498 00/21

שם בעל הרישום Merck Sharp & Dohme (Israel – 1996) Company Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>Combined hormonal contraceptives (CHCs) should not be used in the <u>following presence of any of the conditions listed below. Should any of the conditions appear for the first time during CHC use, the product should be stopped immediately.</u></p> <ul style="list-style-type: none"> <u>Pancreatitis or a history thereof if associated with severe hypertriglyceridaemia.</u> <u>Endometrial hyperplasia</u> 		4.3 Contraindications
<p>3. Other conditions</p> <ul style="list-style-type: none"> The following conditions have been reported to occur or deteriorate with both pregnancy and CHC use, <u>but the evidence of an association with CHC use is inconclusive</u>: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; <u>haemolytic uraemic syndrome</u>; <u>Sydenham's chorea</u>; herpes gestationis; otosclerosis-related hearing loss; hereditary angioedema. <u>Acute or chronic disturbances of liver function may necessitate the discontinuation of CHC use until markers of liver function return to normal. Recurrence of cholestatic jaundice which occurred previously during pregnancy or use of sex steroids necessitates the discontinuation of CHCs.</u> <u>Crohn's disease and ulcerative colitis have been associated with CHC use.</u> 		4.4 Special warnings and precautions for use
<p>4.4.3 Reduced Efficacy</p> <p>The efficacy of CHCs may be reduced in the event of missed tablets (Section 4.2.3), gastrointestinal disturbances (Section 4.2.4) or concomitant medication (Section 4.5.1). <u>Herbal preparations containing St John's wort (Hypericum perforatum) should not be used while taking Mercilon due to the risk of decreased plasma concentrations and reduced clinical effects of Mercilon (see section 4.5.1 Interactions).</u></p>		

<p>Hepatic metabolism:</p> <p>Interactions can occur with drugs that induce microsomal enzymes, which can result in increased clearance of sex hormones (e.g., hydantoins, phenytoin, barbiturates, primidone, bosentan, carbamazepine, rifampicin, rifabutin and possibly also oxcarbazepine, modafinil, topiramate, felbamate, ritonavir, griseofulvin and products containing St. John's wort). Also HIV protease inhibitors with an inducing potential (e.g. ritonavir and nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine and efavirenz), may affect hepatic metabolism. Maximal enzyme induction is generally not seen for 2-3 weeks but may then be sustained for at least 4 weeks after the cessation of drug therapy.</p> <p>Contraceptive failures have also been reported with antibiotics, such as ampicillin and tetracyclines. The mechanism of this effect has not been elucidated.</p> <p>Women on treatment with any of these drugs should temporarily use a barrier method in addition to the CHC or choose another method of contraception. With microsomal enzyme-inducing drugs, the barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation. In case of long-term treatment with microsomal enzyme-inducing drugs another method of contraception should be considered. Women on treatment with antibiotics (except rifampicin and griseofulvin, which also act as enzyme-inducing drugs) should use the barrier method until 7 days after discontinuation. If the period during which the barrier method is used runs beyond the end of the tablets in the CHC pack, the next CHC pack should be started without the usual tablet-free interval.</p>		<p>4.5 Interaction with other medicinal products and other forms of interaction</p>
<p><i>Description of selected adverse reactions</i></p> <p>As with all COCs, changes in vaginal bleeding patterns may occur, especially during the first months of use. These may include changes in bleeding frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or duration.</p> <p>Psychiatric disorders – Uncommon - Libido decreased Psychiatric disorders – Rare - Libido increased Skin and cutaneous tissue disorders - Uncommon – urticarial Investigations - common - Weight increased Investigations - Rare - Weight decreased</p>		<p>4.8 Undesirable effects</p>

בעלון לצרכן

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>חלק מהתרופות עשויות לגרום למרסילון להפסיק לעבוד באופן תקין – לדוגמא:</p> <ul style="list-style-type: none"> • אי-אלו תרופות לטיפול באפילפסיה (פרימידון, פניטואינים, ברביטורטים, קרבאמאזפין, אוקסקרבאזפין, טופירמט, פלבאמאט, מודפניל); • תרופות לטיפול בשחפת (ריפאמפיצין); • תרופות מסוימות לטיפול ב- HIV – (ריטונאביר, נפירנאביר, נביראפין) 		<p>2.4 תרופות אחרות ומרסילון</p>

<ul style="list-style-type: none"> • ואפירנז; • אנטיביוטיקות מסויימות (פניצילינים, טטרהציקלינים); • St. John's Wort (תרופה צמחית); • גריסאופולבין (תרופה אנטי-פטרייתית), ריפאבוטין; • בוסנטאן (ללחץ-דם גבוה בכלי הדם בריאות); • הידנטואינים 		
<p>לא שכיחות (יותר מ-1 מתוך 1000 נשים, אולם לא יותר מ 1 מתוך 100 נשים אשר נטלו מרסילון מושפעות)</p> <ul style="list-style-type: none"> • בעיות עור, כגון פריחה או סרפדת <p>נדירות (פחות מ-1 מתוך 1000 נשים שנטלו מרסילון מושפעות)</p> <ul style="list-style-type: none"> • תגובות של רגישות-יתר • בעיות עור, כגון אריתמה נודוסום, אריתמה מולטיפורם. 		4. תופעות לוואי

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