הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך __30.11.2015__

שם תכשיר באנגלית ומספר הרישום __ Gynera 050-51-25622-00

שם בעל הרישום _באייר ישראל בע"מ_

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**

• Interactions <u>Enzyme inducers</u> Interactions can occur with drugs that induce microsomal enzymes (especially cytochrome P450 3A4) which can result in increased clearance of sex hormones and which may lead to breakthrough bleeding and/or contraceptive failure.	• Interactions <u>Hepatic enzyme inducers</u> Drugs which induce hepatic enzymes (especially cytochrome P450 3A4) increase the metabolism of contraceptive steroids and hence may result in breakthrough bleeding and pregnancy. The following have been shown to have clinically important interactions with COCs: *Antiretroviral agents* • ritonavir; • nelfinavir; • nevirapine. *Anticonvulsants* • barbiturates (including phenobarbitone); • primidone; • phenytoin;- • carbamazepine; • oxcarbazepine; • topiramate. *Antibiotics/antifungals* • griseofulvin; • rifampacin. *Herbal remedies* • St John's wort (Hypericum perforatum) <u>Managing interactions with hepatic enzyme inducers</u> Interactions can occur with drugs that induce microsomal enzymes which can result in increased clearance of sex hormones and which may lead to breakthrough bleeding and/or contraceptive failure. Women on short term	**4.5 Interaction with other medicinal products and other forms of interaction**

Women on short term treatment with any of these drugs should temporarily use a barrier method in addition to the COC or choose another method of contraception. The barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation. If the period during which the barrier method is used runs beyond the end of a pack, the next pack should be started without a break. In this situation, a withdrawal bleed should not be expected until the end of the second pack. If the patient does not have a withdrawal bleed during the tablet-free interval following the end of the second pack, the possibility of pregnancy must be ruled out before resuming with the next pack. For women receiving long-term therapy with hepatic enzyme inducers, another method of contraception should be used. The following have been shown to have clinically important interactions with COCs: *Anticonvulsants*: barbiturates (including phenobarbitone), primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate *Antibiotics/antifungals:* griseofulvin , rifampicin. *Herbal remadies:* St. John's wort *(Hypericum perforatum)* *Antiretroviral agents*: ritonavir, nelfinavir, nevirapine. Note: There are other antiretroviral agents that may increase plasma concentration	treatment with any of these drugs should temporarily use a barrier method in addition to the COC or choose another method of contraception. The barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation. If the period during which the barrier method is used runs beyond the end of a pack, the next pack should be started without a break. In this situation, a withdrawal bleed should not be expected until the end of the second pack. If the patient does not have a withdrawal bleed during the tablet-free interval following the end of the second pack, the possibility of pregnancy must be ruled out before resuming with the next pack. For women receiving long-term therapy with hepatic enzyme inducers, another method of contraception should be used. *Substances increasing the clearance of COCs (diminished efficacy of COCs by enzyme-induction), e.g.:* phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin and products containing St. John's wort. *Substances with variable effects on the clearance of COCs, e.g.:* When co-administered with COCs, many HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors can	

of sex hormones. *Substances decreasing the clearance of COCs (enzyme inhibitors)* Strong and moderate CYP3A4 inhibitors such as azole antifungals (e.g. itraconazole, voriconazole, fluconazole) and macrolides (e.g. erythromycin) can increase plasma concentrations of oestrogen or the progestin or both. Etoricoxib doses of 60 to 120 mg/day have been shown to increase plasma concentrations of ethinylestradiol 1.4 to 1.6-fold, respectively when taken concomitantly with a combined hormonal contraceptive containing 0.035 mg ethinylestradiol. <u>Effects on other drugs</u> Oral contraceptives may affect the metabolism of certain other drugs. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporine, tizanidine, theophylline) or decrease (e.g. lamotrigine).	increase or decrease plasma concentrations of estrogen or progestin. These changes may be clinically relevant in some cases. <u>Effects on other drugs</u> Oral contraceptives may affect the metabolism of certain other drugs. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporin) or decrease (e.g. lamotrigine). Note: The prescribing information of concomitant medications should be consulted to identify potential interactions.	