הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך _____

שם תכשיר באנגלית ומספר הרישום __ **Meliane 109-12-29094-00**

שם בעל הרישום _**באייר ישראל בע"מ**_

טופס זה מיועד לפרוט ההחמרות בלבד !

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

Enzyme inducers 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 remedies:* St. John's wort (*Hypericum perforatum*) *Antiretroviral agents*: ritonavir, nelfinavir, nevirapine. Note: There are other antiretroviral agents that may increase plasma concentration of	Hepatic enzyme inducers 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*) *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 increase or decrease plasma	**4.5 Interaction with other medicinal products and other forms of interaction**

sex hormones. *Substances decreasing the clearance of COCs* (*enzyme inhibitors*) Strong and moderate CYP3A4 inhibitors such as azole antifungals (e.g. itraconazole, vericonazole, fluconazole) and macrolides (e.g. erythromycin) can increase plasma concentrations of the estrogen 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.	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.	