



# Bayer HealthCare

## Bayer Schering Pharma

רוקח/ת נכבד/ה,

הרינו להודיעך על עדכון העלון לרופא ו/או העלון לצרכן של התכשירים המפורטים בהמשך. בפירוט שלהלן כלולים השינויים העיקריים בלבד. תוספות המידע מסומנות בקו תחתון, מחיקות מידע בקו אמצעי. העלונים לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפס ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700.

### Yasmin יסמין

צורת מינון: טבליות

הרכב וחוזק: Drospirenone 3 mg, ethinylestradiol 0.03 mg

התוויה: Oral contraception

**סעיפים שעודכנו ופירוט השינויים בעלון לרופא:**

- Warnings:**

Epidemiological studies have suggested an association between the use of COCs and an increased risk of arterial and venous thrombotic and thromboembolic diseases such as myocardial infarction, deep venous thrombosis, pulmonary embolism and of cerebrovascular accidents. These events occur rarely.

The risk of VTE is highest during the first year of use. This increased risk is present after initially starting a COC or restarting (following a 4 week or greater pill free interval) the same or a different COC. Data from a large, prospective 3-armed cohort study suggest that this increased risk is mainly present during the first 3 months.

Overall the risk for venous thromboembolism (VTE) in users of low estrogen dose (< 50 µg ethinylestradiol) COCs is two to threefold higher than for non-users of COCs who are not pregnant and remains lower than the risk associated with pregnancy and delivery.

Data from a large, prospective 3-armed cohort study has shown that the incidence of VTE in women with or without other risk factors for VTE who used

ethinylestradiol/drospirenone 0.03 mg/3 mg is in the same range as that for users of levonorgestrel-containing COCs and other COCs (various other COC brands).

VTE may be fatal (in 1-2 % of the cases).

Venous thromboembolism (VTE), manifesting as deep venous thrombosis and/or pulmonary embolism, may occur during the use of all COCs.

Symptoms of deep venous thrombosis (DVT) can include: unilateral swelling of the leg or along a vein in the leg; pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg; red or discolored skin on the leg.

Symptoms of pulmonary embolism (PE) can include: sudden onset of unexplained shortness of breath or rapid breathing; sudden coughing which may bring up blood; sharp chest pain which may increase with deep breathing; sense of anxiety; severe light

headedness or dizziness; rapid or irregular heartbeat. Some of these symptoms (e.g. “shortness of breath”, “coughing”) are non-specific and might be misinterpreted as more common or less severe events (e.g. respiratory tract infections).

An arterial thromboembolic event can include cerebrovascular accident, vascular occlusion or myocardial infarction (MI). Symptoms of a cerebrovascular accident can include: sudden numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden, severe or prolonged headache with no known cause; loss of consciousness or fainting with or without seizure. Other signs of vascular occlusion can include: sudden pain, swelling and slight blue discoloration of an extremity; acute abdomen.

Symptoms of MI can include: pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; fullness, indigestion or choking feeling; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats.

Arterial thromboembolic events may be fatal.

The risk of venous or arterial thrombotic/thromboembolic events or of a cerebrovascular accident increases with: age; obesity (body mass index over 30 kg/m<sup>2</sup>); a positive family history (i.e. venous or arterial thromboembolism ever in a sibling or parent at a relatively early age). If a hereditary predisposition is known or suspected, the woman should be referred to a specialist for advice before deciding about any COC use; prolonged immobilization, major surgery, any surgery to the legs, or major trauma. In these situations it is advisable to discontinue COC use (in the case of elective surgery at least four weeks in advance) and not to resume until two weeks after complete remobilization. smoking (with heavier smoking and increasing age the risk further increases, especially in women over 35 years of age); dyslipoproteinemia; hypertension; migraine; valvular heart disease; atrial fibrillation;

In women with hereditary angioedema exogenous estrogens may induce or exacerbate symptoms of angioedema.

Each film-coated tablet of this medicinal product contains 46 mg lactose per tablet.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption who are on a lactose-free diet should take this amount into consideration.

- **Undesirable effects:**

In women with hereditary angioedema exogenous estrogens may induce or exacerbate symptoms of angioedema.

- **Drug interactions:**

Interactions of other drugs (enzyme inducers, some antibiotics) with oral contraceptives may lead to breakthrough bleeding and/or contraceptive failure. Women on treatment with any of these drugs should temporarily use a barrier method in addition to the COC 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. Women on treatment with antibiotics (except rifampicin and griseofulvin) 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 COC pack, the next COC pack should be started without the usual tablet-free interval.

Substances diminishing the efficacy of COCs (enzyme-inducers and antibiotics)

- Enzyme induction (increase of hepatic metabolism): Interactions can occur with drugs that induce microsomal enzymes which can result in increased clearance of sex hormones (e.g. phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin and products containing St. John's wort). Also HIV protease (e.g. ritonavir) and non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine), and combinations of them, have been reported to potentially increase hepatic metabolism.
- Antibiotics (interference with enterohepatic circulation): Some clinical reports suggest that enterohepatic circulation of estrogens may decrease when certain antibiotic agents are given, which may reduce ethinylestradiol concentrations (e.g. penicillins, tetracyclines).

Effects of COCs on other medicaments

Oral contraceptives may affect the metabolism of certain other drugs. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporine) or decrease (e.g. lamotrigine).

Based on in vitro inhibition studies and in vivo interaction studies in female volunteers using omeprazole, simvastatin and midazolam as marker substrates, an interaction of drospirenone at doses of 3 mg with the metabolism of other drugs is unlikely.

Other forms of interactions

Serum potassium. There is a theoretical potential for an increase in serum potassium in women taking Yasmin with other drugs that may increase serum potassium levels. Such drugs include angiotensin-II-receptor antagonists, potassium-sparing diuretics, and aldosterone antagonists. However, in studies evaluating the interaction of drospirenone (combined with estradiol) with an ACE inhibitor or indomethacin, no clinically or statistically significant differences in serum potassium concentrations were observed.

בברכה,  
אילה שניידר הנדלסמן  
רוקחת ממונה