



23 Oct 2011

Changes in the Yasmin® (0.03 mg ethinylestradiol / 3 mg drospirenone)

labeling information

Dear Healthcare Provider,

Bayer HealthCare would like to inform you of important changes to the patient information leaflet (PIL) for Yasmin®. The new PIL contains changes regarding the risk of venous thromboembolism (VTE) in the *Warning* section which are shown in the following text:

"Your chances of having a blood clot are increased by taking the Pill. Of 100,000 women who are not on the Pill and not pregnant, about 5-10 may have a blood clot in a year. Of 100,000 women taking a Pill like Yasmin, 30-40 may have a blood clot in a year, the exact number is unknown. Of 100,000 women who are pregnant, around 60 may have a blood clot in a year. A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2% of cases. The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options"

Please consider the following when prescribing Yasmin®

- All birth control pills containing estrogen and progestogens, including Yasmin®, carry an increased risk of blood clots. VTE is a rare event among women using combined oral contraceptives, and the risk of VTE is lower than during pregnancy and following childbirth.
- Some epidemiological studies have shown that the risk of VTE for drospirenone-containing oral contraceptives (OCc) is higher than for levonorgestrel-containing OCs (so-called second generation preparations) and may be similar to the risk for desogestrol/gestodene-containing OCs (so-called third generation preparations).
- The risk of VTE increases with positive family history, increasing age, obesity (BMI >30), and other reasons.
- All patients should be advised to report symptoms of venous or arterial thrombotic/thromboembolic events, such as unusual pain, redness or swelling in the legs, sudden shortage of breath or difficulty in breathing, sudden cough for no reason.
- All hormonal contraceptives are highly effective and safe and have important health benefits, including those from avoiding unplanned pregnancy. When used appropriately, the benefits of all combined oral contraceptives far outweigh the risk of VTE.



Reporting adverse events

Bayer HealthCare would like to encourage you to report all adverse drug reactions (ADRs) concerning Yasmin® to:

Tel: +966(2)657-1675

Fax : +966(2)657-1085

Email : khaled.a-halim@bayer.com

In addition, you can also report all ADRs to the Saudi Food and Drug Authority (SFDA) through either of the followings:

National Pharmacovigilance and Drug Safety Center (NPC) Saudi Food and Drug Authority-Drug sector 3292 Northern Ring Road Al Nafal District Riyadh 13312 – 6288 Kingdom of Saudi Arabia

Tel : 012759222 ext. 2317, 2353, 2354, 2356, 5769

Fax : 012057662

Email: NPC.Drug@sFDA.gov.sa

<http://www.sFDA.gov.sa/Ar/Drug/Topics/Organogram/NationalPharmacovigilanceCenter/>

Khaled A. Halim

A handwritten signature in blue ink, appearing to be "Khalid", written over a horizontal line.

Medical Director