

## **United Kingdom: Current key information on the combined oral contraceptive, Yasmin - May 2011**

In May 2011, an analysis of the available epidemiological data showed that the risk of venous thromboembolism (VTE) for combined oral contraceptives (COCs) that contain drospirenone is higher than the risk for levonorgestrel-containing second generation COCs, and may be similar to the risk for desogestrel-containing or gestodene-containing third generation COCs. Product information for Yasmin is being updated accordingly.

All hormonal contraceptives, including Yasmin, are highly effective and acceptably safe. They have important health benefits, including those from avoiding unplanned pregnancy. The advice to women is that if they are already taking Yasmin there is no need to stop taking it on the basis of these findings. When used appropriately the benefits of all COCs far outweigh the risk of VTE, which is rare.

If women have any questions about their contraception, they should discuss them with their contraceptive provider but keep taking their contraceptive pill until they have done so. If women stop taking their pill, they will need to use another method of contraception from then on, as they otherwise risk becoming pregnant. VTE associated with use of combined contraceptives is not a new issue. The risk of a venous thrombosis in women who use any combined oral contraceptive pill, is very small and smaller than the risk of VTE associated with pregnancy. When used appropriately the benefits of all combined oral contraceptives far outweigh the risk of VTE, which is rare.

The totality of the available evidence clearly shows that the risk of VTE for drospirenone-containing COCs, including Yasmin, is higher than the risk for levonorgestrel-containing second generation COCs and suggests that the level of the risk may be similar to that for desogestrel/ gestodene-containing third generation COCs.

The product information for Yasmin, as for all COCs, already contains extensive warnings about the risk of VTE and these will be updated to reflect the new data. Levonorgestrel-containing pills have the lowest thrombotic risk and are the safest pill for a woman who wants to start or switch contraception. Prescribers should be aware of the updated information when discussing the most suitable type of contraceptive for a woman who wants to start or switch contraception. Any prescribing decision should also take into account each woman's personal risk factors and any contraindications including her experience with other contraceptive formulations.

All combined oral contraceptives, including Yasmin, should be prescribed with caution to obese women (BMI>30), or those with a higher baseline risk of VTE for other reasons.

Please refer to the following website in MHRA for details:

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON117560>

In Hong Kong, there are three registered products containing drospirenone. They are Yasmin Tab (HK-48905), Angeliq Tab (HK-53676) and Yaz Tab (HK-56563) and all are registered by Bayer Healthcare Ltd. The risk of venous thromboembolism (VTE) has already been included in the current package insert of the above three products. The above analysis of the epidemiology data about the level of risk will be discussed in the coming meeting of the Registration Committee of the Pharmacy and Poisons Board.

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