Direct Healthcare Professional Communication

November 2022

Estradiol Valerate + Norethisterone Enanthate - Risk of Breast Cancer Recurrence in Patients with History of Breast Cancer

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority in agreement with MAH of products containing Estradiol Valerate + Norethisterone Enanthate would like to inform you of the following:

Summary:

- Norethisterone Enanthate and Estradiol Valerate is an injectable combined hormonal contraceptive administered monthly.
- Overall evidence shows an increased risk of breast cancer in women taking combined estrogen-progestogen therapy.
- Norethisterone Enanthate and Estradiol Valerate combination is contraindicated in case of known, past or suspected breast cancer; and if developed, should be stopped immediately
- During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual woman. Women should be advised what changes in their breasts should be reported to their doctor or nurse.

Background on the safety concern

Norethisterone Enanthate and Estradiol Valerate is a combined hormonal contraceptive injected intramuscularly to provide contraception for 4 weeks.

The randomised placebo-controlled trial the Women's Health Initiative study (WHI), and a meta-analysis of prospective epidemiological studies are consistent in finding an increased risk of breast cancer in women taking combined oestrogen-progestogen for HRT that becomes apparent after about 3 (1 – 4) years. An up to 2-fold increased risk of having breast cancer diagnosed is reported in women taking combined estrogen-progestogen therapy for more than 5 years.

Hormonal replacement therapy (HRT), especially estrogen-progestagen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer.

Women who have or have had a history of breast cancer should not use hormonal contraceptives, because breast cancer may be hormonally sensitive, Women with a strong family history of breast cancer should be monitored with particular care.

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Recommendations:

- Norethisterone Enanthate and Estradiol Valerate combination is contraindicated in case of known, past or suspected breast cancer; and if developed, should be stopped immediately.
- Before initiating or reinstituting HRT, a complete personal and family medical history should be taken.
- Physical (including pelvic and breast) examination should be guided.
- During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual woman.
- Women should be advised what changes in their breasts should be reported to their doctor or nurse.
- Investigations, including appropriate imaging tools, e.g. mammography, should be carried out in accordance with currently accepted screening practices, modified to the clinical needs of the individual.

References

EMC

https://www.medicines.org.uk/emc/product/9511/smpc

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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