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HORMONE REPLACEMENT THERAPY AND BREAST CANCER

NEW ADVICE FROM THE COMMITTEE ON SAFETY OF MEDICINES

A large research project, the “Million Women Study”, provides important new information on the risk of breast cancer in association with using hormone replacement therapy (HRT). The Committee on Safety of Medicines (CSM) and its expert working group on HRT has considered these new facts and is issuing advice to prescribers and women.

This new information relates to the risks of breast cancer in users of HRT, including oestrogen only HRT, combined (oestrogen plus progestagen) HRT and tibolone (Livial® - a different type of HRT).

In line with previous findings, the new study has confirmed that oestrogen-only products are associated with a small increase in the risk of breast cancer. For combined HRT, the increase in risk is substantially higher than that for oestrogen-only products. For tibolone (Livial®), the risk of breast cancer is also significantly increased relative to non-users, albeit to a lesser extent than for combined HRT.

With each product, the risk increases the longer it is taken and starts to become apparent within 1-2 years of initiating treatment. Importantly, this study confirmed that, in all cases, this increase in risk begins to decline when HRT is stopped and, by 5 years, returns to the same level as in women who have never taken HRT.

The CSM advises that for short-term use of HRT for the relief of menopausal symptoms, the benefits outweigh the risks for many women. However, for longer-term use of HRT, women should be aware of the increased risk of breast cancer and other adverse effects. The Committee advised that each decision to start HRT should be made on an *individual* basis, and treatment should be regularly reappraised, at least once per year.

The Chairman of CSM, Professor Duff, said:

‘This high quality study is important as it reflects what is actually happening in HRT users in the UK. We have reviewed the study very carefully and realise that these findings may present women and their doctors with a dilemma about long-term HRT treatment. However, what this study clearly shows is that, in all cases, the additional risk of breast cancer begins to decline when HRT is stopped and by 5 years reaches the same level as in women who have never taken HRT. The new findings mean that it is even more important that each decision to start HRT is made on an individual basis, and is reassessed at least annually. Women who are concerned by these new findings should make a routine appointment to discuss these matters with their doctor.’

BACKGROUND

The Million Women Study sought to examine the effect of different types of HRT and tibolone (Livial[®]), on the risks of breast cancer in nearly a million postmenopausal women in the UK over a period of 5 years. These women were recruited through the National Health Service Breast Screening Programme (NHSBSP), which invites all women in the UK aged 50 – 64 years for routine screening every 3 years.

In the UK, Hormone Replacement Therapy (HRT) products are indicated for the treatment of menopausal symptoms, and some products are also licensed for the prevention of osteoporosis. Tibolone is licensed for both indications.

The CSM is the independent expert scientific committee that advises the Government on the safety of medicines.

The MHRA is an agency of the Department of Health and is responsible for regulating medicines and medical devices.

CSM and its Expert Working Group on HRT have already met to discuss the findings of the Million Women Study. They have issued advice to health professionals and women by an urgent communication on the day the Million Women Study findings became available on the Lancet website on midnight of 7th August.

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