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Press release

MHRA authorises enzyme inhibitor Anastrozole to prevent breast cancer in post-menopausal women

Anastrozole is now authorised as a preventative treatment for post-menopausal women at moderate or high risk of breast cancer.

From: **Medicines and Healthcare products Regulatory Agency** **(/government/organisations/medicines-and-healthcare-products-regulatory-agency)**

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The Medicines and Healthcare products Regulatory Agency (MHRA) has today authorised this new indication for Anastrozole, a hormone treatment used for breast cancer in post-menopausal women.

Anastrozole was already authorised for use in the treatment of breast cancer in post-menopausal women and has been used off-label for prevention.

Today's announcement confirms the authorisation for prevention in post-menopausal women at moderate or high risk of developing the disease.

Evidence was based on the IBIS-II study, an international, randomised double-blind, placebo-controlled trial, which showed fewer women developed breast cancer in the anastrozole group compared to the placebo group.

Breast cancer is the most common type of cancer in the UK. Most women diagnosed with breast cancer are over the age of 50, but younger women can also get breast cancer. Around 1 in 7 women will be diagnosed with breast cancer in their lifetime.

The treatment is taken as a 1mg tablet, once a day for 5 years.

Anastrozole is an aromatase inhibitor. This works by cutting down the amount of the hormone oestrogen that a patient's body makes by blocking an enzyme called 'aromatase'.

The most common side effects of the medicine are hot flushes, feeling weak, pain/stiffness in the joints, arthritis, skin rash, nausea, headache, osteoporosis, and depression.

As with any medicine, the MHRA will keep the safety and effectiveness of Anastrozole under close review. Anyone who suspects they are having a side effect from this medicine are encouraged to talk to their doctor, pharmacist or nurse and report it directly to the Yellow Card scheme, either through the website (https://yellowcard.mhra.gov.uk/) or by searching the Google Play or Apple App stores for MHRA Yellow Card.

Notes to editors

1. Authorisation for this new indication for Anastrozole was granted on 6 November 2023 to Accord Healthcare Ltd.
2. More information can be found in the Summary of Product Characteristics and Patient Information leaflets which will be published on the MHRA Products website (https://products.mhra.gov.uk/) within 7 days of approval.
3. For more information about the IBIS-II study, see: International Breast Cancer Intervention Studies. (https://www.ibis-trials.org/thetrials/ibistrials/ibis-2-prevention)
4. For more information on breast cancer, see: Breast cancer in women - NHS (www.nhs.uk) (https://www.nhs.uk/conditions/breast-cancer/)
5. Prescribing off-label is when a product is prescribed for use outside the terms of its licensed use, including for a different indication and/or to a

different patient population. As stated in MHRA guidance, this is allowed in "clinical situations when the use of unlicensed medicines or use of licensed medicines outside the terms of the licence (i.e., 'off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence". In these situations, the prescriber has additional responsibilities regarding information to the patient and recording treatment (see GMC guidelines).

6. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
7. The MHRA is an executive agency of the Department of Health and Social Care.
8. For media enquiries, please contact the news centre on 020 3080 7651 or newscentre@mhra.gov.uk

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