

Easier access to locally-applied HRT to treat postmenopausal vaginal symptoms in landmark MHRA reclassification

For the first time ever in the UK, postmenopausal women will be able to access a low dose Hormone Replacement Therapy (HRT) product from their local pharmacies without prescription, the Medicines and Healthcare products Regulatory Agency (MHRA) announced today.

Gina 10 microgram vaginal tablets (containing estradiol) are used for the treatment of vaginal symptoms such as dryness, soreness, itching, burning and uncomfortable sex caused by oestrogen deficiency in postmenopausal women aged 50 years and above who have not had a period for at least 1 year. This product is locally-applied, meaning it is inserted into the vagina and not taken orally.

The decision to reclassify these vaginal tablets follows a safety review by the MHRA, independent advice from the [Commission on Human Medicines](#) (CHM), and a [public consultation](#). The UK regulator sought views from patients, pharmacists, prescribers and a wide range of stakeholders including the Royal College of Obstetricians & Gynaecologists, the Faculty of Sexual & Reproductive Healthcare, the British Pharmacopoeia Commission and the British Menopause Society.

Low-dose vaginal estradiol has been widely used for the treatment of postmenopausal vaginal symptoms as a prescription medicine since 1991 and has a well-established safety profile. The product will be supplied from a pharmacy when it is considered safe and suitable to do so, following consultation with a pharmacist.

Pharmacists are trained healthcare professionals. They will have access to training materials and a checklist that will enable them to advise women on whether these low dose vaginal tablets are appropriate and safe for them to use and to give the information they need, so they can make informed choices. Other vaginal tablets that also contain estradiol, including Vagifem 10 microgram vaginal tablets, will still be available on prescription.

Dr Laura Squire, Chief Healthcare Quality and Access Officer at the MHRA, said:

This is a landmark reclassification for the millions of women in the UK who are going through the menopause and experience severe symptoms that negatively impact their everyday life. Women will be able to safely obtain a local vaginal HRT product without a prescription, which increases women's access to treatment and gives

them greater control over their choices while relieving pressure on frontline GP services.

In reaching this decision, we have seen positive support from a wide range of people, including many women aged 50 years and above who could benefit from this decision. We would like to thank everyone who submitted their view in our public consultation.

We will continue to improve women's access to medicines for menopausal care when it is safe to do so, and to place their views at the centre of our regulatory decisions.

Minister for Health, Maria Caulfield, said:

Menopause affects hundreds of thousands of women every year, but for some its symptoms can be debilitating and for many they can be misunderstood or ignored.

Making Gina available over the counter is a huge step forward in enabling women to access HRT as easily as possible, ensuring they can continue living their life as they navigate the menopause.

We're putting women's health to the top of the agenda – our Women's Health Strategy published today is testament to that. More widely we're continuing to work with suppliers and manufacturers to secure sustainable short-term and long-term access to HRT and our UK-wide menopause taskforce will tackle taboos and issues surrounding menopause.

Systemic HRT medicines circulate in the blood and are used to treat hot flushes and other menopausal symptoms. They include oral tablets and patches (transdermal patches) and gels which are put on the skin. Local HRT such as Gina is applied directly to the vagina and gradually releases into the vaginal tissue with very little absorption into the bloodstream.

Notes to Editors

- [Consultation outcome](#) – The public consultation received 1229 responses, with over 88% being in favour of the reclassification. All the responses received were carefully considered.
- [Public assessment report for the prescription only medicine to pharmacy reclassification of Gina 10 microgram vaginal tablets.](#)
- We are committed to widening access to medicines for the benefit of public health when it is safe to do so. Further information on reclassification can be found [here](#) and the criteria for prescription control can be found [here](#).
- 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. MHRA is an executive agency of the Department of Health and Social Care.

- The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products.