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press release

EMBARGOED UNTIL 08, September 2022

First clinically proven treatment for vaginal atrophy after menopause to be available for purchase in pharmacy

- ***Gina***®*,10 micrograms vaginal tablets (estradiol), is the only product effective at treating the cause of vaginal dryness without prescription after the menopause.*[1,2]
- *After menopause, around 1 in 2 women experience vaginal dryness, itching or uncomfortable sex, caused by vaginal atrophy.*[3,4,5,6]
- ***Gina***® *works by applying a small amount of oestrogen directly to the vagina, treating the cause of vaginal dryness, to help it feel how it was before the menopause, providing symptom relief from 8-12 weeks.*[1,2,7]

Gatwick, UK, 08, September 2022– Novo Nordisk today announced that Gina®, 10 micrograms vaginal tablets (estradiol), is now available from pharmacies and online for the treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women aged 50 years and above, who have not had a period for at least one year, following a consultation or assessment for suitability with a pharmacist.[1]

The Medicines and Healthcare products Regulatory Agency (MHRA) has reclassified estradiol vaginal tablets from a prescription-only medicine (POM) to a pharmacy-only (P) medicine. This makes Gina the only product available without a prescription that effectively treats the cause of vaginal atrophy after the menopause.

Oestrogen levels decline after the menopause[2] and this can cause changes in vaginal health, with around 1 in 2 women experiencing vaginal dryness, itching or uncomfortable sex, caused by vaginal atrophy.[3,4,5,6] Unlike other symptoms of menopause, these symptoms are chronic and progressive and will not resolve without treatment.[8,9] However, many women do not seek help from their doctor.[10]

For the first time, women in the UK are now able to buy local oestrogen treatment for vaginal atrophy without a prescription following a consultation with their pharmacist. Increasing choice in the way women can access treatment is important with new survey findings showing that around half of women are suffering from vaginal atrophy after menopause.[10] The survey reveals:

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- **Women don't know about it**: 70% of UK women have never heard of what could happen to their vagina post menopause, known as vaginal atrophy, despite it happening to more than half of all women.
- **They aren't getting help:** Only half of women feel comfortable talking to their GP about their vaginal health, with a third of those women struggling to access GP appointments during the pandemic.
- **Life with vaginal atrophy is uncomfortable**: Three in four women say that vaginal atrophy has negatively affected their sex lives, and one in five women struggle to exercise because of vaginal atrophy.

Before Gina, all treatments for the cause of vaginal atrophy required a prescription, and the survey results reveal that 78% of women do not discuss their vaginal atrophy symptoms with a healthcare professional.[10] Novo Nordisk hopes that Gina® being available over the counter will increase the accessibility of treatment for vaginal atrophy.

Dr Paula Briggs, Chair, British Menopause Society said: "The BMS welcomes the introduction of this product which is likely to improve women's access to treatment. Estradiol vaginal tablets have been available on prescription for over 30 years and have a wealth of efficacy and safety data. Urogenital atrophy is one of the most common challenges women face after the menopause and this reclassification means they can now access a low dose vaginal oestrogen which treats the underlying cause of vaginal atrophy, at their local pharmacy."

Sanjay Verghese, Vice President, Novo Nordisk said: "At Novo Nordisk, we're committed to pioneering treatments which can change the lives of people. People who were previously only able to get treatment from their GP now have Gina as an easily available option, that treats the cause and not just the symptoms of vaginal atrophy. At Novo Nordisk, we are confident that Gina can contribute to the growing movement empowering women to not only manage but to thrive after menopause."

Pharmacists are uniquely placed to educate women about how they can treat their post-menopausal vaginal symptoms and offer them the help they deserve. Ahead of Gina being available for pharmacy sale, there is a comprehensive pharmacy team training programme, including support materials to assess the suitability of Gina and guidelines for when women should be referred to their GP.

The RRP for Gina is £29.99 which works out to £2.50 per week. The 1st pack provides 7 weeks supply and subsequent packs provide 12 weeks supply. To find out more about Gina and where to purchase it, visit www.mygina.co.uk

For more information about Novo Nordisk, visit novonordisk.co.uk

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About vaginal atrophy

Vaginal atrophy affects around one in two postmenopausal women in the UK.[3,4,5,6] *Many women are unfamiliar with the term vaginal atrophy and so refer to it as vaginal dryness. Oestrogen levels decline after menopause and these reduced oestrogen levels result in reduced vaginal blood flow, diminished lubrication, decreased flexibility and elasticity of the vagina and increased vaginal pH.*[2] *Due to the progressive and chronic nature of the condition, symptoms do not diminish without treatment.*[8,9]

About the vaginal atrophy survey[10]

A survey of a nationally representative sample of 200 UK menopausal and postmenopausal women with a quota of 50% having suffered vaginal atrophy. Fieldwork was conducted January 31st, 2022, to February 15th, 2022.

- *70% of women in the UK have never heard of vaginal atrophy but 64% are living with it*
- *Almost half of all women are living with vaginal dryness*
- *Only half (48%) of women feel comfortable speaking to their GP about these issues*
- *1 in 3 women are not satisfied with their sex lives post menopause*

Additional data on this survey is available upon request.

About Gina® 10 micrograms vaginal tablets (estradiol)

Gina® is a small 10mcg estradiol vaginal tablet that comes in a pre-loaded applicator which delivers a low dose of oestrogen directly to the vaginal wall that is then gradually released into the vaginal tissue. [1,7] *It treats vaginal atrophy by replacing the oestrogen lost during the menopause. The oestrogen from Gina stays within the vagina and only low levels are released into the bloodstream. These levels remain within the normal postmenopausal range.*[11] *Gina has an initial dose of one vaginal tablet each day for the first two weeks of treatment, followed by a maintenance dose of one tablet twice a week (leaving three or four days between doses). Gina can be used for as long as women and their pharmacists feel it's needed and should be discussed between the pharmacist and patient every three months.*[1]

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 50,800 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.co.uk

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