NEW TO PHARMACY

Pharmacy Team Training Guide

gina®

10 micrograms
vaginal tablets
Estradiol

The only product effective at **treating the cause of vaginal dryness after the menopause** without prescription

POM to P training
Product information can be found on the last page

Content developed by Novo Nordisk Ltd in association with CIG Healthcare Partnership

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Introduction

This training is for pharmacists and the wider pharmacy team. It will give you an overview of:

- **What Gina is**
- **Who can use Gina**
- **How the consultation process in pharmacy will work**

You have an opportunity to help identify patients who may be interested in finding out more about Gina, as well as making sure that your patients have a positive experience of discussing symptoms and purchasing the product from your pharmacy.

The Pharmacy Guide, checklist and additional resources can be accessed here: **hcp.mygina.co.uk**

Working through this guide can be used towards your CPD as part of your revalidation requirements. For the full Gina training programme and additional resources, visit: **pharmacymagazine.co.uk/gina**

Contents

Vaginal atrophy: An overview

The menopause is a natural part of ageing for women and occurs when a woman stops having periods and is no longer able to conceive. The average age of menopause in the UK is 51.[1]

The preceding time leading up to menopause (known as the 'perimenopause') is characterised by irregular cycles of ovulation and menstruation. The menopause is when a woman has not had a period for 12 consecutive months. After this, a woman reaches 'postmenopause'.[1]

Symptoms associated with the menopause are caused by a change in the balance of sex hormones (mainly oestrogen, but progesterone and testosterone are also altered). As well as changes to a woman's menstrual cycle and effects on vaginal health, other symptoms associated with the menopause can appear – these include vasomotor symptoms (such as hot flushes and night sweats) and effects on mood (for example, low mood).[1]

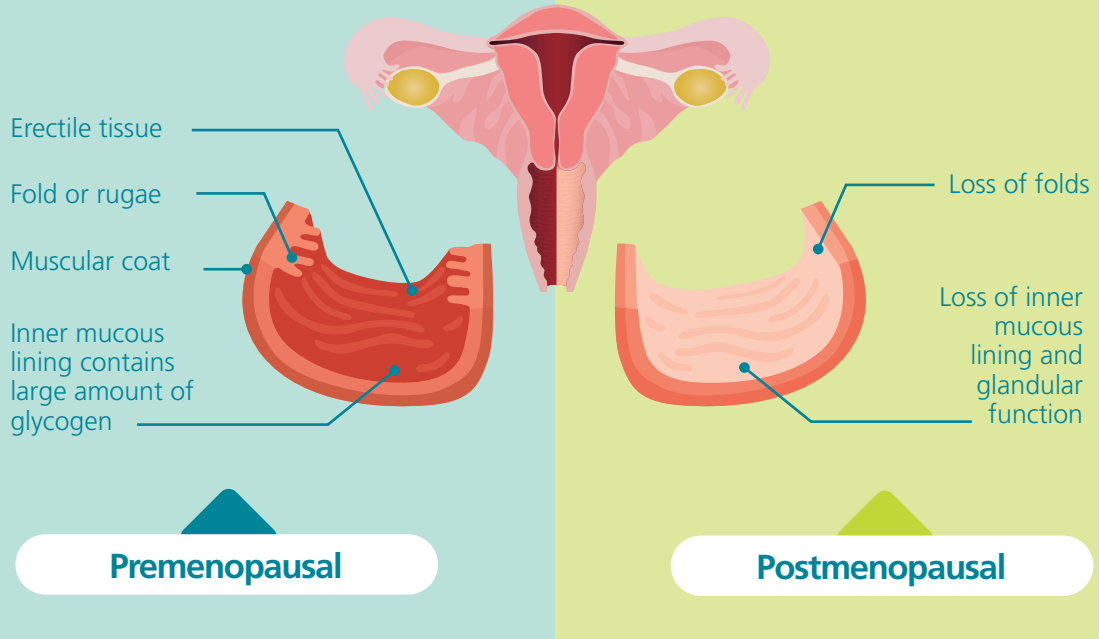
Vaginal changes postmenopause

The decrease in oestrogen levels during and postmenopause can cause thinning of the tissues in and around the vagina, decreased flexibility and elasticity of the vagina, a decrease in the mucus production that provides a moist vaginal environment, and changes to vaginal pH.[2,3]

These changes lead to **vaginal atrophy** (VA), often referred to as vaginal dryness. Symptoms of VA include **dryness, soreness, itching, burning** and/or **discomfort during sex**.

Symptom intensity varies and can have an impact on quality of life.[3] VA is a chronic, progressive condition that does not resolve over time.[4,5]

The image below illustrates how the vaginal tissue can change:



Adapted from Johnson SL, 2002

Impact of VA

Did you know?
VA affects around 1 in 2 postmenopausal women[6,7]

These changes can have a significant impact on women, interfering with aspects of everyday life, including sleep and general enjoyment of life, and may affect their sexual relationships.[8]

Symptoms of VA include:[9]

- Dryness
- Soreness
- Burning
- Itching
- Painful intercourse

> It has impacted my self-confidence and self-consciousness. It's also affected potential relationships

> It's something a lot of people don't understand

> Vaginal dryness kills all spontaneity

> Vaginal dryness makes wanting and having a sexual relationship a bit off as I am usually so sore afterwards that it makes you wonder if it is worth it

Introduction to Gina

What is Gina?

Gina is indicated for the treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women aged 50+, who have not had a period for at least one year.

Gina is a local oestrogen therapy that is gradually released directly into the vagina. Gina treats and relieves vaginal symptoms like dryness, soreness, itching and burning after the menopause.

Gina is the only product available without a prescription that effectively treats the cause of postmenopausal vaginal dryness.

Local oestrogen

Local vaginal oestrogen can be used to deliver a low dose of oestrogen directly to the vagina. Products that deliver vaginal oestrogen have been available on prescription for many years,[10] but Gina provides the option for women to purchase a vaginal oestrogen treatment from their pharmacy.

The availability of this product **without a prescription** is likely to increase awareness of vaginal atrophy and its treatment options among postmenopausal women, as well as giving pharmacy teams the opportunity to provide relevant lifestyle and health advice to women affected by the menopause.

Vaginal oestrogen is not the same as oral systemic HRT, as oestrogen stays within the vagina and low levels are released into the bloodstream. These levels remain within the normal postmenopausal range, which is why the British Menopause Society advises that additional progestogen for endometrial protection is not required.[11]

How does Gina work?

Gina 10 micrograms vaginal tablets (estradiol)

- Gina delivers a low dose of oestrogen that is **clinically proven** to target the cause as well as the symptoms of VA. It replaces the oestrogen that is normally produced in the ovaries, helping to relieve vaginal discomfort.
- Low dose estradiol in the same form as Gina has been available on prescription for over 30 years.[10]

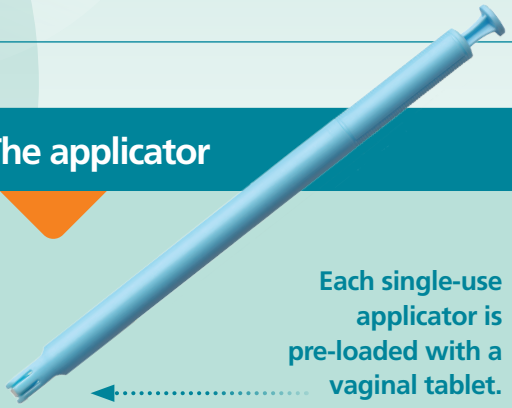
Who can use Gina?

It can be used to treat the symptoms of vaginal atrophy in postmenopausal women aged 50 years and above, who have not had a period for at least ONE year.[12]

No period for >1 year

50+

The applicator



Each single-use applicator is pre-loaded with a vaginal tablet.

Targets the cause of VA

as well as the symptoms

Using Gina

Gina comes in a hygienic, pre-loaded applicator designed to deliver the correct dose every time. The tablet is released into the vagina, where it sticks to the vaginal wall and delivers a gradual and controlled dose of oestrogen.[12]

If a patient stops using Gina, their symptoms may return. At every purchase, the pharmacist will check if use is still appropriate.

Note: *Gina will not provide relief of systemic vasomotor-related symptoms of menopause – it is not licensed for this indication.*

Gina rebalances pH levels in the vagina after two weeks.

Symptom relief may be felt after eight weeks.

Women should see a significant improvement in vaginal symptoms after three months of use.

Your role in consultations

The pharmacist needs to have a consultation with a patient before they can purchase Gina, regardless of whether she has used it before or not.

This training gives you an overview so that you can help with any queries or concerns your patients may have before the consultation.

You may want to **reassure patients that there is no physical examination**; they will just be asked about their symptoms, medical history and medication use. They will also be given advice on how to use the product and any relevant health advice.

Depending on the outcome of the consultation, the pharmacist may advise the patient to see their GP before purchasing the product.

Activity

Discuss with your pharmacist how to deal with patients who say that they have:

a) Used the product before and don't need to speak to the pharmacist

b) Symptoms that have not improved after taking Gina.

Notes:

Pharmacy Checklist

Gina has an optional Pharmacy Checklist that may be used as part of the consultation. Different parts of the Pharmacy Checklist may be used, depending on whether this is a first or repeat purchase.

If a woman hasn't used a local oestrogen treatment before, she will be asked questions about her symptoms to confirm that it is likely that she has VA. She will also be asked about any contraindications, family history (such as any immediate relatives with breast or ovarian cancer, or DVT) and whether she has any other medical conditions that might need GP referral first.

The initial supply will last seven weeks.

When a patient returns to the pharmacy to purchase their second pack after seven weeks, it is important for the pharmacist to check that symptoms have not worsened (to rule out the possibility of an alternative diagnosis).

Thereafter, every three months she will have a consultation to check that it is still appropriate to use Gina.

As you can see, every purchase of Gina needs a consultation.

Activity

Gina is indicated for women over 50 whose periods stopped over a year ago. What can you advise if women do not meet these criteria? Discuss your answer with your pharmacist.

Notes:

Reassuring patients

Anyone wanting to purchase Gina for the first time or make a repeat purchase will need to speak with the pharmacist. Patients should be reassured about using Gina during the consultation process. When it comes to offering Gina to postmenopausal women, there are five main steps to follow:

1 Identify

- Look out for customers who appear to be over the age of 50 and come in regularly for thrush medication, vaginal moisturisers or lubrication products
- There are other conditions that can cause similar symptoms to VA, such as vaginal thrush, so the pharmacist will assess whether there is a need to refer a patient to their GP.

Checking other medical conditions
Women will be asked about any contraindications such as:

- Any vaginal bleeding
- Endometriosis or certain cancers that might be sensitive to or aggravated by oestrogen

Checking family history
Women will be asked about family history (such as any immediate relatives with breast or ovarian cancer, or DVT).

2 Empathise

- Many women feel uncomfortable talking about vaginal dryness, even with close friends and family, so they are likely to be apprehensive
- Remember to offer patients use of the consultation room or another space where you can speak in private
- Try to understand where patients are coming from and give easy-to-understand advice.

3 Reassure

- Patients should not feel alone – remind them that around one in two postmenopausal women experience vaginal atrophy after the menopause
- Low dose vaginal oestrogen in the same form as Gina has been available on prescription for over 30 years
- Many of the safety concerns related to systemic oestrogen are less likely to occur with Gina as it stays within the vagina and low levels are released into the bloodstream.

4 Explain

- Gina comes in a hygienic, pre-loaded applicator designed to deliver the correct dose
- Unlike lubricants and creams, the results are gradual and lasting
- Relief from symptoms can be felt in eight weeks, so remind patients that it may not be until the second pack that they notice improvements (as the first pack lasts seven weeks, and subsequent packs last 12 weeks).

5 Assess

- It's important to check in at each of the treatment intervals to assess how treatment is working.

If during a conversation about Gina a patient mentions any vaginal bleeding or spotting, make sure the pharmacist is aware of this as postmenopausal bleeding can be a sign of endometrial cancer.

Talking to patients about Gina

Raise awareness

As Gina is a pharmacy product, women may not see it behind the counter, so you might need to **raise awareness** with patients.

Patients who are purchasing any of the following products may be interested in finding out more:

- Vaginal lubricants or moisturisers
- Supplements for menopausal symptoms - e.g. black cohosh, red clover, sage tablets and soy isoflavones.

If appropriate, direct these patients to the pharmacist to discuss whether Gina is suitable.

Activity

What do you think are the key benefits for patients of using Gina?

How will you explain the consultation to patients?

Discuss with your colleagues the concerns patients might have, and how you can help to reassure them.

How can you tell patients about the availability of Gina in a sensitive manner?

Test your learning

Test your understanding by answering the questions below. Answers can be found at the bottom of the next page, and there are also scenarios to discuss with your team/pharmacist.

Question 1

What does Gina contain?

a. 10 micrograms estradiol, a form of oestrogen produced by the ovaries ☐

b. 10 micrograms progestin, a form of progesterone produced by the ovaries ☐

Question 2

What symptoms can be relieved by using Gina?

a. Postmenopausal vaginal symptoms such as dryness, painful intercourse and itching ☐

b. Menopausal symptoms such as hot flushes as well as vaginal symptoms like dryness ☐

Question 3

For how long will an initial pack of Gina last when used as directed by someone who is using it for the first time?

a. One month ☐

b. Five weeks ☐

c. Seven weeks ☐

d. Three months ☐

Question 4

All women should have a consultation with the pharmacist, even if they have been using the product for years. True or false?

True ☐ False ☐

Question 5

Using the product packaging, tick which of these would mean that a patient should NOT use Gina (tick all that apply):

a. A patient who has had a heart attack and/or stroke ☐

b. A patient who had a blood clot in their leg three months ago ☐

c. A patient with vaginal bleeding after the menopause ☐

d. A patient who has had breast cancer ☐

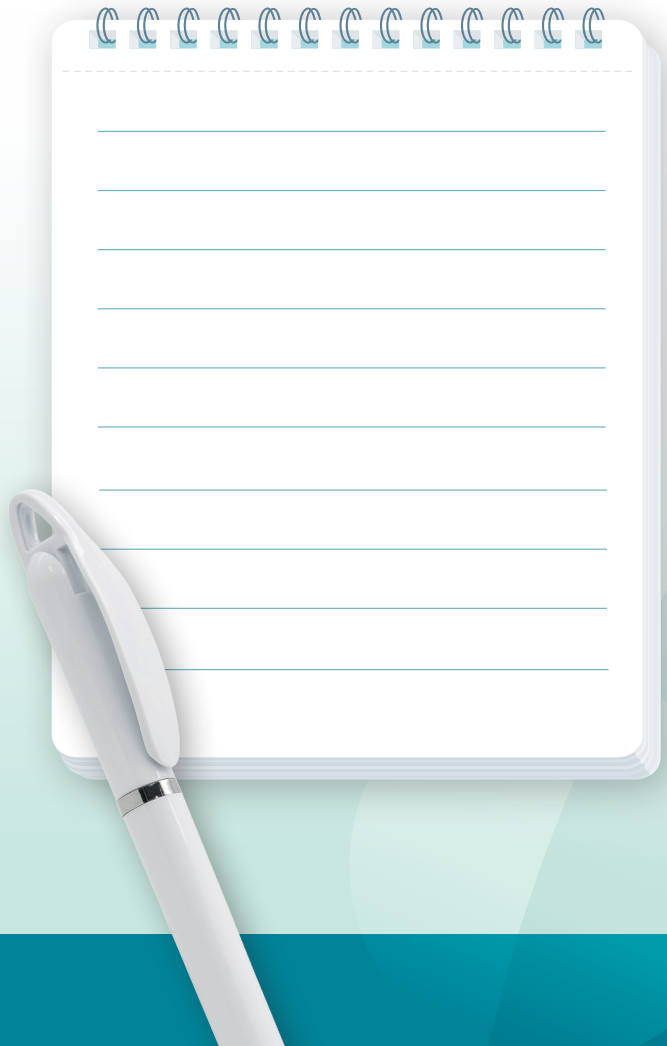
Scenario

A patient who is 55 says that she has read about a new product to treat vaginal itching. She explains that her vaginal area is sore and itchy. She has been finding intercourse with her partner increasingly uncomfortable since her periods stopped six years ago and wonders if this would help.

Consider the following questions and discuss with your pharmacist. Note down the key points from your discussion in the space below.

a. Her symptoms sound like she may have vaginal atrophy. How would the pharmacist then check she could use the product?

b. What symptoms might indicate that a customer has an infection? List these below.



Further reading:

For further reading and information about vaginal atrophy the following may be helpful:

- pcwhf.co.uk
- thebms.org.uk
- womens-health-concern.org

References: 1. National Institute for Health and Care Excellence (NICE). Menopause: Diagnosis and Management. NICE Guideline (NG23); 2019. Available from: https://www.nice.org.uk/guidance/ng23 [Accessed July 2022] **2.** Portman DJ, Gass ML. Vulvovaginal Atrophy Terminology Consensus Conference Panel. Genitourinary syndrome of menopause: new terminology for vulvovaginal atrophy from the International Society for the Study of Women's Sexual Health and the North American Menopause Society. Menopause. Oct 2014;21(10):1063–1068. **3.** Castelo-Branco C, Cancelo MJ, Villero J, et al. Management of postmenopausal vaginal atrophy and atrophic vaginitis. Maturitas 2005;52 Suppl1:S46–52. **4.** Archer DF, Kimble TD, Lin Y, et al. A randomized, multicenter, double-blind, study to evaluate the safety and efficacy of estradiol vaginal cream 0.003% in postmenopausal women with vaginal dryness as the most bothersome symptom. J Women's Health 2018;27(3):231–237. **5.** Wysocki S, Kingsberg S, Krychman M. Management of vaginal atrophy: implications from the REVIVE survey. Clin Med Insights: Reproductive Health 2014;8:23–30. **6.** Kingsberg SA, Larkin L, Krychman M, Parish SJ, Bernick B, Mirkin S. WISDOM survey: attitudes and behaviors of physicians toward vulvar and vaginal atrophy (VVA) treatment in women including those with breast cancer history. Menopause 2019;26:124–131. **7.** Nappi RE, Palacios S, Particco M, et al. The REVIVE (REal Women's VIews of Treatment Options for Menopausal Vaginal ChangEs) survey in Europe: Country-specific comparisons of postmenopausal women's perceptions, experiences and needs. Maturitas 2016;91:81–90. **8.** Kingsberg SA, Wysocki S, Magnus L, et al. Vulvar and vaginal atrophy in postmenopausal women: findings from the REVIVE (REal Women's VIews of Treatment Options for Menopausal Vaginal ChangEs) Survey. J Sex Med 2013;10:1790–1799. **9.** Panay N, Maamari R. Treatment of postmenopausal vaginal atrophy with 10-µg estradiol vaginal tablets. Menopause Int 2012;18(1):15–19. **10.** Nilsson K, Heimer G. Low-dose oestradiol in the treatment of urogenital oestrogen deficiency-a pharmacokinectic and pharmacodynamics study. Maturitas. 1992;15(2):121–127. **11.** British Menopause Society. HRT - Guide; July 2020. Available from: https://thebms.org.uk/wp-content/uploads/2020/07/04-BMS-TfC-HRT-Guide-JULY2020-01D.pdf [Accessed July 2022]. **12.** Gina Summary of Product Characteristics.

Answers: 1:a, 2:a, 3:c, 4:True, 5:All should be ticked.

Essential information

Gina® 10 micrograms vaginal tablets Estradiol hemihydrate

Presentation: Vaginal tablet containing estradiol hemihydrate equivalent to estradiol 10 micrograms. Each tablet is contained in a disposable, single-use applicator.

Indication: 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 1 year.

Posology and Administration: Administered intravaginally by use of an applicator. Initial dose of one vaginal tablet daily for two weeks followed by maintenance dose of one vaginal tablet twice a week.

Contra-indications: Hypersensitivity to ingredients; known, past or suspected endometrial cancer; undiagnosed genital bleeding; untreated endometrial hyperplasia; women with an intact uterus who have been treated with unopposed systemic oestrogens; vulval dermatoses; current vaginal infection, vulval rash, severe vaginal itching; known, past or suspected oestrogen-dependent malignant tumours; previous or current venous thromboembolism; active or recent arterial thromboembolic disease; known thrombophilic disorders; acute liver disease or history of liver disease as long as liver function tests have failed to return to normal; porphyria.

Precautions: HRT should only be initiated for symptoms that adversely affect quality of life. Careful appraisal of the risks and benefits should be undertaken at every pharmacy visit for resupply and HRT should only be continued as long as the benefit outweighs the risk. A complete personal and family medical history should be obtained. The need for referral to a doctor should be guided by this and the contraindications and warnings for use. Women should be advised to report any unexpected vaginal bleeding or changes in their breasts to their doctor or nurse. Women should be referred to a doctor before treatment initiation if they: have endometriosis unless there has been a prescription for vaginal oestrogens and health status is unchanged since the last prescription and she has no recent symptoms of endometriosis; endometrial hyperplasia unless there has been a prescription for vaginal oestrogens and health status is unchanged since the last prescription or she has had a hysterectomy; are receiving hormonal therapy unless there has been a prescription for a concurrent vaginal oestrogen and the health status is unchanged since the last prescription; are switching to Gina from another vaginal oestrogen if it was used for less than 3 months or it was used at the recommended dose and bothersome symptoms are experienced. During treatment women should be referred to a doctor if symptoms do not start to improve by 3 months of treatment. The intravaginal applicator may cause minor local trauma. Treatment should be discontinued immediately and advice sought from a doctor if new onset of vaginal bleeding or spotting, new onset of vaginal itching, vaginal infection not adequately treated by a pharmacy treatment or symptoms of endometriosis occur. Prompt advice should be sought from a doctor if: jaundice or deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache, pregnancy. Women should speak to a doctor if the following conditions are present, have previously occurred or have been aggravated during pregnancy or taking hormone treatment: leiomyoma; risk factors for thromboembolic disorders; risk factors for oestrogen-dependent tumours; hypertension; liver disorders; diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or severe headache; systemic lupus erythematosus; epilepsy; asthma and otosclerosis.

Continued suitability of treatment should be verified at each supply with special consideration given to any symptoms of endometrial hyperplasia or carcinoma. It is not recommended to add a progestagen. Evidence suggests an increased risk of breast cancer in women taking combined oestrogen-progestagen and possibly oestrogen-only systemic HRT that is dependent on the duration of taking HRT. Use of oestrogen-only systemic HRT has been associated with a slightly increased risk of having ovarian cancer. Systemic HRT is associated with a 1.3- to 3-fold risk of developing venous thromboembolism (VTE) especially in the first year of use. Consider risk factors for VTE. Consider temporarily stopping HRT four to six weeks prior to surgery if prolonged immobilisation expected; do not restart until woman completely mobilised. Carefully consider benefit-risk of use of HRT in women on anticoagulant treatment. Patients should contact their doctor immediately if they become aware of a potential thromboembolic symptom. Systemic oestrogen only therapy is associated with up to a 1.5-fold increased risk of ischaemic stroke. The risk increases with age. Oestrogens may cause fluid retention, monitor patients with cardiac or renal dysfunction. Women with pre-existing hypertriglyceridaemia should be followed closely during oestrogen replacement or HRT. Oestrogens may increase plasma proteins including thyroid, corticoid and sex-hormone-binding globulin leading to increased circulating corticosteroids and sex steroids. The effect of estradiol on plasma binding proteins is likely to be less with local vaginal administration compared to systemic administration. There is some evidence to demonstrate an increased risk of probable dementia in women who start using continuous combined or oestrogen only HRT after the age of 65. The risks above apply to a lesser extent for oestrogen products for vaginal application however they should be considered in case of long term or repeated use of this product.

Interactions: It is unlikely that any clinically relevant drug interactions will occur with Gina®. However, interactions with other locally applied vaginal treatments should be considered.

Pregnancy and lactation: Not indicated.

Undesirable effects: Very low rates reported (similar to placebo) of breast pain, peripheral oedema and postmenopausal bleedings; they are most likely present only at the beginning of treatment. Other adverse events reported are: **Common (≥1/100 to <1/10)**: headache, abdominal pain, vaginal haemorrhage, vaginal discharge or discomfort. **Uncommon (≥ 1/1,000 to <1/100)**: vulvovaginal mycotic infection, nausea, rash, weight increased, hot flush and hypertension. Other side effects reported in association with systemic oestrogen/progestagen treatment: gallbladder disease, skin and subcutaneous disorders (chloasma, erythema multiforme, erythema nodosum, vascular purpura, probable dementia). Post-marketing experience: The following adverse drug reactions, have been spontaneously reported for patients being treated with estradiol 25 micrograms vaginal tablets and are considered possibly related to treatment. The reporting rate of these spontaneous adverse reactions is very rare (<1/10,000 patient years): Neoplasms benign and malignant (including cysts and polyps): breast cancer, endometrial cancer. Immune system disorders: generalised hypersensitivity reactions (e.g. anaphylactic reaction/shock). Metabolism and nutrition disorders: fluid retention. Psychiatric disorders: insomnia. Nervous system disorders: migraine aggravated. Vascular disorders: deep venous thrombosis, Gastrointestinal disorders: diarrhoea. Skin and subcutaneous tissue disorders: urticaria, rash erythematous, rash pruritic, genital pruritus. Reproductive system and breast disorders: endometrial hyperplasia, vaginal irritation, vaginal pain, vaginismus, vaginal ulceration. General disorders and administration site conditions: drug ineffective. Investigations: weight increased, blood oestrogen increased. The Summary of Product Characteristics (SmPC) should be consulted for a full list of side effects and further details of risk estimates.

PL Number: PL 04668/0273

Legal Category: P

Cost (excl VAT): RRP is £24.99 24 vaginal tablets with applicators
For full product information please refer to the SmPC which can be obtained from the Marketing Authorisation Holder:
Novo Nordisk Limited, 3 City Place, Beehive Ring Road, Gatwick, West Sussex, RH6 0PA,Tel: 01293 613555

Date last revised: July 2022

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Novo Nordisk Limited

(Telephone Novo Nordisk Customer Care Centre 0800 023 2573)

Calls may be monitored for training purposes.

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