
Appendix: Pharmacy Checklist

Pharmacy Checklist

This Pharmacy Checklist is designed to support you during consultations with women who are requesting Gina. It provides questions for your customer to answer in order for you to check their suitability for Gina and determine which action to take at each visit.

Section 1: Women who **have never previously used Gina** (first visit to the pharmacy) **2**

Section 2: Women who are **returning for their second visit (7 weeks)** **6**
or **first 3-monthly visit**

Section 3: Women who are returning for their **ongoing 3-monthly visits** **9**

Additional Information:

Women **switching from another local oestrogen therapy including Vagifem** **12**
(without treatment break)

Treatment break whilst using Gina or other local oestrogen therapy **12**

gina[®]

10 micrograms vaginal tablets
Estradiol

Section 1: Women who **have never previously used Gina** (first visit to the pharmacy)

Please answer these questions if you have **never previously used a local oestrogen therapy**

If the answer to Q1 is YES, and all the answers to the other questions are NO, you can supply Gina with no need for further confirmation of suitability.
If any of the answers to Q2 – Q7 are yes/unsure, you will need to ask further questions to check suitability for supply of Gina.

Questions	Answers			Guidance/Actions/Explanation
1 Are you experiencing any of these vaginal symptoms? • dryness • soreness • itching • burning • painful intercourse	Yes	No	Unsure	These are the symptoms of vaginal atrophy. If the woman is not experiencing any of these symptoms, she may have another condition and Gina will not be suitable for her.
2 Are you younger than 50 years old?	Yes	No	Unsure	If the woman is under 50 years of age, do not supply Gina and advise her that Gina is not licensed for women under 50 years, but her GP can provide advice and treatment.
3 Did you have your last period less than a year ago?	Yes	No	Unsure	If the woman had her last period less than 1 year ago, do not supply Gina and advise her that Gina is not licensed for women who are not postmenopausal, but her GP can provide advice and treatment.
4 Have you been experiencing any of the following? Vaginal symptoms • undiagnosed bleeding • smelly, or unusual vaginal discharge • severe vaginal itching (for example, that interferes with sleep) Any changes to the look or feel of your vulva • sore red patches • thickening, a lump or scarring • itchy, white, smooth/crinkled patches of skin easily damaged • rash Other symptoms • pelvic pain or pain on urination • lower abdominal pain, bloating or swelling	Yes	No	Unsure	These are red flag symptoms. If the woman is experiencing any of the red flag symptoms that might indicate differential diagnoses, do not supply Gina and advise her to see her GP for investigation and treatment.

Questions	Answers			Guidance/Actions/Explanation
5 Do you currently have, or have you previously had any health conditions or are you being investigated for any health conditions? (e.g. cancer, a thickening of the lining of the uterus/endometrial hyperplasia, endometriosis, liver disorders or jaundice, a blood clot) OR do any of your first-degree relatives (parent, sibling) have a health condition? (e.g. cancer or blood clots)	Yes	No	Unsure	Do not supply Gina if the woman has: • Cancer ◦ Known, past or suspected endometrial cancer ◦ Known, past or suspected oestrogen-dependent malignant tumours (e.g. breast cancer, ovarian cancer) • Untreated or suspected endometrial hyperplasia • Thromboembolic/thrombophilic conditions ◦ Previous or current blood clots in the legs (venous thrombosis) or lungs (pulmonary embolism) ◦ Active or recent arterial thromboembolic disease (angina, myocardial infarction, ischaemic stroke) ◦ A thrombophilic disorder (e.g. protein C, protein S or antithrombin deficiency, family history) • Vulval dermatoses • Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal • Porphyria Women with any of these conditions should be referred to their GP for advice and treatment of their VA. Check health of immediate family before and during treatment (i.e. no new case of breast or ovarian cancer, DVT or pulmonary embolism in a close relative (parent, sibling or child). These women have an increased risk of developing these conditions. As HRT may add to this risk, they should be referred to their GP. Refer to GP for assessment before supplying Gina if the woman has: • a history of endometriosis, unless she has: ◦ previously been prescribed a local oestrogen therapy and there have been no changes to her health status since her last prescription, and no recent symptoms of endometriosis • a history of endometrial hyperplasia, unless she has: ◦ previously been prescribed a local therapy and there have been no changes to her health status since her last prescription, OR ◦ had a hysterectomy Women who have a current vaginal infection, prior to starting treatment, should be treated before starting treatment with Gina.

Questions	Answers			Guidance/Actions/Explanation
6 Are you currently taking any regular medication, or have you previously taken any other medication (including a different local oestrogen therapy)?	Yes	No	Unsure	Pharmacists should investigate any medicines that could be indicative of a contraindicated condition. • Anticoagulants: women taking anticoagulants can be supplied Gina as long as they are not being taken for a contraindicated condition • Other local oestrogen therapy, including prescription Vagifem: for women who are currently using a local oestrogen therapy refer to Additional Information section • Hormonal therapy, including systemic HRT: women taking hormonal therapy, including systemic HRT, can be supplied with Gina as long as: ○ they have previously been prescribed a local oestrogen therapy for concurrent use and their health status has not changed since their last local oestrogen therapy prescription, OR ○ their GP has confirmed their suitability for Gina • Unopposed systemic oestrogen: women with an intact uterus who have previously been treated with unopposed systemic oestrogens should not be supplied with Gina Refer to GP for assessment before supplying Gina if the woman has: • been receiving hormonal therapy, including systemic HRT, and has not previously been prescribed a local oestrogen therapy • been using a different local oestrogen therapy for <3 months
7 Do you have any allergies?	Yes	No	Unsure	If allergies to estradiol, lactose or one of the excipients (refer to SmPC or Pharmacy Guide for a full list), do not supply Gina and refer to GP.

Advise women that if they experience any of the following while taking Gina, they should stop using Gina immediately and seek prompt advice from their GP:

- If they develop any of the conditions listed under the 'Do not use' section in the Patient Information Leaflet and on the pack
- If they have any **new** vaginal bleeding, spotting or itching
- If they have endometriosis and their symptoms have come back

Advise women that if they experience any of the following while taking Gina, they should seek prompt medical advice from their GP:

- Yellowing of the skin or whites of the eyes (possible jaundice or deterioration in liver function)
- Significant increase in blood pressure (symptoms may include headache, tiredness, dizziness)
- New migraine-type headache which happens for the first time (may indicate hypertension)
- Pregnancy, which Gina is contraindicated for

Dosing information, if Gina is suitable

For women who **have never previously used a local oestrogen therapy:**

- **Initial dose:** 1 vaginal tablet daily for the initial 2 weeks
- **Maintenance dose:** 1 vaginal tablet twice a week, leaving 3 or 4 days between each dose

Advise the woman to return to the pharmacy after finishing the first pack at 7 weeks.

Section 2: Women who are **returning for their second visit (7 weeks) or first 3-monthly visit**

Please answer these questions if you **started Gina on the initial dose** and are **returning after completing your first or second pack**

If the answers to all the questions are NO, you can supply Gina with no need for further confirmation of suitability. If any of the answers are yes/unsure, you will need to ask further questions to check suitability for resupply of Gina.

Questions	Answers			Guidance/Actions/Explanation
1 If you just completed your first pack, have your vaginal symptoms become worse? OR If you just completed your second pack, have your vaginal symptoms become worse or remained the same?	Yes	No	Unsure	Do not supply Gina if the woman has had: - any worsening in symptoms after her first pack - OR - no improvement in symptoms after her second pack She may not have VA. Explain that she should see her GP to check for differential diagnoses.
2 Have you been experiencing any of the following? Vaginal symptoms - undiagnosed bleeding - smelly, or unusual vaginal discharge - severe vaginal itching (for example, that interferes with sleep) Any changes to the look or feel of your vulva - sore red patches - thickening, a lump or scarring - itchy, white, smooth/crinkled patches of skin easily damaged - rash Other symptoms - pelvic pain or pain on urination - lower abdominal pain, bloating or swelling	Yes	No	Unsure	These are red flag symptoms. If the woman is experiencing any of the red flag symptoms that might indicate differential diagnoses, do not supply Gina and advise her to see her GP for investigation and treatment.

Questions	Answers			Guidance/Actions/Explanation
3 Have you had any changes in your health, are you being investigated for any health conditions, or have you started using any new medications since you started using Gina? OR have any of your first-degree relatives (parent, sibling) had a change in their health condition? (e.g. cancer or blood clots)	Yes	No	Unsure	Do not supply Gina if the woman has developed any contraindicated conditions since her last supply: • Cancer ◦ Known, past or suspected endometrial cancer ◦ Known, past or suspected oestrogen-dependent malignant tumours (e.g. breast cancer, ovarian cancer) • Untreated or suspected endometrial hyperplasia • Thromboembolic/thrombophilic conditions ◦ Previous or current blood clots in the legs (venous thrombosis) or lungs (pulmonary embolism) ◦ Active or recent arterial thromboembolic disease (angina, myocardial infarction, ischaemic stroke) ◦ A thrombophilic disorder (e.g. protein C, protein S or antithrombin deficiency, family history) • Vulval dermatoses • Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal • Porphyria Women with any of these conditions should be referred to their GPs for advice and treatment of their VA. If the woman has started using anticoagulants; other local oestrogen therapy, including prescription Vagifem; hormonal therapy, including systemic HRT; unopposed systemic oestrogen; or any medicines that could be indicative of a contraindicated condition since using Gina, see Section 1, Q6. Check health of immediate family. Explain why and refer them to their GP if case (current or past) of breast or ovarian cancer, DVT or pulmonary embolism in a close relative (parent, sibling or child). Refer to GP for assessment before supplying Gina if the woman has: • a current vaginal infection that cannot be managed by pharmacy treatment
4 Have you experienced any problems whilst using Gina (e.g. problems using the applicator)?	Yes	No	Unsure	If the woman has had any problems using Gina that cannot be treated in a Pharmacy setting, do not supply Gina and refer to GP.
5 Have you had a break in treatment?	Yes	No	Unsure	If the woman has had a treatment break, refer to Additional Information section.

Advise women that if they experience any of the following while taking Gina, they should stop using Gina immediately and seek prompt advice from their GP:

- If they develop any of the conditions listed under the 'Do not use' section in the Patient Information Leaflet and on the pack
- If they have any **new** vaginal bleeding, spotting or itching
- If they have endometriosis and their symptoms have come back

Advise women that if they experience any of the following while taking Gina, they should seek prompt medical advice from their GP:

- Yellowing of the skin or whites of the eyes (possible jaundice or deterioration in liver function)
- Significant increase in blood pressure (symptoms may include headache, tiredness, dizziness)
- New migraine-type headache which happens for the first time (may indicate hypertension)
- Pregnancy, which Gina is contraindicated for

Dosing information, if Gina is suitable

- **Maintenance dose:** 1 vaginal tablet twice a week, leaving 3 or 4 days between each dose

Advise the woman to return to the pharmacy after finishing her next pack in 3 months' time.

Section 3: Women who are returning for their ongoing 3-monthly visits

Please answer these questions if you are **returning for your ongoing 3-monthly visit**

If the answer to Q1 is YES, and all the answers to the other questions are NO, you can supply Gina with no need for further confirmation of suitability.
If any of the answers to Q2 – Q5 are yes/unsure, you will need to ask further questions to check suitability for supply of Gina.

Questions	Answers			Guidance/Actions/Explanation
1 Are you satisfied with the improvement in vaginal symptoms you have experienced on Gina?	Yes	No	Unsure	If the woman is not satisfied with the improvement in symptoms, she may not have VA and/or require alternative treatment. Do not supply Gina. Explain that she should see her GP to check for assessment and treatment.
2 Have you been experiencing any of the following? Vaginal symptoms - undiagnosed bleeding - smelly, or unusual vaginal discharge - severe vaginal itching (for example, that interferes with sleep) Any changes to the look or feel of your vulva - sore red patches - thickening, a lump or scarring - itchy, white, smooth/crinkled patches of skin easily damaged - rash Other symptoms - pelvic pain or pain on urination - lower abdominal pain, bloating or swelling	Yes	No	Unsure	These are red flag symptoms. If the woman is experiencing any of the red flag symptoms that might indicate differential diagnoses, do not supply Gina and advise her to see her GP for investigation and treatment.

Questions	Answers			Guidance/Actions/Explanation
3 Have you had any changes in your health, are you being investigated for any health conditions, or have you started using any new medications since you started using Gina? OR have any of your first-degree relatives (parent, sibling) had a change in their health condition? (e.g. cancer or blood clots)	Yes	No	Unsure	Do not supply Gina if the woman has developed any contraindicated conditions since her last supply: • Cancer ◦ Known, past or suspected endometrial cancer ◦ Known, past or suspected oestrogen-dependent malignant tumours (e.g. breast cancer, ovarian cancer) • Untreated or suspected endometrial hyperplasia • Thromboembolic/thrombophilic conditions ◦ Previous or current blood clots in the legs (venous thrombosis) or lungs (pulmonary embolism) ◦ Active or recent arterial thromboembolic disease (angina, myocardial infarction, ischaemic stroke) ◦ A thrombophilic disorder (e.g. protein C, protein S or antithrombin deficiency, family history) • Vulval dermatoses • Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal • Porphyria Women with any of these conditions should be referred to their GPs for advice and treatment of their VA. If the woman has started using anticoagulants; other local oestrogen therapy, including prescription Vagifem; hormonal therapy, including systemic HRT; unopposed systemic oestrogen; or any medicines that could be indicative of a contraindicated condition since using Gina, see Section 1, Q6. Check health of immediate family. Explain why and refer them to their GP if case (current or past) of breast or ovarian cancer, DVT or pulmonary embolism in a close relative (parent, sibling or child). Refer to GP for assessment before supplying Gina if the woman has: • a current vaginal infection that cannot be managed by pharmacy treatment

Questions	Answers			Guidance/Actions/Explanation
4 Have you experienced any problems whilst using Gina (e.g. problems using the applicator)?	Yes	No	Unsure	If the woman remains suitable and has not experienced any worsening of symptoms or any problems using Gina, you can resupply Gina. If the woman has had any problems using Gina that cannot be treated in a Pharmacy setting, do not supply Gina and refer to GP.
5 Have you had a break in treatment?	Yes	No	Unsure	If the woman has had a treatment break, refer to Additional Information section.

Advise women that if they experience any of the following while taking Gina, they should stop using Gina immediately and seek prompt advice from their GP:

- If they develop any of the conditions listed under the 'Do not use' section in the Patient Information Leaflet and on the pack
- If they have any **new** vaginal bleeding, spotting or itching
- If they have endometriosis and their symptoms have come back

Advise women that if they experience any of the following while taking Gina, they should seek prompt medical advice from their GP:

- Yellowing of the skin or whites of the eyes (possible jaundice or deterioration in liver function)
- Significant increase in blood pressure (symptoms may include headache, tiredness, dizziness)
- New migraine-type headache which happens for the first time (may indicate hypertension)
- Pregnancy, which Gina is contraindicated for

Dosing information, if Gina is suitable

- **Maintenance dose:** 1 vaginal tablet twice a week, leaving 3 or 4 days between each dose

Advise the woman to return to the pharmacy after finishing this pack in 3 months' time.

Additional information

Women switching from another local oestrogen therapy including Vagifem (without treatment break)

Women can switch from another local oestrogen therapy or prescription Vagifem to Gina as long as they have been using their current local oestrogen therapy for >3 months at the recommended dose and their symptoms are adequately controlled.

Women switching from a local oestrogen to Gina should start on the **maintenance dose** with **3-monthly visits** to the pharmacy. This is because these women will already have an established VA diagnosis. Progress, red flag symptoms, contraindications, and family history will need to be checked at each visit.

Dosing information, *if Gina is suitable*

- **Maintenance dose:** 1 vaginal tablet twice a week, leaving 3 or 4 days between each dose

Advise the woman to return to the pharmacy after finishing this pack in 3 months' time.

Treatment break whilst using Gina or other local oestrogen therapy

If the woman has had a treatment break, ask whether bothersome VA symptoms have come back.

- **Bothersome symptoms have not come back:** start/continue on the maintenance dose
- **Bothersome symptoms have come back:** advise the woman to begin/restart treatment using the initial dose for 2 weeks, followed by the maintenance dose

