



Form 154 – Breast Health Supplement to the Medication Inventory WHI Extension Study

Date Received: <input type="text"/> - <input type="text"/> - <input type="text"/> (MM/DD/YY)		- Affix label here-
Reviewed By: <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>		
Participant ID: _____ - _____ - _____		First Name _____ M.I. _____
Contact Type: <input type="checkbox"/> ₁ Phone		Last Name _____
<input type="checkbox"/> ₂ Mail	Visit Type: <input type="checkbox"/> ₃ Annual	<input type="checkbox"/> FCA <input type="checkbox"/> OUI <input type="checkbox"/> OU2
<input type="checkbox"/> ₈ Other	<input type="checkbox"/> ₄ Non-Routine	Language: <input type="checkbox"/> ₁ English <input type="checkbox"/> ₂ Spanish
OFFICE USE ONLY		

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0414). Do not return the completed form to this address.

Instructions:

To help us learn about the health of WHI participants, we would like to know more about some of the medications you may take.

As part of your participation in the Women’s Health Initiative, you previously reported a diagnosis of breast cancer or breast cancer in situ. This form asks about medications that you may have used to treat breast cancer.

If you would like to have a WHI staff member at the Clinical Coordinating Center complete this form with you over the phone, please feel free to call 1-800-218-8415.

The first set of questions asks about medications known as **SERMS (selective estrogen receptor modulators)**. These medications include tamoxifen (Nolvadex[®]), raloxifene (Evista[®]), and toremifene (Fareston[®]).

Since your breast cancer diagnosis:

1. Have you ever taken **tamoxifen (Nolvadex[®])**?

- ₀ No
₁ Yes →
₉ Don't know

1.1 How long did you take or have you taken tamoxifen?
(Use your best estimate; mark only one.)

<input type="checkbox"/> ₁ Less than 1 month	<input type="checkbox"/> ₄ 1-2 years
<input type="checkbox"/> ₂ 1-5 months	<input type="checkbox"/> ₅ 3-4 years
<input type="checkbox"/> ₃ 6-11 months	<input type="checkbox"/> ₆ 5 or more years

2. Have you ever taken **raloxifene (Evista[®])**?

- ₀ No
₁ Yes →
₉ Don't know

2.1 How long did you take or have you taken raloxifene?
(Use your best estimate; mark only one.)

<input type="checkbox"/> ₁ Less than 1 month	<input type="checkbox"/> ₄ 1-2 years
<input type="checkbox"/> ₂ 1-5 months	<input type="checkbox"/> ₅ 3-4 years
<input type="checkbox"/> ₃ 6-11 months	<input type="checkbox"/> ₆ 5 or more years

3. Have you ever taken **toremifene (Fareston[®])**?

- ₀ No
₁ Yes →
₉ Don't know

3.1 How long did you take or have you taken toremifene?
(Use your best estimate; mark only one.)

<input type="checkbox"/> ₁ Less than 1 month	<input type="checkbox"/> ₄ 1-2 years
<input type="checkbox"/> ₂ 1-5 months	<input type="checkbox"/> ₅ 3-4 years
<input type="checkbox"/> ₃ 6-11 months	<input type="checkbox"/> ₆ 5 or more years

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These next questions ask about medications known as **anti-estrogen therapies** or **aromatase inhibitors**. These medications include anastrozole (Arimidex[®]), exemestane (Aromasin[®]), and letrozole (Femara[®]).

Since your breast cancer diagnosis:

4. Have you ever taken **anastrozole (Arimidex[®])**?

- ₀ No
₁ Yes →
₉ Don't know

4.1 How long did you take or have you taken anastrozole?
(Use your best estimate; mark only one.)

- ₁ Less than 1 month ₄ 1-2 years
₂ 1-5 months ₅ 3-4 years
₃ 6-11 months ₆ 5 or more years

5. Have you ever taken **exemestane (Aromasin[®])**?

- ₀ No
₁ Yes →
₉ Don't know

5.1 How long did you take or have you taken exemestane?
(Use your best estimate; mark only one.)

- ₁ Less than 1 month ₄ 1-2 years
₂ 1-5 months ₅ 3-4 years
₃ 6-11 months ₆ 5 or more years

6. Have you ever taken **letrozole (Femara[®])**?

- ₀ No
₁ Yes →
₉ Don't know

6.1 How long did you take or have you taken letrozole?
(Use your best estimate; mark only one.)

- ₁ Less than 1 month ₄ 1-2 years
₂ 1-5 months ₅ 3-4 years
₃ 6-11 months ₆ 5 or more years

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Spanish translation underway

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- FORM:** 154 – BREAST CANCER PREVENTION AND TREATMENT MEDICATIONS
- Version:** 1 – November, 2008
- Description:** Self-administered or interviewer-administered; 3-page booklet; key-entered at the Clinical Coordinating Center (CCC).
- When used:** Collected one time as part of the annual contacts for Clinical Trial (CT) and Observational Study (OS) participants enrolled in the WHI Extension Study who have indicated a previous breast biopsy or diagnosis of breast cancer on WHI Form 33/33D.
- Purpose:** To collect updated information on specific types of medications (SERMS and aromatase inhibitors) currently being prescribed for the prevention and treatment of breast cancer.
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GENERAL INSTRUCTIONS

1. The form is printed in both English (*Form 154*) and Spanish (*Form 154S*) versions.
2. The *Form 154* for WHI Extension Study participants will be labeled and mailed from the CCC directly to the participant. Form is only mailed to participants with a previous breast biopsy or diagnosis of breast cancer.
 - The CCC mails the form to the participant and asks her to mail it back in a return envelope by a specified date. Following the CCC mailing, if the participant does not return the *Form 153* within 3 months of the first mailing, it will be sent again. If the form is not returned within 2 months of the second mailing, the form will be sent a third time. If the form is still not returned, CCC staff will contact the participants by telephone to collect the information from willing participants. The CCC will data enter the forms.
3. In the event that this form is collected by FC staff, the form should be sent to the CCC for data entry.

Item Instructions

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|------|--|---|
| 1. | Tamoxifen (Nolvadex) –
Ever Taken | No/Yes/DK. Participants indicating “No” or “DK” skip to Q2. |
| 1.1. | Tamoxifen – Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 2. | Raloxifene (Evista) –
Ever Taken | No/Yes/DK. Participants indicating “No” or “DK” skip to Q3. |
| 2.1. | Raloxifene – Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 3. | Toremifene (Fareston) –
Ever Taken | No/Yes/DK. Participants indicating “No” or “DK” skip to Q4. |
| 3.1. | Toremifene – Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 4. | Anastrozole (Arimidex)
– Ever Taken | No/Yes/DK. Participants indicating “No” or “DK” skip to Q5. |
| 4.1. | Anastrozole – Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 5. | Exemestane (Aromasin)
– Ever Taken | No/Yes/DK. Participants indicating “No” or “DK” skip to Q6. |
| 5.1. | Exemestane – Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 6. | Letrozole (Femara) –
Ever Taken | No/Yes/DK. Participants indicating “No” or “DK” skip to Q7. |
| 6.1. | Letrozole – Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 7. | Ever Taken Any Other
SERM or Aromatase
Inhibitor | No/Yes/DK. Participants indicating “No” or “DK” skip to Q8. |
| 7.1. | Other SERM or
Aromatase Inhibitor –
Duration | Participant indicates length of time the medication was taken: 1. Less than 1 month; 2. 1-5 months; 3. 6-11 months; 4. 1-2 years; 5. 3-4 years; 6. 5 or more years. |
| 8. | Barriers to Breast Cancer
Medications | Check all that apply. |