Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARIMIDEX?

ARIMIDEX contains the active ingredient anastrozole. ARIMIDEX is used to treat breast cancer in women who no longer have their menstrual periods either naturally, due to their age or after surgery, radiotherapy or chemotherapy.

For more information, see Section <u>1. Why am I using ARIMIDEX?</u> in the full CMI.

2. What should I know before I use ARIMIDEX?

Do not use if you have ever had an allergic reaction to ARIMIDEX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ARIMIDEX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARIMIDEX and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ARIMIDEX?

- The usual dose is one tablet every day.
- Swallow ARIMIDEX tablets whole, with a glass of water.

More instructions can be found in Section <u>4. How do I use ARIMIDEX?</u> in the full CMI.

5. What should I know while using ARIMIDEX?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using ARIMIDEX. Be sure to keep all your appointments with your doctor so your progress can be checked. 	
Things you should not do	 Do not give ARIMIDEX to anyone else, even if they have the same condition as you. Do not take ARIMIDEX to treat any other complaints unless your doctor tells you to. Do not stop taking ARIMIDEX unless you have discussed it with your doctor. 	
Driving or using machines	Be careful driving or operating machinery until you know how ARIMIDEX affects you.	
Looking after your medicine	 Keep your tablets in the blister pack until it is time to take them. Keep it in a cool, dry place where the temperature stays below 30°C. 	

For more information, see Section 5. What should I know while using ARIMIDEX? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some may be minor and temporary. However, some side effects may be serious. Tell your doctor immediately if you have sudden signs of allergy such as shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or any other parts of the body, rash, itching or hives on the skin, severe skin reactions with lesions, ulcers or blisters, liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin and eyes).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Active ingredient: anastrozole

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARIMIDEX. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARIMIDEX.

Where to find information in this leaflet:

- 1. Why am I using ARIMIDEX?
- 2. What should I know before I use ARIMIDEX?
- 3. What if I am taking other medicines?
- 4. How do I use ARIMIDEX?
- 5. What should I know while using ARIMIDEX?
- 6. <u>Are there any side effects?</u>
- 7. Product details

1. Why am I using ARIMIDEX?

ARIMIDEX contains the active ingredient anastrozole. ARIMIDEX is a non-steroidal aromatase inhibitor, which reduces the amount of oestrogen (female sex hormone) made by the body. In some types of breast cancer, oestrogen can help the cancer cells grow. By blocking oestrogen, ARIMIDEX may slow or stop the growth of

cancer. ARIMIDEX is used to treat breast cancer in women who no longer have their menstrual periods either naturally,

no longer have their menstrual periods either naturally due to their age or after surgery, radiotherapy or chemotherapy.

Your doctor may have prescribed ARIMIDEX for another reason.

ARIMIDEX is not addictive.

2. What should I know before I use ARIMIDEX?

Warnings

Do not use ARIMIDEX if:

- you are allergic to anastrozole, other anti-oestrogen medicines or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are still having menstrual periods
- you are a man

ARIMIDEX should only be taken by women who are no longer having menstrual periods.

Men are not normally treated with ARIMIDEX.

Check with your doctor if you:

- have any other medical conditions
- have liver problems
- have kidney problems

- take any medicines for any other condition
- have allergies to any medicines or any other substances, such as foods, preservatives or dyes (symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.)
- have osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines)

Aromatase inhibitors may decrease bone mineral density (BMD) in women who have been through menopause, with a possible increased risk of fractures. Your doctor should discuss with you your treatment options for managing this possible increased risk of fractures. Aromatase inhibitors may cause inflammation in tendons (see Side effects). At any sign of tendon pain or swelling rest the painful area and contact your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Do not take ARIMIDEX if you are pregnant or intend to become pregnant.

ARIMIDEX may affect your developing baby if you take it during pregnancy.

Do not breastfeed while taking ARIMIDEX.

Your baby can take in ARIMIDEX from breast milk if you are breastfeeding.

Children

• Do not give ARIMIDEX to a child.

ARIMIDEX is not recommended for use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines should not be taken with ARIMIDEX. These include:

- tamoxifen, a medicine used to treat breast cancer
- any medicine that contains oestrogen such as medicines used in Hormone Replacement Therapy (HRT) or oral contraceptives
- any health food products that contain natural estrogens used for post-menopausal symptoms

 medicines from a class called "Luteinising Hormone Releasing (LHRH) agonists", such as goserelin or leuprorelin

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARIMIDEX.

4. How do I use ARIMIDEX?

How much to take

- The usual dose is one tablet every day.
- Swallow ARIMIDEX tablets whole, with a glass of water.
- Follow the directions given to you by your doctor or pharmacist carefully, they may differ from the information contained in the leaflet.

When to take ARIMIDEX

• Take ARIMIDEX at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take ARIMIDEX before, with or after food.

How long to take ARIMIDEX

Continue taking ARIMIDEX for as long as your doctor or pharmacist tells you.

ARIMIDEX helps to control your condition, but does not cure it. Therefore you must take ARIMIDEX every day. Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take ARIMIDEX

ARIMIDEX should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, as long as it is 12 hours before the next dose is due.

If it is less than 12 hours to the next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much ARIMIDEX

If you think that you have used too much ARIMIDEX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

5. What should I know while using ARIMIDEX?

Things you should do

- Be sure to keep all your appointments with your doctor so your progress can be checked.
- Tell any other doctors, dentists or pharmacists who are treating you that you are taking ARIMIDEX.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ARIMIDEX.
- If you go into hospital, please let the medical staff know that you are taking ARIMIDEX.

Remind any doctor, dentist or pharmacist you visit that you are using ARIMIDEX.

Things you should not do

- Do not give ARIMIDEX to anyone else, even if they have the same condition as you.
- Do not take ARIMIDEX to treat any other complaints unless your doctor tells you to.
- Do not stop taking ARIMIDEX unless you have discussed it with your doctor.
- Do not take ARIMIDEX if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARIMIDEX affects you.

Some patients may occasionally feel weak or sleepy.

Looking after your medicine

• Keep your tablets in the blister pack until it is time to take them.

If you take ARIMIDEX out of the blister pack it will not keep well.

• Keep it in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car on hot days or on a window sill.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

ARIMIDEX helps most postmenopausal women with breast cancer, but it may have unwanted side effects in a few people.

If you get any side effects do not stop taking ARIMIDEX without first talking to your doctor or pharmacist.

You may experience the following more common side effects of ARIMIDEX:

Very common (may affect more than 1 in 10 people)	What to do
 hot flushes feeling weak or a lack of energy joint pain or stiffness bone loss (osteoporosis) mild skin rash feeling sick (nausea) headache feeling depressed 	Speak to your doctor if you have any of these very common side effects and they worry you.

Common (may affect up to 1 in 10 people)	What to do
 feeling sleepy vaginal dryness vaginal bleeding thinning of hair (hair loss) diarrhoea loss of appetite (anorexia) vomiting carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of hand) pins and needles loss of taste or changing taste of food or drink 	Speak to your doctor if you have any of these common side effects and they worry you.

These side effects are mostly mild to moderate in nature.

Serious side effects

Serious side effects		What to do
•	sudden signs of allergy such as shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin severe skin reactions with lesions, ulcers or blisters liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin and eyes)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects are uncommon or rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Other side effects not listed here may occur in some people.

ARIMIDEX may be associated with changes in your blood, urine or liver. Your doctor may want to perform tests from time to time to check on your progress and detect any unwanted side effects.

Uncommon side effects can include, trigger finger which is a condition in which one of your fingers or your thumb catches in a bent position.

Cases of inflammation of a tendon or tendonitis (connective tissues that connect muscles to bone) have been observed during the use of similar class of medicines, which might also occur during treatment with ARIMIDEX.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ARIMIDEX contains

Active ingredient (main ingredient)	anastrozole	
Other ingredients (inactive ingredients)	 lactose monohydrate povidone sodium starch glycolate magnesium stearate (E572) hypromellose macrogol 300 titanium dioxide (E171) 	
Potential allergens	lactose and titanium dioxide	

Do not take this medicine if you are allergic to any of these ingredients.

What ARIMIDEX looks like

ARIMIDEX 1 mg is a round, white, biconvex film-coated tablet with the following markings:

The are marked with a letter 'A' with an arrow head attached to the right leg of the 'A' on one side and marked Adx1 on the other (Aust R 54672).

ARIMIDEX comes in a blister pack containing 30 tablets.

Who distributes ARIMIDEX

AstraZeneca Pty Ltd ABN 54 009 682 311 66 Talavera Road MACQUARIE PARK NSW 2113 Telephone:- 1800 805 342

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