## **ARIANNA® 1**

## **Consumer Medicine Information (CMI) summary**

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

## 1. Why am I taking ARIANNA 1?

ARIANNA 1 contains the active ingredient anastrozole. ARIANNA 1 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 1. Why am I taking ARIANNA 1? in the full CMI.

#### 2. What should I know before I take ARIANNA 1?

Do not take if you have ever had an allergic reaction to ARIANNA 1 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 take ARIANNA 1? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ARIANNA 1 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 take ARIANNA 1?

- The usual dose is one tablet every day.
- Swallow ARIANNA 1 tablets whole with plenty of water.

More instructions can be found in Section 4. How do I take ARIANNA 1? in the full CMI.

#### 5. What should I know while taking ARIANNA 1?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are taking ARIANNA 1.</li> <li>Be sure to keep all your appointments with your doctor so your progress can be checked.</li> </ul>
Things you should not do	<ul> <li>Do not give ARIANNA 1 to anyone else, even if they have the same condition as you.</li> <li>Do not take ARIANNA 1 to treat any other complaints unless your doctor tells you to.</li> <li>Do not stop taking ARIANNA 1 unless you have discussed it with your doctor.</li> </ul>
Driving or using machines	Be careful driving or operating machinery until you know how ARIANNA 1 affects you.
Looking after your medicine	<ul> <li>Keep your tablets in the original pack until it is time to take them.</li> <li>Keep it in a cool, dry place where the temperature stays below 25°C.</li> </ul>

For more information, see Section 5. What should I know while taking ARIANNA 1? 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.

## ARIANNA® 1

Active ingredient(s): anastrozole

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking ARIANNA 1. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ARIANNA 1.

#### Where to find information in this leaflet:

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

## 1. Why am I taking ARIANNA 1?

ARIANNA 1 contains the active ingredient anastrozole. ARIANNA 1 is a non-steroidal aromatase inhibitor, which reduces the amount of estrogen (female sex hormone) made by the body. In some types of breast cancer, estrogen can help the cancer cells grow. By blocking estrogen, ARIANNA 1 may slow or stop the growth of cancer.

ARIANNA 1 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.

Your doctor may have prescribed ARIANNA 1 for another reason.

ARIANNA 1 is not addictive.

# 2. What should I know before I take ARIANNA 1?

#### Warnings

## Do not take ARIANNA 1 if:

- you are allergic to:
  - o anastrozole, the active ingredient of ARIANNA 1
  - o any of the other ingredients in ARIANNA 1, as listed at the end of this leaflet
  - o other anti-estrogen medicines.
- Some of the symptoms of an allergic reaction may include:
  - o skin rash, itching or hives;
  - swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing;
  - wheezing or shortness of breath.
- you are still having menstrual periods

ARIANNA 1 should only be taken by women who are no longer having menstrual periods.

you are a man

Men are not normally treated with ARIANNA 1.

#### Check with your doctor if you:

- have or have had 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
- 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 Section <u>6</u>. Are there any side effects). At any sign of tendon pain or swelling - rest the painful area and contact your doctor.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking ARIANNA 1.

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 ARIANNA 1 if you are pregnant or intend to become pregnant.

There is a possibility of harm to the developing baby as the medicine may be absorbed within the womb.

#### Do not breastfeed while taking ARIANNA 1.

Your baby can take in ARIANNA 1 from breast milk if you are breastfeeding.

#### Children

#### Do not give ARIANNA 1 to a child.

ARIANNA 1 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 ARIANNA 1. These include:

- tamoxifen, a medicine used to treat breast cancer
- any medicine that contains estrogen 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 ARIANNA 1.

## 4. How do I take ARIANNA 1?

#### How much to take

- The usual dose is one tablet every day.
- Swallow ARIANNA 1 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 ARIANNA 1

#### Take ARIANNA 1 at about the same time each day.

Taking your tablet(s) at about 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 ARIANNA 1 before, with or after food.

#### How to long to take ARIANNA

## Keep taking ARIANNA 1 for as long as your doctor or pharmacist tells you.

ARIANNA 1 helps to control your condition, but does not cure it. Therefore, you must take ARIANNA 1 every day. Do not stop taking it unless your doctor tells you to - even if you feel better.

#### If you forget to take ARIANNA 1

ARIANNA 1 should be taken 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 miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist or doctor for some hints.

#### If you take too much ARIANNA 1

If you think that you or anyone else has taken too much ARIANNA 1, urgent medical attention may be needed.

#### You should immediately:

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

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while taking ARIANNA 1?

#### Things you should do

- Be sure to keep all your appointments with your doctor so your progress can be checked.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ARIANNA 1.
- If you go into hospital, please let the medical staff know that you are taking ARIANNA 1.
- If you become pregnant while taking ARIANNA 1, tell your doctor immediately.

Your doctor needs to know immediately so that ARIANNA 1 can be replaced by another medicine.

Remind any doctor, dentist or pharmacist you visit that you are taking ARIANNA 1.

## Things you should not do

- Do not give ARIANNA 1 to anyone else, even if they have the same condition as you.
- Do not take ARIANNA 1 to treat any other complaints unless your doctor tells you to.
- Do not stop taking ARIANNA 1 unless you have discussed it with your doctor.
- Do not take ARIANNA 1 if the packaging is torn or shows signs of tampering.
- Do not take ARIANNA 1 for a longer time than your doctor has prescribed.
- Do not let yourself run out of ARIANNA 1 over the weekend or on holidays.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how ARIANNA 1 affects you.

ARIANNA 1 may occasionally cause drowsiness, dizziness or other symptoms such as feeling weak or sleepy which could affect your ability to drive or operate machinery.

#### Looking after your medicine

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

If you take tablets out of the blister pack they will not keep well.

#### Keep it where the temperature stays below 25°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 or on window sills.

Heat and dampness can destroy some medicines.

#### Keep it where young children cannot reach it.

A locked cupboard at least one-and a-half metres above the ground is a good place to store medicines.

#### Getting rid of any unwanted medicine

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

Do not take 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. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. 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.

ARIANNA 1 helps most postmenopausal women with breast cancer, but it may have unwanted side effects in a some people.

## If you get any side effects do not stop taking ARIANNA 1 without first talking to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

You may experience the following more common side effects of ARIANNA 1:

#### Less serious side effects

Very common (may affect more than 1 in 10 people)	What to do
<ul> <li>hot flushes</li> <li>feeling weak or a lack of energy</li> <li>joint pain or stiffness</li> <li>bone loss (osteoporosis)</li> <li>mild skin rash</li> <li>feeling sick (nausea)</li> <li>headache</li> <li>feeling depressed</li> </ul>	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	Speak to your doctor if you
<ul> <li>vaginal dryness</li> </ul>	
vaginal bleeding	have any of

Common (may affect up to 1 in 10 people)	What to do
<ul> <li>thinning of hair (hair loss)</li> <li>diarrhoea</li> <li>loss of appetite (anorexia)</li> <li>vomiting</li> <li>carpal tunnel syndrome</li></ul>	these common
(tingling, pain, coldness,	side effects and
weakness in parts of hand) <li>pins and needles</li> <li>loss of taste or changing taste of</li>	they worry
food or drink	you.

These side effects are mostly mild to moderate in nature.

#### Serious side effects

Serious side effects	What to do
<ul> <li>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</li> <li>extremely severe skin reactions (Stevens-Johnson syndrome) with lesions, ulcers or blisters</li> <li>liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin and eyes)</li> </ul>	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.

ARIANNA 1 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 ARIANNA 1.

#### 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 ARIANNA 1 contains

Active ingredient (main ingredient)	Anastrozole 1 mg	
Other ingredients (inactive ingredients)	<ul> <li>Lactose monohydrate</li> <li>Hypromellose</li> <li>Sodium starch glycollate type A</li> <li>Macrogol 300</li> <li>Magnesium stearate</li> <li>Povidone</li> <li>Titanium dioxide</li> </ul>	
Potential allergens	Lactose	

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

#### What ARIANNA 1 looks like

ARIANNA 1 are white to off white, round, biconvex, film-coated tablets debossed with "AHI" on one side and plain on other side (AUST R 259991).

ARIANNA 1 comes in blister packs containing 30 tablets.

#### Who distributes ARIANNA 1

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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ARIANNA® is a Viatris company trade mark

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