

ARIANNA®

anastrozole

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ARIANNA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARIANNA against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What ARIANNA is used for

ARIANNA 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.

ARIANNA may slow or stop the growth of cancer by blocking estrogen.

ARIANNA 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.

Follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed ARIANNA for another reason.

ARIANNA is only available with a doctor's prescription.

ARIANNA is not addictive.

Before you take ARIANNA

When you must not take it

Do not take ARIANNA if you are pregnant or intend to become pregnant breast-feeding.

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.

Your baby can take in ARIANNA from breast milk if you are breast-feeding.

Do not take ARIANNA if you are allergic to:

- Anastrozole, the active ingredient of ARIANNA
- Any of the other ingredients in ARIANNA, as listed at the end of this leaflet
- Other anti-estrogen medicines.

Some of the symptoms of an allergic reaction may include 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.

Do not take ARIANNA if you are still having menstrual periods.

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

Do not take ARIANNA if you are male.

Men are not normally treated with ARIANNA.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Do not give ARIANNA to a child.

ARIANNA is not recommended for use in children.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.

ARIANNA should not be used during pregnancy or while breast-feeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney disease
- liver problems
- Osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as a diet low in calcium, smoking, 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 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.

Taking other medicines

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

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

- Tamoxifen, a medicine used to treat breast cancer
- any health food products that contain natural estrogens used for post-menopausal symptoms
- any medicine that contains estrogen such as medicines used in Hormone Replacement Therapy (HRT) or oral contraceptives
- medicines from a class called "Luteinising Hormone Releasing Hormone (LHRH) agonists", such as goserelin or leuprorelin.

Talk to your doctor or pharmacist if you have any concerns or questions about taking ARIANNA.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARIANNA.

How to take ARIANNA

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How to take it

Always swallow the tablets whole with plenty of water.

You can take the tablets with or without food.

How much to take

The usual dose is one tablet every day.

When to take it

Take your ARIANNA 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 the tablets.

It does not matter whether you take ARIANNA before or after food.

How long to take it for

Keep taking ARIANNA for as long as your doctor tells you to.

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

If you forget to take it

If you miss a dose, 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, do not take the dose you have missed.

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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ARIANNA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ARIANNA

Things you must do

If you become pregnant while taking ARIANNA, tell your doctor immediately.

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

Be sure to keep all your appointments with your doctor so your progress can be checked.

Before starting any new medicine, tell your doctor, dentist or pharmacist that you are taking ARIANNA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARIANNA.

If you go into hospital, please let the medical staff know that you are taking ARIANNA.

Things you must not do

Do not take ARIANNA for a longer time than your doctor has prescribed.

Do not let yourself run out of ARIANNA over the weekend or on holidays.

Do not stop taking ARIANNA unless you have discussed it with your doctor.

Do not use ARIANNA to treat any other conditions unless your doctor tells you to.

Do not give ARIANNA to anyone else, even if they have the same condition as you.

Things to be careful of

Effects on driving and operating machinery.

ARIANNA may occasionally cause drowsiness, dizziness or other symptoms which could affect your ability to drive or operate machinery. Make sure you know how you are affected by this medicine before you drive or use machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARIANNA.

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

All medicines can have side effects. Sometimes they are serious, most of

the time they are not. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical treatment if you get some of the side effects.

If you get any side effects do not stop taking ARIANNA 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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- hot flushes
- lack of energy
- feeling sleepy
- vaginal dryness
- vaginal bleeding
- joint pain or stiffness
- thinning of hair (hair loss)
- mild skin rash
- feeling sick (nausea)
- headache
- 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
- feeling depressed.

ARIANNA 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.

The above list includes the more common side effects of ARIANNA, some of which may disappear with

continued treatment. Mostly these are mild to moderate in nature.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- 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
- extremely severe skin reactions (Stevens-Johnson syndrome) 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).

The above list includes very serious side effects. You may require urgent medical attention or hospitalisation. These side effects are rare.

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. These side effects are generally mild to moderate and often resolve themselves over time.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After taking ARIANNA

Storage

Keep ARIANNA where children cannot reach it.

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

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ARIANNA or any other medicine in the bathroom or near a sink.

Do not leave ARIANNA in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARIANNA, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ARIANNA is available in 1 tablet strength:

- 1 mg - white film-coated, round, biconvex, beveled edge tablet debossed with 'M' on one side and '34' on the other side.

ARIANNA comes in blister packs containing 30 tablets.

Ingredients

The active ingredient in ARIANNA is anastrozole.

Each ARIANNA tablet contains 1mg of anastrozole.

The tablets also contain the following inactive ingredients:

- Lactose
- Hypromellose
- Sodium starch glycollate
- Magnesium stearate
- Titanium dioxide
- Polydextrose
- Triacetin
- Polyethylene glycol 8000
- Purified water

The tablets do not contain sucrose or gluten.

Supplier

ARIANNA is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

ARIANNA 1 mg film-coated tablet
blister pack - AUST R 158023

This leaflet was prepared on
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