PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ARIMIDEX 1 mg, Tablets

Anastrozole

Contains sugar: lactose monohydrate 93 mg

Read all of this leaflet carefully before you start taking ARIMIDEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ARIMIDEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4)

What is in this leaflet

1. What ARIMIDEX is and what it is used for
2. What you need to know before you take ARIMIDEX
3. How to take ARIMIDEX
4. Possible side effects
5. How to store ARIMIDEX
6. Contents of the pack and other information

1. What ARIMIDEX is and what it is used for

ARIMIDEX belongs to a group of medicines called aromatase inhibitors. This means that it interferes with some of the actions of aromatase, an enzyme within the body which effects the level of certain female sex hormones such as oestrogens.

ARIMIDEX is used to treat breast cancer in post-menopausal women.

2. What you need to know before you take ARIMIDEX

Do not take ARIMIDEX:

- if you are hypersensitive (allergic) to anastrozole or any of the other ingredients of ARIMIDEX (listed in section 6).
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with ARIMIDEX:

- If you are suffering from any disorder or disease which affects your heart, liver or kidneys. Please inform your doctor.

ARIMIDEX is not recommended if you are pre-menopausal and it should not be given to children.

Special warning

ARIMIDEX lowers the level of female hormones and this may lead to a loss of the mineral content of bones which might decrease their strength and as a possible consequence the risk of fractures may increase. This possible increased risk should be managed according to treatment guidelines for managing bone health in post-menopausal women. Women are encouraged to discuss this possible risk and treatment options with their medical practitioners.

ARIMIDEX may cause inflammation in tendons (see section 4). At any sign of tendon pain or swelling, rest the painful area and contact your doctor.

Other medicines and ARIMIDEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Tamoxifen or medicines containing oestrogen (female sex hormone). It may lessen the effect of ARIMIDEX.

Pregnancy and breastfeeding

You should not take ARIMIDEX if you are pregnant or breastfeeding your baby (see **"Do not take ARIMIDEX"**).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Your tablets may adversely affect your ability to drive a car or to operate machinery. Some patients may occasionally feel weak or sleepy. If this happens to you, ask your doctor for advice.

ARIMIDEX contains lactose

ARIMIDEX contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking ARIMIDEX.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ARIMIDEX.

3. How to take ARIMIDEX

Do not share medicines prescribed for you with any other person.

Always take ARIMIDEX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- The usual dose is one tablet taken daily.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.

If you have the impression that the effect of ARIMIDEX is too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.

If you take more ARIMIDEX than you should

If you take more tablets than your normal dose, contact your doctor or nearest hospital immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ARIMIDEX

Take the last missed dose as soon as you remember, as long as it is at least 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.

4. Possible side effects

ARIMIDEX can have side effects.

Not all side effects reported for ARIMIDEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ARIMIDEX, please consult your health care provider for advice.

Contact your doctor promptly if the following happens to you, as you may need further examinations or treatment:

- Very severe skin reactions (Stevens-Johnson syndrome) with lesions, ulcers or blisters.
- Allergic reaction with swelling of the face, lips, tongue and/or throat (angioedema) which may cause difficulty in swallowing and/or breathing.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Hot flushes
- Feeling weak
- Joint pain/stiffness
- Inflammation of the joints (arthritis)
- Loss of bone mass (bones break easily)

- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)
- Vaginal dryness
- Hair thinning
- Nausea
- Diarrhoea
- Headache
- Vaginal bleeding (usually in the first few weeks of treatment)
- Loss of appetite
- Vomiting
- Sleepiness
- Depression
- Rash, including inflammation of small blood vessels in the skin leading to skin rash
- Allergic reactions such as hives or nettle-rash
- Bone pain
- Muscle pain
- Tickling, tingling or numbness of skin, loss or lack of taste

Less frequent side effects:

- Trigger finger (a condition in which one of your fingers or your thumb catches in a bent position)
- Increased calcium with or without the increase of parathyroid hormone in the blood. If you experience nausea, vomiting and thirst, you should tell your doctor. These symptoms may indicate possible increased blood calcium levels. Your doctor may have to do certain blood tests to determine if there is increased calcium in your blood occurring with or without an increase of parathyroid hormone, a hormone that regulates calcium.

An increased level of cholesterol (a type of fat in the blood) could also be seen with ARIMIDEX.

A small increase in heart disease caused by reduced blood flow in the vessels of the heart was seen (ischaemic heart disease). This condition may present itself as chest pain.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacis

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ARIMIDEX.

5. How to store ARIMIDEX

Store all medicines out of reach of children.

- Store at or below 30 °C
- Keep your tablets in the container they came in.
- Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ARIMIDEX contains

The active substance is Anastrozole. Each tablet contains 1 mg Anastrozole.

The other ingredients are: hypromellose, lactose monohydrate, magnesium stearate, macrogol 300, povidone, sodium starch glycollate, titanium dioxide.

What ARIMIDEX looks like and contents of the pack

Round, white biconvex film-coated, intagliated tablets, impressed with a logo consisting of the letter ‘A’ with an arrow head attached to the foot of the extended right leg of the ‘A’, on one side and a tablet strength marking (‘Adx 1’) on the other side.

PVC/aluminium foil packs of 30 tablets in a carton.

Holder of Certificate of Registration

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