Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)- 1986

This medicine is dispensed with a doctor's prescription only

Arimidex®
Film-coated tablets

Composition:
Each tablet contains: anastrozole 1 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not intended for children and adolescents.

1. What is this medicine intended for?
Treatment of breast cancer in post-menopausal women.

Therapeutic group:
Aromatase enzyme inhibitors. Arimidex works by cutting down the amount of the hormone called estrogen that your body makes. Arimidex does this by blocking a natural substance (an enzyme) in your body called aromatase.

2. Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient anastrozole or to any of the other ingredients in this medicine (listed in section 6).
- You are pregnant or breast-feeding (see section 'Pregnancy and breast-feeding').

Special warnings about using Arimidex
Before treatment with Arimidex, tell your doctor if you:
- Still have menstrual periods and have not yet gone through the menopause.
- Are taking a medicine that contains tamoxifen or medicines that contain estrogen (see section 'Drug interactions').
- Have, or have ever had a condition that affects the strength of your bones (osteoporosis or osteopenia). 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. During treatment, you may need to undergo bone density tests. Your doctor may prescribe medication to prevent or treat bone loss. Women with severe osteoporosis are not suitable for treatment with anastrozole.

- Have problems with your liver or kidneys.
- Have heart problems or have had a stroke.

Additional warnings:
- If you go into the hospital, let the medical staff know you are taking Arimidex.

Children and adolescents
Arimidex should not be given to children and adolescents.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.
Do not take Arimidex if you are already taking any of the following medicines:
- Certain medicines for treatment of breast cancer (selective estrogen receptor modulators), e.g. medicines that contain tamoxifen. This is because these medicines may reduce the effectiveness of Arimidex.
- Medicines that contain estrogen, such as hormone replacement therapy (HRT).

Tell your doctor or pharmacist if you are taking:
- Medicine belonging to the LHRH analogue group such as gonadorelin, buserelin, goserelin, leuprorelin and triptorelin. These medicines are used to treat breast cancer, certain gynaecological conditions, and infertility.

Using this medicine and food
Arimidex can be taken before, with or after food.

Pregnancy and breast-feeding
Do not take Arimidex if you are pregnant or breast-feeding. Stop taking Arimidex if you discover you are pregnant and talk to your doctor.

If you are planning to become pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines
This medicine should not affect your ability to drive a vehicle or operate tools or machines. However, some patients may occasionally feel weak or sleepy during treatment with Arimidex. If this happens to you, ask your doctor or pharmacist for advice.

Important information about some of this medicine's ingredients
Arimidex contains lactose
The tablets contain lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking Arimidex.
Arimidex sodium content
Arimidex contains less than 23 mg sodium per tablet and is therefore considered essentially sodium free.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The recommended dose is one tablet once a day,
Try to take your tablet at the same time each day.
Swallow the tablet whole with water.
Arimidex can be taken before, with or after food.
Keep taking Arimidex for as long as your doctor tells you to. It is a long-term treatment, and you may need to take it for several years. Check with your doctor or pharmacist if you are not sure.
Take this medicine at scheduled times as determined by your doctor.

Do not exceed the recommended dose.

There is no information about chewing and crushing the tablets.

If you have taken a higher dose
If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you have forgotten to take a dose, take your next dose as usual. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your health improves and/or you feel better, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Arimidex may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Side effects that require special attention. Stop use and contact your doctor immediately, if any of the following serious side effects appear:

Common side effects (affects 1-10 in 100 users)

- Allergic (hypersensitivity) reactions including face, lips, or tongue.

Rare side effects (affects 1-10 in 10,000 users)

- Rare inflammation of your skin that may include red patches or blisters.

Very rare side effects (affects up to 1 in 10,000 users)

- An extremely severe skin reaction (Stevens-Johnson syndrome) with ulcers or blisters.
- Allergic (hypersensitivity) reactions with swelling of the throat that may cause difficulty in swallowing or breathing (angioedema).

Additional side effects

Very common side effects (affect more than one in ten users)

- Headache.
- Hot flushes.
- Nausea.
- Skin rash.
- Pain or stiffness in your joints.
- Inflammation of the joints (arthritis).
- Weakness.
- Bone loss (osteoporosis).
- Depression.

Common side effects (affect 1-10 in 100 users)

- Loss of appetite.
- Raised or high levels of cholesterol in your blood. This would be seen in a blood test.
- Feeling sleepy.
- Carpal tunnel syndrome (expressed as tingling, pain, coldness, weakness in parts of the hand).
- Tickling, tingling or numbness of skin, loss/lack of taste.
- Diarrhoea.
- Vomiting.
- Changes in liver function that are seen in blood tests.
- Thinning of your hair (hair loss).
- Bone pain.
- Vaginal dryness.
- Bleeding from the vagina (usually in the first few weeks of treatment – if the bleeding continues, talk to your doctor).
- Muscle pain.

Uncommon side effects (affect 1-10 in 1,000 users)

- Changes in certain blood tests for liver function such as gamma-GT and bilirubin tests.
- Inflammation of the liver (hepatitis).
- Hives or nettle rash (itchy skin rash).
- Trigger finger, a condition in which your ability to straighten your thumb or finger is impaired.
- Increased amounts of calcium in your blood. If you experience nausea, vomiting and thirst, you should tell your doctor. The doctor will consider performing blood tests to check this.

Rare side effects (affect 1-10 in 10,000 users)

- Inflammation of the small blood vessels causing red or purple colouring of the skin. Very rare symptoms of joint, stomach, and kidney pain may appear. This is known as '**Henoch-Schönlein purpura**'.

Side effects with frequency not known (frequency cannot be estimated from the available data)

- Dry eye
- Lichenoid eruption (small, red or purple itchy bumps on the skin)
- Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)
- Rupture of a tendon (connective tissues that connect muscles to bones)

- Memory impairment

Effects on your bones
Arimidex lowers the level of the hormone called estrogen in your body, which may lead to a loss of the mineral content of your bones, making them less strong, and in some cases may result in fractures. Your doctor will manage the risks according to treatment guidelines for managing bone health in women who have gone through the menopause. You should talk to your doctor about the risks and treatment options.

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 30˚C.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Lactose monohydrate, sodium starch glycolate, povidone, magnesium stearate, hypromellose, macrogol 300, titanium dioxide.

What the medicine looks like and contents of the pack:
White, round, biconvex film-coated tablet, with a logo imprinted on one side and the strength on the other side.
Each package contains 28 tablets in packets.

Registration holder: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer: Haupt Pharma Muenster GmbH, Schleebrueggenkamp 15, Muenster, Nordrhein-Westfalen, 48159, Germany

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Registration number of the medicine in the Ministry of Health's National Drug Registry:
105-16-28931-00