Package leaflet: Information for the user

Anastrozole 1 mg Film-Coated Tablets1 mg film-coated tablets

Anastrozole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their sign of I illness 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 Anastrozole 1 mg Film-Coated Tablets is and what it is used for

Anastrozole 1 mg Film-Coated Tablets contains a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. Anastrozole 1 mg Film-Coated Tablets is used to treat breast cancer in women who have gone through the menopause.

Anastrozole 1 mg Film-Coated Tablets works by cutting down the amount of the hormone called estrogen that your body makes. It does this by blocking a natural substance (an enzyme) in your body called 'aromatase'.

2. What you need to know before Anastrozole 1 mg Film-Coated Tablets

Do not take Anastrozole 1 mg Film-Coated Tablets
- if you are allergic to anastrozole or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast-feeding (see the section 'Pregnancy and breast-feeding').

Do not take Anastrozole 1 mg Film-Coated Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Anastrozole 1 mg Film-Coated Tablets.

Warnings and precautions
Before treatment with Anastrozole 1 mg Film-Coated Tablets check with your doctor or pharmacist
- if you still have menstrual periods and have not yet gone through the menopause.
- if you are taking a medicine that contains tamoxifen or medicines that contain estrogen (see the section called 'Taking other medicines').
- if you have ever had a condition that affects the strength of your bones (osteoporosis).
- if you have problems with your liver or kidneys.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Anastrozole 1 mg Film-Coated Tablets.
If you go into the hospital, let the medical staff know you are taking Anastrozole 1 mg Film-Coated Tablets.

Other medicines and Anastrozole 1 mg Film-Coated Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes medicines that you buy without a prescription and herbal medicines. This is because Anastrozole 1 mg Film-Coated Tablets can affect the way some medicines work and some medicines can have an effect on Anastrozole 1 mg Film-Coated Tablets.

Do not take Anastrozole 1 mg Film-Coated Tablets if you are already taking any of the following medicines:
- Certain medicines used to treat breast cancer (selective estrogen receptor modulators), e.g., medicines that contain tamoxifen. This is because these medicines may stop Anastrozole 1 mg Film-Coated Tablets from working properly.
- Medicines that contain estrogen, such as hormone replacement therapy (HRT).

If this applies to you, ask your doctor or pharmacist for advice.

Tell your doctor or pharmacist if you are taking the following:
- A medicine known as an 'LHRH analogue'. This includes gonadorelin, buserelin, goserelin, leuprorelin and triptorelin. These medicines are used to treat breast cancer, certain female health (gynaecological) conditions, and infertility.

Pregnancy and breast-feeding

Do not take Anastrozole 1 mg Film-Coated Tablets if you are pregnant or breast -feeding. Stop [Nationally approved
name] if you become pregnant and talk to your doctor.
Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Anastrozole 1 mg Film-Coated Tablets is not likely to affect your ability to drive or use any tools or machines. However, some people may occasionally feel weak or sleepy while taking Anastrozole 1 mg Film-Coated Tablets. If this happens to you, ask your doctor or pharmacist for advice.

Anastrozole 1 mg Film-Coated Tablets contains lactose which is a type of sugar

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Anastrozole 1 mg Film-Coated Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- 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 a drink of water.
- It does not matter if you take Anastrozole 1 mg Film-Coated Tablets before, with or after food.

Keep taking Anastrozole 1 mg Film-Coated Tablets 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.

Use in children

Anastrozole 1 mg Film-Coated Tablets should not be given to children and adolescents.

If you take more Anastrozole 1 mg Film-Coated Tablets than you should

If you take more Anastrozole 1 mg Film-Coated Tablets than you should, talk to a doctor straight away.

If you forget to take Anastrozole 1 mg Film-Coated Tablets

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

If you stop taking Anastrozole 1 mg Film-Coated Tablets
Do not stop taking your tablets unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)
- Headache.
- Hot flushes.
- Feeling sick (nausea).
- Skin rash.
- Pain or stiffness in your joints.
- Inflammation of the joints (arthritis).
- Feeling weak.
- Bone loss (osteoporosis).

Common side effects (may affect up to 1 in 10 people)
- Loss of appetite.
- Raised or high levels of a fatty substance known as cholesterol in your blood. This would be seen in a blood test.
- Feeling sleepy.
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand).
- Diarrhoea.
- Being sick (vomiting).
- Changes in blood tests that show how well your liver is working.
- Thinning of your hair (hair loss).
- Allergic (hypersensitivity) reactions including face, lips, or tongue.
- 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 (may affect up to 1 in 100 people)
- Changes in special blood tests that show how your liver is working (gamma-GT and bilirubin).
- Inflammation of the liver (hepatitis).
- Hives or nettle rash.
- Trigger finger (a condition in which your finger or thumb catches in a bent position).
- Increased amounts of calcium in your blood. If you experience nausea, vomiting and thirst, you should tell your doctor, or pharmacist or nurse as you may need to have blood tests.

Rare side effects (may affect up to 1 in 1,000 people)
- Rare inflammation of your skin that may include red patches or blisters.
- Skin rash caused by hypersensitivity (this can be from allergic or anaphylactoid reaction).
- Inflammation of the small blood vessels causing red or purple colouring of the skin. Very rarely symptoms of joint, stomach, and kidney pain may occur; this is known as ‘Henoch-Schönlein purpura’.

Very rare side effects (may affect up to 1 in 10,000 people)
- An extremely severe skin reaction with ulcers or blisters on the skin. This is known as ‘Stevens-Johnson

syndrome'.

- Allergic (hypersensitivity) reactions with swelling of the throat that may cause difficulty in swallowing or breathing. This is known as 'angioedema'.

If any of these happen to you, call an ambulance or see a doctor straight away - you may need urgent medical treatment.

Effects on your bones
Anastrozole 1 mg Film-Coated Tablets lowers the amount of the hormone called estrogen that is in your body. This may lower the mineral content of your bones. Your bones may be less strong and may be more likely to fracture. Your doctor will manage these 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.

Reporting of side effects
If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via thenational reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anastrozole 1 mg Film-Coated Tablets

[PVC/aluminiumblister]
This medicinal product does not require any special storage conditions.

*[HDPEcontainer]*Do not store above 30°C.

Keep this medicine out of the sight and reach of children. Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them.

Do not use this medicine after the expiry date which is stated on the carton]. The expiry date refers to the last day of that month.

Keep your tablets in the container they came in.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information
What Anastrozole 1 mg Film-Coated Tabletscontains

The **active substance** is **anastrozole**.

One film-coated tablet contains 1 mg anastrozole.

The other ingredients are:

Tablet core**:** lactose monohydrate, cellulose microcrystalline, sodium starch glycollate type A, magnesium stearate, silica colloidal anhydrous, hydroxypropylcellulose

Tablet coating:
Opadry II white: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide

What Anastrozole 1 mg Film-Coated Tabletslooks like and contents of the pack

White, round and biconvex film-coated tablets with embossment “A1” on one side.

[UK/H/1171/001]

Anastrozole 1 mg Film-Coated Tablets1 mg film-coated tablets are available in PVC/aluminium blister packs orHDPE containers containing 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 film-coated tablets.

[UK/H/1172/001]

Anastrozole 1 mg Film-Coated Tablets1 mg film-coated tablets are available in PVC/aluminium blister packs or HDPE containers containing 10, 20, 28, 30, 50, 56, 84, 98, 100 film-coated tablets.

[UK/H/1173/001]

Anastrozole 1 mg Film-Coated Tablets1 mg film-coated tablets are available in PVC/aluminium blister packs or HDPE containers containing 28, 30, 50, 56, 60, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder ***and Manufacturer***

MarketingAuthorisation

SANDOZ GmbH,KUNDL BIOCHEMIESTRASSE 106250, AUSTRIA.

Manufacturer

Salutas Pharma GmbH Otto-von-Guericke-Allee 139179 Barleben Germany

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