



## Package leaflet: Information for the user

### Anastrozole 1mg film-coated tablets

**Read all of this leaflet carefully before you start using 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 signs of 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 is and what it is used for
2. What you need to know before you take Anastrozole
3. How to take Anastrozole
4. Possible side effects
5. How to store Anastrozole
6. Contents of the pack and other information

#### 1. What Anastrozole is and what it is used for

Anastrozole belongs to a group of medicines called aromatase inhibitors. Anastrozole works by interfering with the action of an enzyme called aromatase, which affects the level of certain female sex hormones such as oestrogens. Anastrozole is used in the treatment of advanced breast cancer in post-menopausal women.

#### 2. What you need to know before you take Anastrozole

##### Do not take Anastrozole:

- 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 called 'Pregnancy and breast-feeding').

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Anastrozole

- if you still have menstrual periods and have not yet gone through the menopause
- if you have ever had a condition that affects the strength of your bones (osteoporosis)
- if you are taking a medicine that contains tamoxifen or medicines that contain estrogen (see the section called 'Other medicines and Anastrozole')
- if you have problems with your liver or kidneys.

##### Other medicines and Anastrozole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Anastrozole can affect the way some medicines work and some medicines can have an effect on Anastrozole.

Do not take Anastrozole 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 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 and '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 if you are pregnant or breast-feeding. Stop Anastrozole if you become pregnant and talk to your doctor.

Ask your doctor or pharmacist for advice before taking any medicines.

##### Driving and using machines

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

##### Anastrozole contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as Anastrozole contains lactose.

#### 3. How to take Anastrozole

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

Remember to take your medicine.

Your doctor will tell you how long to take the tablets for. Only stop taking your tablets if your doctor tells you.

##### The recommended dose is:

- In adults (including the elderly), the recommended dose is one tablet (1mg of anastrozole) taken daily
- In patients with mild or moderate kidney disorder or mild liver disorder, the recommended dose is also one table (1mg of anastrozole) taken daily.

Swallow the tablet whole with a drink of water.

Try to take your tablet at the same time each day.

Keep taking Anastrozole for as long as your doctor or pharmacist 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.

##### Use in children and adolescents

Anastrozole should not be given to children and adolescents.

##### If you take more Anastrozole than you should

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

##### If you forget to take Anastrozole

You should take Anastrozole as prescribed. If you forget to take a dose, just take your next dose as normal. Do not take a double dose to make-up for a forgotten dose.

##### If you stop taking Anastrozole

Do not stop treatment with Anastrozole before consulting your doctor because treatment with Anastrozole is a long-term treatment. Contact your doctor if you have any problems with the use of Anastrozole.

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

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#### 4. Possible side effects

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

If you experience the following, stop taking Anastrozole and tell your doctor immediately or go to the casualty department of the nearest hospital:

- a severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).
- extremely 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.

These are serious but very rare side effects. If any of these happen to you, call an ambulance or see a doctor straight away - you may need urgent medical attention or hospitalisation.

##### Other side-effects:

Tell your doctor or pharmacist if you notice these effects or experience any other problem with your treatment:

##### Very common: may affect more than 1 in 10 people

- hot flushes
- headache
- feeling sick (nausea)
- skin rash
- pain or stiffness in your joints
- inflammation of the joints (arthritis)
- feeling weak
- bone loss (osteoporosis)
- depression.

##### Common: may affect up to 1 in 10 people

- loss of appetite
- raised or high levels of 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)
- tickling, tingling or numbness of skin, loss/lack of taste
- 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: 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: may affect 1 to 10 people in 10,000

- 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'.

##### Effects on your bones

Anastrozole lowers the amount of the hormone called estrogen that is in your body. This may lead to a loss of the mineral content of bones, which might decrease their strength and in some cases might result in fractures. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the yellow card scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Anastrozole

Keep out of the sight and reach of children.

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

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

#### 6. Contents of the pack and other information

##### What Anastrozole contains

- The active substance is anastrozole.
- The other ingredients are lactose monohydrate, sodiumcarboxymethylstarch, povidone, magnesium stearate, hydroxypropylmethylcellulose, macrogol, cotton seed oil, modified starch and titanium dioxide (E171).

##### What Anastrozole looks like and contents of the pack

Anastrozole comes in white, round biconvex film-coated tablets. Each pack contains 14, 28 and 30 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:** Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

**Manufacturer:** CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

##### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Anastrozole 1mg film-coated tablets	PL 29831/0461

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in 03/2021.**

**WOCKHARDT**

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