

**PACKAGE LEAFLET:**  
**INFORMATION FOR THE USER**  
**Anastrozole 1 mg film-coated tablets**  
anastrozole

**The name of the medicine is Anastrozole 1 mg film-coated tablets, called Anastrozole in the rest of the leaflet.**

**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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 tablets contain a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. Anastrozole is used to treat breast cancer in women who have gone through the menopause.

Anastrozole works by cutting down the amount of the hormone called oestrogen 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 you take Anastrozole**

**Do not take Anastrozole:**

- if you are allergic to Anastrozole or any other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast-feeding (see the section called 'Pregnancy and breast-feeding').

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

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Anastrozole:

- 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 oestrogen (see the section called "Other medicines and Anastrozole").
- 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.

If you go into the hospital, let the medical staff know you are taking Anastrozole.

**Other medicines and Anastrozole**

Tell your doctor or pharmacist if you are taking or have recently taken 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 oestrogen receptor modulators), e.g. medicines that contain tamoxifen. This is because these medicines may stop Anastrozole from working properly.

- Medicines that contain oestrogen, 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 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 medicine.

**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 tablets contain lactose**

Anastrozole 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, contact your doctor before taking this medicine.

**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.

- 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 before, with or after food.

Keep taking Anastrozole 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.

**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 Anastrozole than you should, talk to a doctor straight away.

**If you forget to take Anastrozole**

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**

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: may affect more than 1 in 10 people**

- Hot flushes.
- Feeling weak.
- Pain or stiffness in your joints.
- Skin rash.
- Feeling sick (nausea).
- Headache.
- Inflammation of the joints (arthritis).
- Bone loss (osteoporosis).

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

- Vaginal dryness.
- Bleeding from the vagina (usually in the first few weeks of treatment – if the bleeding continues, talk to your doctor).
- Thinning of your hair (hair loss).
- Diarrhoea.

- 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.
- Being sick (vomiting).
- Feeling sleepy.
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand).
- Changes in blood tests that show how well your liver is working.
- Tickling, tingling or numbness of skin, loss/lack of taste.
- Allergic (hypersensitivity) reactions including face, lips, or tongue.
- Bone pain.
- Muscle pain.

**Uncommon: may affect up to 1 in 100 people**

- Trigger finger (a condition in which your finger or thumb catches in a bent position).
- 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.
- 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 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: 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 lowers the amount of the hormone called oestrogen 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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.

**For UK** - You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**For Ireland** - You can report directly via; HPRAPharmacovigilance Earlsfort Terrace, IRL- Dublin 2  
Tel: +353 1 6764971, Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie) By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Anastrozole**

Keep this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

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. Each film-coated tablet contains 1 mg Anastrozole.
- The other ingredients are: lactose monohydrate, sodium starch glycolate (Type A), povidone K-30 (E1201), magnesium stearate (E572), hypromellose 5 cP (E464), macrogol 400 and titanium dioxide (E171).

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

Anastrozole tablets are white to off white, circular, film coated biconvex tablets of diameter around 6.1 mm, debossed with 'DB02' on one side and plain on other side. The tablets are provided in PVC/Aluminium blister of 10 and 14 tablets; in packs of 14, 28, 30, 90, 98 and 100 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

**Marketing Authorisation Holder**

**For UK :**

Fresenius Kabi Oncology Plc.  
Lion Court, Farnham Road  
Bordon, Hampshire, GU35 0NF  
United Kingdom

**For IRL :**

Fresenius Kabi Deutschland GmbH  
Else-Kröner-Straße 1,  
61352 Bad Homburg v.d.Höhe  
Germany

**Manufacturer:**

Fresenius Kabi Oncology Plc.  
Lion Court, Farnham Road  
Bordon, Hampshire, GU35 0NF  
United Kingdom

Fresenius Kabi Deutschland GmbH  
Pfungstweide 53  
61169 Friedberg  
Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria	Anastrozol Kabi 1 mg Filmtabletten
Belgium	Anastrozole Fresenius Kabi 1 mg, filmomhulde tabletten
Bulgaria	Анастрозол Каби 1 mg филмирани таблетки
Cyprus	Anastrozole Kabi, 1 mg/tab, Επικαλυμμένο με λεπτό υμένιο δισκίο
Greece	Anastrozole Kabi, 1 mg/tab, Επικαλυμμένο με λεπτό υμένιο δισκίο
Hungary	Anastrozol Kabi 1 mg filmtabletta
Ireland	Anastrozole 1 mg film-coated tablets
The Netherlands	Anastrozol Fresenius Kabi 1 mg filmomhulde tabletten
Portugal	Anastrozol Kabi
Romania	Anastrozol Kabi 1 mg comprimate filmate
Slovenia	Anastrozol Kabi 1 mg filmsko obložene tablete.
United Kingdom	Anastrozole 1 mg film-coated tablets

**This leaflet was last revised in February 2019.**