Package leaflet: Information for the user

Amidex 1 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 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.

In this leaflet

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1. What Amidex is and what it is used for
Amidex contains a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. Amidex is used to treat breast cancer in women who have gone through the menopause.

Amidex 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 Amidex
DO NOT take Amidex
- 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')

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Amidex
- 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 Amidex')
- 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 Amidex .
If you go into the hospital, let the medical staff know you are taking Amidex.

Other medicines and Amidex
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 Amidex can affect the way some medicines work and some medicines can have an effect on Amidex.

Do not take Amidex 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 Amidex 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

Driving and using machines
Amidex 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 Amidex. If this happens to you, ask your doctor or pharmacist for advice.

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Amidex
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 Amidex before, with or after food

Keep taking Amidex 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
Amidex should not be given to children and adolescents.

If you take more Amidex than you should
If you take more Amidex than you should, talk to a doctor straight away.

If you forget to take Amidex
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 Amidex
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)
- headache
- hot flushes
- 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 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)
- 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 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 'angio-oedema'

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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amidex
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 outer carton and the blister packaging (strips of tablets) after 'EXP'. The expiry date refers to the last day of that month.

Keep your tablets in the container they came in.

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 Amidex 1 mg film-coated tablets contain
- The active substance is: anastrozole.
- One film-coated tablet contains 1 mg anastrozole.

- The other ingredients are:
  Tablet core:
  Lactose monohydrate
  Sodium starch glycolate (type A)
  Povidone K25
  Magnesium stearate

  Film coating:
  Hypromellose
  Macrogol 6000
  Cottonseed oil, hydrogenated
  Starch, pregelatinised modified (origin: maize)
  Titanium dioxide

What Amidex 1 mg film-coated tablets look like and contents of the pack
Amidex 1 mg are white, round, film-coated tablets imprinted with an 'A1' on one side.

Amidex 1 mg film-coated tablets are available in packs containing 28, 30, 50, 90, 98, 100 film coated tablets or 28x1, 30x1, 50x1, 90x1, 98x1, 100x1 film-coated tablets perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing authorisation holder
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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Anastelb
Finland:	Anastelb 1 mg kalvopäällysteiset tabletit
France:	Anastrozole EG 1 mg, comprimé pelliculé
Hungary:	Anastrozol STADA 1 mg filmtabletta
Ireland:	Amidex 1 mg film-coated tablets
Romania:	Anastelb 1 mg, comprimate filmate
Sweden:	Anastelb 1 mg filmdragerade tabletter

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