

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, 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 Website: [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 Tablets

- 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.
- This medicinal product does not require any special storage conditions
- Always return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to.
- Do not use this medicine after the expiry date which is stated on the label 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 Tablets contains

- The active substance is anastrozole. Each film-coated tablet contains 1 mg of anastrozole.
- The other ingredients are lactose monohydrate, povidone k-30, sodium starch glycolate, magnesium stearate, Hypromellose 5cp, Macrogol 300, titanium dioxide (E171).

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

- White to off-white, round biconvex, film-coated tablets debossed with "B" on one side and "1" on other side.
- This medicine is available in packs of 20, 28, 30, 84, 98, 100 and 300 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

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**Anastrozole 1 mg film-coated tablets; PL 17907/0495**

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Pharmacode

#### Package leaflet: Information for the patient

### Anastrozole 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, 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 Tablets are and what they are used for
2. What you need to know before you take Anastrozole Tablets
3. How to take Anastrozole Tablets
4. Possible side effects
5. How to store Anastrozole Tablets
6. Contents of the pack and other information

#### 1. What Anastrozole Tablets are and what they are used for

Anastrozole Tablets contains a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. It is used to treat breast cancer in women who have gone through the menopause and as a preventative treatment in postmenopausal women at moderate or high risk of breast cancer.

Anastrozole 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 you take Anastrozole Tablets

##### Do not take Anastrozole 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 called 'Pregnancy and breast-feeding').

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

##### Warnings and precautions

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

- 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 'Taking other medicines').
- if you have, or have ever had a condition that affects the strength of your bones (osteoporosis or osteopenia).

Anastrozole lowers the levels of female hormones and this may lead to a loss of the mineral content of bones, which might decrease their strength. You may have to have bone density tests during treatment. Your doctor can give you medicine to prevent or treat the bone loss. Women with severe osteoporosis are not suitable for anastrozole treatment.

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

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

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10mm

10mm

10mm

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

#### Children and adolescents

Do not give this medicine to children because it is unlikely to be safe.

#### Other medicines and Anastrozole Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Anastrozole Tablets.

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.

#### Anastrozole Tablets with food, drink and alcohol

There is no effect on absorption of Anastrozole Tablets when taken with a meal.

#### Pregnancy, breast-feeding and fertility

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 this medicine if you are pregnant or breast-feeding. Stop taking it, if you become pregnant and talk to your doctor.

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

#### Driving and using machines

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

#### Anastrozole Tablets 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.

#### Information on sodium content

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

### 3. How to take Anastrozole Tablets

Always take this medicine exactly as your doctor or pharmacist 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 this medicine before, with or after food.

Keep taking Anastrozole Tablets 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 Tablets should not be given to children and adolescents.

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

If you take more Anastrozole Tablets than you should, talk to a doctor straight away. If you have taken more Anastrozole Tablets than you were told to, or if someone else has taken any Anastrozole Tablets, contact the accident and emergency department of your nearest hospital. Take any leftover tablets or empty box with you for easier identification.

#### If you forget to take Anastrozole 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 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, pharmacist or nurse.

### 4. Possible side effects

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

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

Stop taking Anastrozole Tablets and seek urgent medical treatment, if you experience any of the following serious side effects:

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

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

#### Rare (may affect up to 1 in 1,000 people):

- Rare inflammation of your skin that may include red patches or blisters (erythema multiforme).

#### 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'.

#### Other side effects:

#### 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 to 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).
- 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)

- 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'.

#### 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

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