

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

MYLAN ANASTROZOLE 1 mg film-coated tablets

Anastrozole

Contains sugar: lactose monohydrate 93 mg

Read all of this leaflet carefully before you start taking MYLAN ANASTROZOLE 1 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

MYLAN ANASTROZOLE 1 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MYLAN ANASTROZOLE 1 mg is and what it is used for.
2. What you need to know before you take MYLAN ANASTROZOLE 1 mg.
3. How to take MYLAN ANASTROZOLE 1 mg.
4. Possible side effects.
5. How to store MYLAN ANASTROZOLE 1 mg.
6. Contents of the pack and other information.

1. What MYLAN ANASTROZOLE 1 mg is and what it is used for

MYLAN ANASTROZOLE 1 mg belongs to a group of medicines called aromatase inhibitors. This means that it interferes with some of the actions of aromatase, an enzyme within the body which effects the level of certain female sex hormones such as oestrogens.

MYLAN ANASTROZOLE 1 mg is used to treat early breast cancer and advanced breast cancer in post-menopausal women.

2. What you need to know before you take MYLAN ANASTROZOLE 1 mg

Do not take MYLAN ANASTROZOLE 1 mg:

- if you are hypersensitive (allergic) to anastrozole or any of the other ingredients of MYLAN ANASTROZOLE 1 mg tablets (listed in section 6),
- if you are a pre-menopausal woman,
- if you are pregnant or breastfeeding,
- if you have severe kidney problems,
- if you have moderate or severe liver disease.

Warnings and precautions

Take special care with MYLAN ANASTROZOLE 1 mg:

Check with your doctor or pharmacist before taking MYLAN ANASTROZOLE 1 mg:

- if you ever had a condition that affects the strength of your bones (such as osteoporosis).

Taking MYLAN ANASTROZOLE 1 mg may cause a reduction in bone mineral density and increase your risk of fractures,

- if you have problems with your liver or kidneys,

MYLAN ANASTROZOLE 1 mg is not recommended for use in children.

Other medicines and MYLAN ANASTROZOLE 1 mg

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Tamoxifen. This is because tamoxifen may stop MYLAN ANASTROZOLE 1 mg 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.

MYLAN ANASTROZOLE 1 mg with food and drink

MYLAN ANASTROZOLE 1 mg can be taken with or without food.

Pregnancy and breastfeeding

MYLAN ANASTROZOLE 1 mg should not be taken if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking MYLAN ANASTROZOLE 1 mg.

Driving and using machines

It is not always possible to predict to what extent MYLAN ANASTROZOLE 1 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above

activities until they are aware of the measure to which MYLAN ANASTROZOLE 1 mg affects them.

Do not drive or operate any tools or machines if MYLAN ANASTROZOLE 1 mg makes you feel weak or sleepy.

MYLAN ANASTROZOLE 1 mg contains lactose monohydrate

MYLAN ANASTROZOLE 1 mg contains lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking MYLAN ANASTROZOLE 1 mg.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take MYLAN ANASTROZOLE 1 mg.

3. How to take MYLAN ANASTROZOLE 1 mg

Do not share medicines prescribed for you with any other person.

Always take MYLAN ANASTROZOLE 1 mg exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

MYLAN ANASTROZOLE 1 mg should not be given to children.

If you have the impression that the effect of MYLAN ANASTROZOLE 1 mg is too strong or too weak, talk to your doctor or pharmacist.

Adults including the elderly:

- The usual dose is one tablet taken once a day.
- Try to take the tablet at the same time each day.
- Swallow the tablet whole with a drink of water.
- It does not matter if you take MYLAN ANASTROZOLE 1 mg before, with or after food.

Keep taking MYLAN ANASTROZOLE 1 mg for as long as your doctor tells you to. It is a long-term treatment and you may need to take it for some time. This will be decided by your doctor.

If you take more MYLAN ANASTROZOLE 1 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison center.

If you forget to take MYLAN ANASTROZOLE 1 mg

- 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 MYLAN ANASTROZOLE 1 mg

Do not stop taking your tablets unless your doctor tells you to or unless you experience serious allergic reactions (see Possible side effects).

4. Possible side effects

MYLAN ANASTROZOLE 1 mg can have side effects.

Not all side effects reported for MYLAN ANASTROZOLE 1 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYLAN ANASTROZOLE 1 mg, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happen, stop taking MYLAN ANASTROZOLE 1 mg and tell your doctor

immediately or go to the casualty department at your nearest hospital – you may need urgent medical treatment:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing.
- an extremely severe skin reaction with ulcers or blisters on the skin. This is known as Stevens-Johnson syndrome.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYLAN ANASTROZOLE 1 mg. You may need urgent medical attention or hospitalisation.

Frequent side-effects:

- anorexia (decreased appetite and serious weight loss)
- raised or high levels of a fatty substance known as cholesterol in your blood (this would be seen in a blood test)
- increased appetite
- depression
- headache
- dizziness
- drowsiness
- tingling, pain, coldness, weakness in parts of the hand (carpal tunnel syndrome)
- excessive drowsiness or sleepiness (somnolence)
- unpleasant tingling feeling in arms or legs, loss or lack of taste
- hot flushes
- redness of the neck and face (flushing)
- swelling of feet and lower legs (peripheral oedema)
- chest pain

- shortness of breath
- cough
- inflammation with pain in the throat (pharyngitis)
- nausea
- vomiting
- diarrhoea
- constipation
- abdominal pain
- dry mouth
- changes in blood tests that show how well your liver is working
- hair thinning (alopecia)
- suddenly appearing redness of the skin (rash)
- sweating
- allergic reactions including pruritus
- joint pain/stiffness
- pain in a muscle or muscles (myalgia)
- back and bone pain
- inflammation of the joints (arthritis)
- bone loss (osteoporosis)
- vaginal dryness
- vaginal bleeding
- lack or loss of strength or energy (asthenia)
- pain
- pain in the lower part of the body (pelvic pain)

Less frequent side-effects:

- unusual tiredness or weakness (anaemia)
- a reduction in the number of white cells in the blood which may cause fever or chills, cough or hoarseness, sore throat (leukopenia with or without infection)
- sudden shortness of breath (thromboembolism)
- pain in leg or tenderness in leg or foot, swelling of leg or foot (thrombophlebitis)
- increased amounts of calcium in your blood (hypercalcaemia) with or without the increase of parathyroid hormone in the blood. If you experience nausea, vomiting and thirst, you should tell your doctor. These symptoms may indicate possible increased blood calcium levels. Your doctor may have to do certain blood tests to determine if there is increased calcium in your blood occurring with or without an increase of parathyroid hormone, a hormone that regulates calcium.
- weight gain
- sleeplessness (insomnia)
- nervousness
- anxiety
- confusion
- dizziness, severe and continuing headache (high blood pressure)
- inflammation of one or more bronchi due to exposure to cold, to the breathing of irritant substances, and to acute infection (*bronchitis*)
- inflammation of a sinus (*sinusitis*)
- inflammation inside the nose with a runny nose (*rhinitis*)
- changes in special blood tests that show how your liver is working (gamma-GT and bilirubin)

- inflammation of the liver (hepatitis)
- skin rash with irregular red patches (*erythema multiforme*)
- an extremely severe skin reaction with ulcers or blisters on the skin (*stevens-johnson syndrome*)
- sudden swelling of the skin or mucous membranes (e.g. throat or tongue) with difficulty breathing and/or itching and rash; smooth, slightly elevated area on the skin, which is redder and paler than the surrounding skin and immediate hypersensitivity reaction (called anaphylaxis) resulting in life-threatening breathing difficulty, usually followed by collapse of the arteries and veins and shock
- 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'
- trigger finger (a condition in which one of your fingers or your thumb catches in a bent position)
- breast pain
- bone fractures
- flu feeling

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MYLAN ANASTROZOLE 1 mg.

5. How to store MYLAN ANASTROZOLE 1 mg

Store all medicines out of reach of children.

Store at or below 25°C. The blisters must be kept in the carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLAN ANASTROZOLE 1 mg contains

The active substance is anastrozole 1 mg per tablet.

The other ingredients are lactose monohydrate, sodium starch glycolate, povidone, magnesium stearate, hypromellose, macrogol 300, titanium dioxide.

What MYLAN ANASTROZOLE 1 mg looks like and contents of the pack

White film-coated round biconvex tablets, debossed with “ANA” and “1” on one side.

MYLAN ANASTROZOLE 1 mg tablets are packed in PVC/PE/PVDC/Aluminium blister strips of 10 tablets packed into a carton box of 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 300 or 500 tablets per box.

Holder of Certificate of Registration

Viatrix South Africa (Pty) Ltd

4, Brewery Street,

Viatrix South Africa (Pty) Ltd
MYLAN ANASTROZOLE 1 mg
Film-coated tablet; 1 mg Anastrozole

Johannesburg,

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