

PACKAGE LEAFLET: INFORMATION FOR THE USER

Anastrazol Vegal 1 mg film-coated tablets Anastrozole

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Anastrazol Vegal is and what it is used for
2. Before you take Anastrazol Vegal
3. How to take Anastrazol Vegal
4. Possible side effects
5. How to store Anastrazol Vegal
6. Further information

1. WHAT ANASTRAZ IS AND WHAT IT IS USED FOR

Anastrazol Vegal contains a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. Anastrazol Vegal is used to treat breast cancer in women who have gone through the menopause.

Anastrazol Vegal 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. BEFORE YOU TAKE ANASTRAZOL VEGAL

Do not take Anastrazol Vegal

- if you are allergic (hypersensitive) to anastrozole or any of the other ingredients of Anastrazol Vegal (see section 6: Further information).
- if you are pregnant or breast-feeding (see the section called 'Pregnancy and breast-feeding').

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

Take special care with Anastrazol Vegal

Before treatment with Anastrazol Vegal check with your doctor or pharmacist

- 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 estrogen (see the section called 'Taking other medicines').
- 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 Anastrazol Vegal.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes medicines that you buy without a prescription and herbal medicines. This is because Anastrozol Vegal can affect the way some medicines work and some medicines can have an effect on Anastrozol Vegal.

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

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

Driving and using machines

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

Important information about some of the ingredients of Anastrozol Vegal

Anastrozol Vegal contains 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 ANASTRAZOL VEGAL

Always take Anastrozol Vegal exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The usual 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 Anastrozol Vegal before, with or after food.

Keep taking Anastrozol Vegal 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

Anastrozol Vegal should not be given to children and adolescents.

If you take more Anastrozol Vegal than you should

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

If you forget to take Anastrozol Vegal

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 Anastrozol Vegal

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, Anastrozol Vegal can cause side effects, although not everybody gets them.

Very common side effects (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).

Common side effects (affect 1 to 10 people in 100)

- 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).
- 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 side effects (affect 1 to 10 people in 1,000)

- 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 side effects (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'.

Very rare side effects (affect less than 1 person 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

Anastrozol Vegal lowers the amount of the hormone called estrogen 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.

5. HOW TO STORE ANASTRAZOL VEGAL

Do not store above 30°C.

Keep this medicine out of the reach and sight of children. Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them.

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

Keep your tablets in the container they came in.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Anastrozol Vegal contains**

- The active substance is anastrozole. Each film-coated tablet contains 1 mg of anastrozole.
- The other ingredients are: lactose monohydrate, povidone, sodium starch glycollate, magnesium stearate, hypromellose, macrogol 6000, titanium dioxide and talc.

What Anastrozol Vegal looks like and contents of the pack

White to off-white, round, biconvex tablet.

The tablets are provided in blister packs of 28 tablets.

Marketing Authorisation Holder

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This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]