

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Anastrozole Niche 1mg 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 Anastrozole Niche is and what it is used for
2. Before you take Anastrozole Niche
3. How to take Anastrozole Niche
4. Possible side effects
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### **1. WHAT ANASTROZOLE NICHE IS AND WHAT IT IS USED FOR**

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

Anastrozole Niche 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 ANASTROZOLE NICHE**

#### **Do not take Anastrozole Niche**

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

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

#### **Take special care with Anastrozole Niche**

Before treatment with Anastrozole Niche 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 '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 Anastrozole Niche.

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

### **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 Anastrozole Niche can affect the way some medicines work and some medicines can have an effect on Anastrozole Niche.

Do not take Anastrozole Niche 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 Anastrozole Niche 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 Anastrozole Niche if you are pregnant or breast feeding. Stop Anastrozole Niche 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 Niche 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 Niche. If this happens to you, ask your doctor or pharmacist for advice.

### **Important information about some of the ingredients of Anastrozole Niche**

Anastrozole Niche 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 ANASTROZOLE NICHE**

Always take Anastrozole Niche 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 Anastrozole Niche before, with or after food.

Keep taking Anastrozole Niche 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**

Anastrozole Niche should not be given to children and adolescents.

### **If you take more Anastrozole Niche than you should**

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

### **If you forget to take Anastrozole Niche**

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 Niche**

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, Anastrozole Niche 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).

### **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).

### **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**

Anastrozole Niche 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 ANASTROZOLE NICHE**

Keep 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.

This medicinal product does not require any special storage conditions.

Do not use Anastrozole Niche after the expiry date which is stated on the outer packaging / blister after 'EXP'. The expiry date refers to the last day of that month.

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 Anastrozole Niche contains**

- The active substance is anastrozole. Each film-coated tablet contains 1 mg anastrozole.
- The other ingredient(s) are:
- Tablet core: lactose monohydrate, sodium starch glycolate (type A), magnesium stearate
- Film-coating: Opadry II white 85F18422 consisting of poly (vinyl alcohol) – partially hydrolysed, titanium dioxide, macrogol 3350, talc.

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

- Anastrozole Niche tablets are white, round, film-coated tablets, with the number '1' on one side and plain on the reverse.

Pack Size:

Anastrozole Niche 1mg film-coated tablets are available in pack sizes of 28 tablets contained in a carton.

### **Marketing Authorisation Holder**

Niche Generics Limited,  
1 The Cam Centre,  
Wilbury Way,  
Hitchin,  
Hertfordshire,  
SG4 0TW,  
United Kingdom.

## **Manufacturers**

EirGen Pharma Limited,  
64-65 Westside Business Park,  
Old Kilmeaden Road,  
Waterford,  
Ireland.

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

Ireland	Anastrozole Niche 1mg film-coated tablets.
Italy	Anastrozolo Professionalcare 1mg 28 compresse rivestite con film.

This leaflet was last revised: MM/YYYY