

## **Package leaflet: Information for the user**

### **Anastrozole Bluefish 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 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 or 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 Bluefish is and what it is used for
2. What you need to know before you take Anastrozole Bluefish
3. How to take Anastrozole Bluefish
4. Possible side effects
5. How to store Anastrozole Bluefish
6. Contents of the pack and other information

#### **1. What Anastrozole Bluefish is and what it is used for**

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

Anastrozole Bluefish 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'.

You must talk to a doctor if you do not feel better or if you feel worse.

#### **2. What you need to know before you take Anastrozole Bluefish**

##### **Do not take Anastrozole Bluefish**

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

##### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse before taking Anastrozole Bluefish

- 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 'Other medicines and Anastrozole Bluefish').
- 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 Bluefish.

If you go to the hospital, let the medical staff know you are taking Anastrozole Bluefish.

### **Other medicines and Anastrozole Bluefish**

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 Anastrozole Bluefish can affect the way some medicines work and some medicines can have an effect on Anastrozole Bluefish.

Do not take Anastrozole Bluefish 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 Bluefish 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 Bluefish if you are pregnant or breast-feeding.

Stop taking Anastrozole Bluefish 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 Bluefish 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 Bluefish. If this happens to you, ask your doctor or pharmacist for advice.

### **Anastrozole Bluefish contains lactose**

Anastrozole Bluefish 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 medicinal product.

### **Anastrozole Bluefish contains sodium**

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

## **3. How to take Anastrozole Bluefish**

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 Anastrozole Bluefish before, with or after food.

Keep taking Anastrozole Bluefish 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. Check with your doctor or pharmacist if you are not sure.

### **Use in children and adolescents**

Anastrozole Bluefish should not be given to children and adolescents.

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

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

**If you forget to take Anastrozole Bluefish**

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 Bluefish**

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 or nurse.

**4. Possible side effects**

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

Tell your doctor immediately:

If you experience any of the following very rare symptoms after taking this medicine, these symptoms can be serious:

- Swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath (angioedema).
- Serious allergic reactions with blistering of the skin, mouth, eyes and genitals (Stevens-Johnsons syndrome).

**Very common side effects (may affect more than 1 in 10 people)**

- Depression.
- 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 (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 side effects (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, pharmacist or nurse as you may need to have blood tests.

#### **Rare side effects (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’.

#### **Effects on your bones**

Anastrozole Bluefish 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.

#### **Reporting of side effects**

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

### **5. How to store Anastrozole Bluefish**

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 carton and blister strip after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Bluefish contains**

The active substance is Anastrozole. Each film-coated tablet contains 1 mg Anastrozole. The other ingredients are Lactose monohydrate 93 mg, Povidone (K30), Sodium starch glycolate, Magnesium stearate. The tablets are coated with Hypromellose, Macrogol 300, Titanium dioxide (E171).

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

Anastrozole Bluefish are white and round film-coated tablets of diameter 6.0 - 6.2 mm. The tablets are packed in blister packs containing 28, 30, 98 & 100 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and manufacturer**

#### **Marketing Authorisation Holder**

Bluefish Pharmaceuticals AB  
P.O. Box 49013  
100 28 Stockholm  
Sweden

**Manufacturer**

Bluefish Pharmaceuticals AB, Gävlegatan 22, 113 30 Stockholm, Sweden.

Geneparm S.A., 18th km Marathonos Avenue, 153 51 Pallini Attikis, Greece

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

AT Anastrozol Bluefish 1 mg Filmtabletten  
ES Anastrozole Bluefish 1 mg comprimidos recubiertos con película  
EFG  
FR Anastrozole Bluefish 1 mg comprimés peliculés  
IE Anastrozole Bluefish 1 mg film-coated tablets  
IT Adiunastrol 1 mg compresse rivestite con film  
PL Anastrozole Bluefish, 1 mg, tabletki powlekane  
SE Anastrozole Bluefish 1 mg filmdragerade tabletter  
IS Anastrozole Bluefish 1 mg filmhúðaðar töflur

**This leaflet was last revised in**