

### 1.3.1 Package Leaflet

#### Package leaflet: Information for the user

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

### **1. What Anastrozol Synthon 1 mg is and what it is used for**

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

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 Anastrozol Synthon 1 mg

### Do not take Anastrozol Synthon 1 mg

- 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 **Anastrozol Synthon 1 mg** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **Anastrozol Synthon 1 mg**.

### Warnings and precautions

Talk to your doctor, or pharmacist or nurse before taking **Anastrozol Synthon 1 mg**.

- 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 **Anastrozol Synthon 1 mg**’).
- 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 **Anastrozol Synthon 1 mg**.

If you go into the hospital, let the medical staff know you are taking **Anastrozol Synthon 1 mg**.

### Other medicines and Anastrozol Synthon 1 mg

Tell your doctor or pharmacist if you are taking, or 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 can affect the way some medicines work and some medicines can have an effect on anastrozole.

Do not take **Anastrozol Synthon 1 mg** 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 Synthon 1 mg** 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 Synthon 1 mg** if you are **pregnant or breast-feeding**. Stop **Anastrozol Synthon 1 mg** if you become pregnant and talk to your doctor.

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

### **Driving and using machines**

Anastrozole 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.

### **Anastrozol Synthon 1 mg contains lactose**

Anastrozole 1 mg 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.

### **Anastrozol Synthon 1 mg contains sodium**

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

## **3. How to take Anastrozol Synthon 1 mg**

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 **Anastrozol Synthon 1 mg** before, with or after food.

Keep taking **Anastrozol Synthon 1 mg** 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**

**Anastrozol Synthon 1 mg** should not be given to children and adolescents.

### **If you take more Anastrozol Synthon 1 mg than you should**

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

**If you forget to take Anastrozol Synthon 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 Anastrozol Synthon 1 mg**

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.

**Stop taking Anastrozol Synthon 1 mg and seek urgent medical treatment if you experience any of the following serious but very rare side effects:**

- 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’.

**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)
- depression

**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)

- 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 (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**

Anastrozole 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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Anastrozol Synthon 1 mg

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.

Do not use this medicine after the expiry date which is stated on the packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. 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 Anastrozol Synthon 1 mg contains

- The active substance is anastrozole. Each film-coated tablet contains 1 mg of anastrozole.
- The other ingredients in the tablet core are lactose monohydrate, sodium starch glycolate (type A), povidone (E1201), and magnesium stearate (E572).  
The ingredients in the tablet coating are macrogol 400, hypromellose (E464), and titanium dioxide (E171).

### What Anastrozol Synthon 1 mg looks like and contents of the pack

White film-coated round biconvex tablet, with the inscriptions "ANA" and "1" on one side.

Anastrozole is available in blisters of 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 300 tablets and in hospital blisters of 28, 50, 84, 98, 300 or 500 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing Authorisation Holder:*

Synthon BV  
Microweg 22  
6545 CM Nijmegen  
Nederland

#### *Manufacturers:*

Synthon BV  
Microweg 22  
6545 CM Nijmegen  
Nederland

Synthon Hispania SL.  
C/Castelló,1,  
Poligono Las Salinas  
08330 Sant Boi de Llobregat  
Barcelona  
Spanje

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

Germany  
Anastrozol Sandoz 1 mg Filmtabletten

Estonia  
Anastrozole Sanoswiss 1 mg

Finland  
Anazol

France

Anastrozole GNR 1 mg, comprimé pelliculé

Greece  
Londer

Ireland  
Anastrozole Synthon 1 mg

Iceland  
Astrozol 1 mg

Latvia  
Anastrozole Sanoswiss 1 mg apvalkotās tabletes

Lithuania  
Anastrozole Sanoswiss 1 mg, plėvele dengtos tabletės

The Netherlands  
Anastrozol Synthon 1 mg, filmomhulde tabletten

Austria  
Anastrozol +pharma 1 mg Filmtabletten

Portugal  
Anastrozol Generis 1 mg comprimidos revestidos por película

**This leaflet was last approved in September 2023**