

Patient Leaflet according to Pharmacists' Regulations  
(Preparations) 5746 – 1986

This medicine is marketed only by a doctor's prescription

## **ANASTROZOLE INOVAMED 1MG** Coated Tablets

### **1) Name, form and ingredients of the medicine:**

**Name of medicine:** Anastrozole inovamed 1mg

**Form:** coated tablets

**Active substance in each tablet:**

each coated tablet contains 1mg Anastrozole.

**Each tablet also contains:** 93mg lactose. Each tablet contains less than 3mg sodium.

For a list of the inactive ingredients and allergens in this medicine – see section 6.  
**Please read the entire leaflet carefully prior to using this medicine.**

The leaflet contains brief information about the medicine. If you have any additional questions, please consult your doctor or pharmacist. This medicine has been prescribed in order to treat your disease. Do not pass it on to others. It may harm them, even if you think their disease is similar.

This medicine is not designated for children and adolescents.  
**Summary of vital information about the medicine:**

The medicine is designated for treatment of breast cancer among post-menopausal women.

The medicine is not designated for children and adolescents.

Accepted daily dosage for adults is one tablet.

The tablet should be swallowed intact with water, independent of mealtimes.

**What is this medicine for?**

The medicine is designated for treatment of breast cancer among post-menopausal women.

**Therapeutic group:** aromatase enzyme inhibitors.

### **2) Prior to using the medicine:**

**Do not use the medicine:**

- If you are allergic to the active substance or to any other of the medicine's ingredients. The active substance is listed in section 1, and the additional substances are listed in section 6.
- If you are pre-menopausal, pregnant or lactating
- If you suffer from certain dysfunctions or diseases that influence the liver and kidneys.
- If you are taking tamoxifen or medicines containing estrogens (female hormones) including alternative hormonal treatment, for fear of detracting from the influence of anastrozole.

**Do not use this medicine without consulting a doctor prior to beginning the treatment if:**

- You are pre-menopausal, pregnant or lactating.
- You are suffering or have suffered from a condition that influences bone strength (see section 4 – Side Effects)
- You are taking particular medicines specified below (inter-medine reactions)
- If you suffered from defects or diseases of the liver or kidneys

**If you have forgotten to take this medicine at the designated time,** do not take a double dose. Take your next dose at the usual time and consult your doctor. Do not take a double dose to compensate for the dosage you forgot. If you have accidentally taken a double dose, call your doctor or pharmacist immediately.

**Adhere to the treatment recommended by your physician.** Even if your health and feeling has improved, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take any medication blindly! Check the label and dose every time you take the medicine. Put on your glasses if you need them. If you have any additional questions concerning the use of this medicine, please consult your doctor or pharmacist.

### **4) Side effects:**

As is the case with any other medicine, using this medicine may lead to side effects in some users. Do not be alarmed when reading the list of side effects. It is possible that you will not experience any of them.

Extremely common side effects (influence more than 1 of 10 patients):

- Headaches
- Heat waves
- Nausea
- Skin rash
- Hardening or pain in joints
- Arthritis
- Weakness
- Loss of bone (osteoporosis)

Common side effects (influence 1-10 of 100 patients):

- Anorexia (lack of appetite)
- High cholesterol (increased or high levels of fatty substances in the blood called lipids)
- Dizziness
- Carpal tunnel disease (pain, pricking, chill or weakness in the hand)
- Sense of tickling, prickling or lack of sensation of the skin, decline/loss of sense of taste
- Diarrhea
- Vomiting
- Modifications in liver function blood tests may occur when using Anastrozole.

- Thinning hair
- Allergic reaction, swollen face, lips or tongue
- Aching bones
- Dryness of the vagina
- Vaginal bleeding (usually in first weeks of treatment. If bleeding continues, **apply to your physician**)
- Muscle aches

Uncommon side effects (influencing 1-10 of 1,000 patients):

- Symptoms of liver damage/infection: including bad general overall feeling, with or without jaundice (yellow skin and/or eyes) liver aches or swollen liver, dark urine, loss of appetite: **apply to your physician immediately**
- Allergic reactions including urticaria (nettle rash) or mustard rash (itching skin rash) including inflammation of the small blood vessels in the skin (capillaries) causing skin rash.
- Trigger finger – inability to straighten one's thumb or finger

- Increase in blood calcium level. If you suffer from nausea, vomiting and sense of thirst you must inform your doctor. They may will symptoms attesting to increased blood calcium level. The doctor will decide whether to do blood tests in order to ascertain the situation.

Extremely rare side effects (influencing under one of 10,000 patients):

- Extremely severe skin reactions (Steven-Johnson Syndrome) with bruising, ulcers or blisters: **see your physician immediately.**
- Allergic reaction accompanied by swelling of the face, lips, tongue and/or throat (angioedema) that could cause problems when swallowing and/or breathing: **see your physician immediately.**

**Stop the use of this medicine and contact your doctor immediately** if you feel pain in your chest or shortness of breath, they may be symptoms of heart disease.

Anastrozole decreases the level of female hormones which may cause loss of the bones' mineral content and decreased strength, in some cases causing fractures.

If any side effect becomes serious, or should you experience a side effect not mentioned in this leaflet, please consult your doctor.

### **5) How to store this medicine?**

Prevent poisoning! This medicine and any other medicine should be stored in a closed location out of the reach of children and/or babies so as to prevent poisoning. Do not induce vomiting without an explicit instruction from your doctor.

Do not use this medicine after the expiration date (exp.date) marked on the package/bottle/carton/label.

The expiration day refers to the last day of the month specified.

**Storage conditions:** store at a temperature lower than 30°C.

### **6) Additional information:**

**In addition to the active ingredient, the medicine also contains the following inactive ingredients:**

Lactose, Monohydrate, Sodium Starch Glycolate, Povidone, Magnesium Stearate, Macroglol (PEG 400), Hypromellose (HPMC) and Titanium Dioxide.

**What does the medicine look like and what does the packet contain?**  
The medicine is in the form of a white tablet, arched on both sides, with AMA and 1 impressed on one side.

The tablets are packed in plastic trays ("blister packs") that are packed inside cardboard boxes.

**Package size:** the medicine is distributed in the following package:  
• Cardboard boxes containing plastic trays with 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 300 or 500 tablets. The number of plastic trays per cardboard box may vary according to package size. The number of tablets in each package is marked on the cardboard box.

- It is possible that not all package sizes will be marketed.

**Registration owner:** Inovamed Ltd., private company 513988089, POB 62 Even Yehuda 40500.

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