ANASTRAZOLE
GP PHARM

Package leaflet: information for the user

"Anastrozol 1 mg film-coated tablets"

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.
- 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.

What in this leaflet:

1 What "Anastrozol 1 mg film-coated tablets" is and what it is used for

"Anastrozol 1 mg film-coated tablets" contains a substance called anastrozole. This belongs to a group of medicines called "aromatase inhibitors".

"Anastrozol 1 mg film-coated tablets" is used to treat breast cancer in women who have gone through the menopause. .

"Anastrozol 1 mg film-coated tablets" 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 1 mg film-coated tablets"

Do not take "Anastrozol 1 mg film-coated tablets"

- if you are allergic (hypersensitive) to anastrozole or any of the other ingredients of "Anastrozol 1 mg film-coated tablets" (listed in section 6).

- if you are pregnant or breast-feeding (see the section called 'Pregnancy and breast-feeding').

Do not take "Anastrozol 1 mg film-coated tablets" if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Anastrozole 1 mg film-coated tablets.

Warnings and precautions
Before treatment with "Anastrozol 1 mg film-coated tablets" 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 "Anastrozol 1 mg film-coated tablets" .

If you go into the hospital, let the medical staff know you are taking "Anastrozol 1 mg film-coated tablets" .

Other medicines and "Anastrozol 1 mg film-coated tablets"
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take "Anastrozol 1 mg film-coated tablets" 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 1mg film-coated tablets" 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 if you are pregnant or breast-feeding. Stop "Anastrozol 1 mg film-coated tablets" if you become pregnant and talk to your doctor.

If you are pregnant or breast-feedingm think you may be pregnanat or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
"Anastrozol 1 mg film-coated tablets" 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 1 mg film-coated tablets" . If this happens to you, ask your doctor for advice.

"Anastrozol 1 mg film-coated tablets" contains lactose
"Anastrozol 1 mg film-coated tablets" 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 "Anastrozol 1 mg film-coated tablets"

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 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 o water.
- It does not matter if you take Anastrozol 1 mg film-coated tablet before, with or after food.

Keep taking "Anastrozol 1 mg film-coated tablets" 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 1 mg film-coated tablets" should not be given to children and adolescents.

If you take more "Anastrozol 1 mg film-coated tablets" than you should
If you take more "Anastrozol 1 mg film-coated tablets" than you should, talk to your doctor straight away.

If you forget to take "Anastrozol 1 mg film-coated tablets"
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 1 mg film-coated tablets"

Do not stop taking your tablets unless your doctors 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, this medicine can cause side effects, although not everybody gets them.

Very common: at least 1 in 10 treated patients
Common: at least 1 in 100 treated patients
Uncommon: at least 1 in 1,000 treated patients
Very rare: less than 1 in 10,000 treated patients

Very common side effects:
- Headaches
- Hot flashes
- Feeling sick (nausea)
- Skin rash
- Pain or stiffness in your joints
- Inflammationof the joints (arthritis)
- Feeling weak
- Bone loss (osteoporosis)

Common side effects:
- 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:
- 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:
- 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:
- 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 1 mg film-coated tablets" 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 "Anastrozol 1 mg film-coated tablets"

Keep this medicine out of the sight and reach of children.

Do not use "Anastrozol 1 mg film-coated tablets" after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product 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 "Anastrozol 1 mg film-coated tablets" contains

- The active substance is anastrozole.
- The other ingredients are: Lactose Monohydrate, Sodium starch glycolate, Povidone, Magnesium stearate, Hypromellose, Titanium dioxide (E171), Macrogol 400.

What "Anastrozol 1 mg film-coated tablets" looks like and contents of the pack

"Anastrozol 1 mg film-coated tablets" tablets are white, biconvex, round, film-coated.
Each pack contains 20, 28 or 30 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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