Package leaflet: Information for the patient

Anastrozol ratiopharm 1 mg, filmomhulde tabletten

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What /.../ is and what it is used for

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

/.../ 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 /.../

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

Warnings and precautions
Talk to your doctor or pharmacist before taking /.../
- 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/…/').
- 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 /.../.

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

Children and adolescents
/.../ should not be given to children and adolescents.

Other medicines and /.../
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription and herbal medicines. This is because /.../ can affect the way some medicines work and some medicines can have an effect on /.../.

Do not take /.../ 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 /.../ 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 /.../ if you are pregnant or breast-feeding. Stop /.../ if you become pregnant and talk to your doctor.

Driving and using machines
/.../ 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 /.../. If this happens to you, ask your doctor or pharmacist for advice.

/.../ contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

/.../ contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take /.../

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 /.../ before, with or after food.

Keep taking /.../ 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.

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

If you forget to take /.../

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 /.../
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, this medicine can cause side effects, although not everybody gets them.

Stop taking /.../ 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'.

Other side effects:

Very common (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 (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 (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 or pharmacist as you may need to have blood tests.

Rare (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
- /.../ 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../

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 after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Keep your tablets in the container they came in.

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 /.../ contains
- The active substance is anastrozole.
  Each film-coated tablet contains 1 mg anastrozole.

- The other ingredients:
  Tablet core: lactose monohydrate, magnesium stearate (E572), povidone K-30, sodium starch glycolate type A.
  Film-coating: hypromellose (E464), macrogol 400 and 6000 and titanium dioxide (E171).

What /.../ looks like and contents of the pack

/.../ are white to off white, round tablets. One side of the tablet is marked with the number “93” and the other side with “A10”.

/.../ is available in pack sizes of 10, 28, 30, 50, 90, 90 (3x30), 98 or 100 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Registratiehouder:
Ratiopharm GmbH
Graf-Arco-Str.3
89079 Ulm
Duitsland

Fabrikant:
Pharmachemie B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Teva Pharmaceutical Works Ltd.
Pallagi Ut 13
4042 Debrecen
Hongarije

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 34004

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Nederland: Anastrozol ratiopharm 1 mg, filmomhulde tabletten
Oostenrijk: Anastrozol-ratiopharm 1 mg Filmtabletten
Slowakije: Anastrozol-ratiopharm 1 mg

Deze bijsluiter is voor het laatst goedgekeurd in juni 2021.