

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Anastrogen is and what it is used for
2. Before you take Anastrogen
3. How to use Anastrogen
4. Possible side effects
5. How to store Anastrogen
6. Further information

1. WHAT Anastrogen IS AND WHAT IT IS USED FOR

Anastrogen belongs to a group of medicines called aromatase inhibitors. This means that it interferes with some of the actions of aromatase, an enzyme within the body which affects the level of certain female sex hormones such as oestrogens.

Anastrozole is used in the treatment of advanced hormone-sensitive breast cancer in post-menopausal women. It is also used in early hormone-sensitive breast cancer after primary treatment or after 2 to 3 years' treatment with tamoxifen.

2. BEFORE YOU TAKE Anastrogen

Do not take Anastrogen

- if you are hypersensitive to anastrozole or any of the other ingredients of Anastrogen
- if you have not gone through menopause yet
- if you are pregnant or a breast feeding mother
- if you suffer from certain disorders or diseases which affect your liver or the kidney function.
- if you are taking tamoxifen or oestrogen-containing medicines, for example hormone replacement therapy.

Anastrogen should not be given to children.

Take special care with Anastrogen

- if you are unsure whether or not you have gone through menopause. Your doctor should check your hormone levels.
- if you have severe kidney problems.
- if you have moderate or severe liver disease.
- if you have any history of or are suffering from any condition which affects the strength of your bones. Anastrozole lowers the levels of female hormones and this may lead to a loss of the mineral content of bones, which might decrease their strength. You may have to have bone density tests during treatment. Your doctor can give you medicine to prevent or treat the bone loss.
- if you are taking any LHRH analogues (medicines used to treat breast cancer, certain gynaecological conditions and infertility). No studies have been done on the combination of LHRH analogues and anastrozole. Therefore anastrozole and LHRH analogues should not be used in combination.

If you go to hospital, let the medical staff know that you are taking anastrozole.

Taking other medicines

You should not take Anastrozole if you are taking any of the following (see also 'Do not take Anastrogen', above):

- Medicines that contain oestrogen e.g HRT
- Tamoxifen, another breast cancer treatment

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Anastrogen with food and drink

Anastrogen can be taken before, during or after a meal, but also you can take them without food. The tablet should be swallowed with water.

Pregnancy and breast-feeding

Do not take Anastrogen if you are pregnant or if you are breast-feeding your baby.

Please contact your doctor immediately if you think you may be pregnant.

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

Driving and using machines

Anastrogen is unlikely to adversely affect your ability to drive a car or to operate machinery. However, you may occasionally feel weak or sleepy. Should this happen to you, ask your doctor for advice.

Important information about some of the ingredients of Anastrogen

Anastrogen 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.

3. HOW TO USE Anastrogen

Always take Anastrogen exactly as your doctor has told you. You should check with your doctor if you are not sure.

Adults including the elderly: Take one tablet daily. Swallow with a glass of water. You should try to take your tablet at the same time each day.

Children: Anastrozole is not recommended for children.

If you take more Anastrogen than you should: If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Anastrogen: Do not take a double dose to make up for a forgotten tablet. Just resume your usual schedule.

If you stop taking Anastrogen: Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The following side effects are possible for anastrozole:

Very common (occurring in more than 1 in 10 people):

- Hot flushes

Common side effects (occurring in more than 1 in 100 but less than 1 in 10 people):

- Feeling weak
- Joint pain or joint stiffness
- Vaginal dryness
- Hair thinning
- Rash
- Nausea
- Diarrhoea
- Headache
- Carpal Tunnel Syndrome (tingling, pain, coldness, weakness in parts of the hand)
- Abnormal liver tests

Uncommon side effects (occurring in more than 1 in 1000 but less than 1 in 100 people):

- Vaginal bleeding (usually in the first few weeks of treatment)
- Anorexia
- Raised or high levels of fatty substances called lipids in the blood
- Vomiting
- Sleepiness
- Abnormal liver tests and hepatitis

Very rare side effects (occurring in less than 1 in 10,000 people):

Contact a doctor immediately if the following happens to you, as you may need further examinations or treatment.

- Extremely severe skin reactions (Stevens-Johnson syndrome) with lesions, ulcers or blisters.
- Allergic reaction with swelling of the face, lips, tongue and/or throat (angioedema), which may cause difficulty in swallowing and/or breathing. Hives which can produce raised red skin bumps anywhere on the body.

Other possible side effects:

Anastrozole lowers oestrogen levels. This may cause reduction in bone mineral content that can decrease bone strength and in some cases may result in fractures.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE Anastrogen

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

Do not use Anastrogen after the expiry date which is stated on the carton after <EXP>.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Anastrogen contains

- The active substance is anastrozole. Each film-coated tablet contains 1 mg anastrozole.
- The other ingredients are:

Tablet core: Lactose monohydrate, Maize starch, Povidone K-30, Cellulose microcrystalline pH102, Sodium starch glycolate Type A, Colloidal silica anhydrous, Magnesium stearate (E572), Talc.

Film-coating: Hypromellose 5cp (E464), Macrogol 400, Titanium dioxide (E171), Talc.

What Anastrogen looks like and contents of the pack

Anastrogen tablets are white, round, film-coated tablets with a diameter of 6.6 mm approximately.

The tablets are provided in blisters of 10 and 14.

Pack sizes: 28 & 30 tablets

Marketing Authorisation Holder and Manufacturer.

MARKETING AUTHORISATION HOLDER: VIOGEN Pharmaceuticals, 309 El. Venizelou Str., 17674, Kallithea, Athens, Greece.

MANUFACTURER: Remedica Ltd., Limassol Industrial Estate, P.O Box 51706, CY-3508 Limassol, Cyprus.

This medicinal product is authorised in the Member States of the EEA under the following names: **CZ** Anastrozole Cynone 1 mg potahované tablety, **ES** Anacyne comprimidos de 1 mg recubiertos con película, **IT** Anacyne 1 mg compresse rivestite con film, **PT** Anacyne 1 mg, comprimidos revestidos por película, **EL** Anastrogen.

This leaflet was last approved in {12/2009}.