

Aremed 1 mg film-coated tablets[®]

Anastrozole (1 mg)

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What Aremed is used for

Aremed is used to treat breast cancer in post-menopausal women.

How Aremed works

Aremed 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 called oestrogens.

Before you use Aremed

- When you must not use it

Do not take Aremed:

- if you are pregnant or breast-feeding your baby.
 - if you are allergic to anastrozole or any of the other ingredients of Aremed listed at the end of this leaflet.
- having severe renal impairment (creatinine clearance less than 20 ml/min).

- Before you start to use it

Take special care with Aremed

- if you are suffering from any disorder or disease which affects your heart, liver or kidneys. Please inform your doctor.

Aremed is not recommended if you are pre-menopausal, and it should not be given to children.

- Taking other medicines

Please inform your doctor:

- if you take tamoxifen or medicine containing oestrogen (female sex hormone). It may lessen the effect of Aremed.
- if you are taking or have recently taken any other medicines, even those not prescribed.

Please note that these statements may also apply to medicine used some time ago.

How to use Aremed

- How much to use and when to use it

- follow your doctor's instructions about when and how to take your tablets.
- the usual dose is one tablet taken daily.
- try to take your tablet at the same time each day.
- swallow the tablet whole with a drink of water.

- How long to use it

Take Aremed as directed by your Healthcare provider. Do not stop taking your dose without talking to your Healthcare provider.

- If you forget to use it

Take your last missed dose as soon as you remember, as long as it is at least 12 hours before the next dose is due. If it is less than 12 hours to the next dose, do not take the dose you have missed.

- If you use too much (overdose)

If you take more than your normal dose, contact your doctor or nearest hospital.

While you are using it

- Things you must do

It is important to keep taking Aremed every day and as your doctor has told you to. The instructions on the label should remind you of what the doctor has said. Try to take the tablets at the same time each day.

- Things you must not do

Do not stop taking your dose without talking to your Healthcare provider.

If you forget to take a dose, take the last missed dose as soon as you remember, as long as it is at least 12 hours before the next dose is due. If it is less than 12 hours to the next dose, do not take the dose you have missed.

- Things to be careful of

Aremed lowers the level of female hormones and this may lead to a loss of the mineral content of bones which might decrease their strength and as a possible consequence the risk of fractures may increase. This possible increased risk should be managed according to treatment guidelines for managing bone health in postmenopausal women. Women are encouraged to discuss this possible risk and treatment options with their physicians.

Pregnancy

Aremed must not be used if you are pregnant.

Breast-feeding

Aremed must not be used if you are breast-feeding.

Driving and using machines

Your tablets are unlikely to adversely affect your ability to drive a car or to operate machinery. However, some patients may occasionally feel weak or sleepy. If this happens to you, ask your doctor for advice.

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Aremed 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.

Side effects

Like all medicines, Aremed can have side effects.

Contact your doctor promptly 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. This type of skin reaction is very rare.
- allergic reaction with swelling on the face, lips, tongue and/or throat (angioedema) which may cause difficulty in swallowing and/or breathing.
- inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), liver pain or liver swelling.

Tell your doctor if any of the following side-effects bother you:

- hot flushes
- feeling weak
- joint pain or joint stiffness (arthritis)
- bone loss (osteoporosis)
- carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)
- vaginal dryness
- thinning of the hair (hair loss)
- nausea
- diarrhea
- headache
- vaginal bleeding (usually in the first few weeks of treatment)
- anorexia (loss of appetite)
- vomiting
- sleepiness
- depression

• tickling, tingling or numbness of skin, loss/lack of taste

• rash, including inflammation of small blood vessels in the skin leading to skin rash

• trigger finger (a condition in which one of your fingers or your thumb catches a bent position)

• bone loss

• allergic reactions, such as hives or nettle-rash

• muscle pain

• increased calcium with or without the increase of parathyroid hormone in the blood. If you experience nausea, vomiting and thirst, you should tell your doctor. These symptoms may indicate possible increased blood calcium levels. Your doctor may have to do certain blood tests to determine if there is increased calcium in your blood occurring with or without an increase of parathyroid hormone, a hormone that regulates calcium.

An increased level of cholesterol (a type of fat in your blood) could also be seen with Aremed.

Changes in blood tests of liver function could also be seen with Aremed.

In a large clinical trial, a small increase in heart disease caused by reduced blood flow in the vessels of the heart was seen (ischemic heart disease). This condition may present itself as chest pain.

Do not be alarmed by this list of possible events. You may not have any of them. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Aremed

- Storage

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

Do not use this medicine after the expiry date which is stated on the carton after "EXP".

Do not store above 30 °C. Protect from light and moisture.

- Disposal

• If your doctor decides to stop your treatment, dispose of your tablets in an appropriate way.

• 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.

Product Description

- What it looks like

White, round, film-coated tablets with diameter of 6,6 mm approximately.

Aremed comes in blister packs containing 28 tablets in blisters of 14 film-coated tablets.

- Ingredients

- Active ingredient(s)

The active substance is anastrozole.

- Inactive ingredients

The other ingredients are: lactose monohydrate, maize starch, povidone, cellulose microcrystalline, sodium starch glycolate, silica colloidal anhydrous, magnesium stearate, talc,

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hypromellose, macrogol 400 and
titanium dioxide E171.

- MAL number:

MAL11125009AZ

Manufacturer

Remedica Ltd
Aharnon Str.,
Limassol Industrial Estate,
3056 Limassol, Cyprus

Product Registration Holder

Eucogen Sdn Bhd
No. 6A, Jalan Sungai Burung U 32/U,
Bukit Rimau, Seksyen 32, 40460
Shah Alam.

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16/04/2024

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