PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Agerdex 1 mg film-coated tablets
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 Agerdex is and what it is used for

Agerdex 1 mg film-coated tablets contain a substance called anastrozole. This belongs to a group of medicines called ‘aromatase inhibitors’. Agerdex is used to treat breast cancer in women who have gone through the menopause.

Agerdex works by cutting down the amount of the hormone called oestrogen 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 Agerdex

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Agerdex
- 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 oestrogen (see the section called ‘Other medicines and Agerdex’).
- 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 Agerdex.

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

Other medicines and Agerdex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any medicines.
This includes medicines that you buy without a prescription and herbal medicines. This is because Agerdex can affect the way some medicines work and some medicines can have an effect on Agerdex.

Do not take Agerdex if you are already taking any of the following medicines:
- Certain medicines used to treat breast cancer (selective oestrogen receptor modulators), e.g. medicines that contain tamoxifen. - Medicines that contain oestrogen, such as hormone replacement therapy (HRT).

This is because these medicines may stop Agerdex from working properly.

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 Agerdex if you are pregnant or breast-feeding. Stop Agerdex if you become pregnant and talk to your doctor.

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

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

Agerdex contains lactose and sodium
Agerdex tablets contain 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 medicinal product.

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

3. How to take Agerdex

Always take Agerdex 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 (1 mg Agerdex) taken once daily.
- 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 Agerdex before, with or after food.

Keep taking Agerdex 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 and adolescents
Agerdex should not be given to children and adolescents.

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

If you forget to take Agerdex
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 Agerdex
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.

If any of the following happen, do not take more Agerdex. Tell your doctor immediately or go to the casualty department at your nearest hospital:

Uncommon (may affect up to 1 in 100 people):
- Inflammation of the liver (hepatitis) with nausea, vomiting, loss of appetite, fever, itching, yellowing of the skin and eyes, light coloured bowel motions or dark coloured urine.

Rare (may affect up to 1 in 1,000 people):
- Skin rash caused by hypersensitivity (this can be from a severe allergic 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 (may affect up to 1 in 10,000 people):
- 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 include:

Very common: may affect more than 1 in 10 people
- Headache
- Hot flushes
- Feeling sick (nausea)
- Skin rash
- Pain or stiffness in your joints
- Inflammation of the joints (arthritis)
- Feeling weak
- Bone loss (osteoporosis)
- Depression

Common: may affect up to 1 to 10 people
- Loss of appetite
- Raised or high levels of a fatty substance known as cholesterol in the 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 test 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 to 100 people
- Changes in special blood tests that show how your liver is working (gamma-GT and bilirubin)
- Hives or nettle rash
- Raised or high levels 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.
- Trigger finger (a condition in which your finger or thumb catches in a bent position).

Rare: may affect up to 1 to 1,000 people
- Rare inflammation of your skin that may include red patches or blisters, known as erythema multiforme

Effects on your bones
Agerdex lowers the amount of the hormone called oestrogen that is in your body. This may lower the mineral content in 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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Agerdex

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister foil or carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicine 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. Content of the pack and other information

What Agerdex contains
- The active substance is anastrozole. One tablet contains 1 mg of anastrozole.
- The other ingredients in the tablet core are lactose monohydrate (see section 2 'Agerdex contains lactose and sodium'), sodium starch glycolate, povidone (E1201) and magnesium stearate (E572).
- The ingredients in the tablet coating are macrogol, hypromellose (E464) and titanium dioxide (E171).

What Agerdex looks like and contents of the pack
Agerdex is a white film-coated round tablet, with the inscriptions "ANA" and "1" on one side.

Agerdex is available in blisters of 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 300 tablets and in hospital blisters of 28, 50, 84, 98, 300 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers
McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

The Netherlands	Anastrozol Mylan 1 mg, filmomhulde tabletten
Austria	Anastrozol Arcana 1 mg Filmtabletten
Czech Republic	Anastrozol Mylan
Spain	Anastrozol Viatris 1 mg comprimidos recubiertos con película EFG
France	Anastrozole Viatris 1 mg, comprimé pelliculé
Ireland	Agerdex 1 mg film-coated tablets
Italy	Anastrozolo Mylan Generics
Portugal	Anastrozol Mylan
United Kingdom (Northern Ireland)	Anastrozole 1 mg Film-coated Tablet

This leaflet was last revised in 07/2022