

AROMASIN(R)

Exemestane

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AROMASIN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AROMASIN against the benefits it is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What AROMASIN is used for

AROMASIN is used to treat breast cancer in women who no longer have their menstrual periods, either naturally due to their age (after menopause) or because they have had their ovaries surgically removed.

AROMASIN is used to reduce the risk of recurrence or spreading of the breast cancer. It is also used when the cancer has not responded or has returned after treatment with another medicine or medicines.

How AROMASIN works

AROMASIN is an aromatase inactivator. It works by significantly reducing the supply of oestrogen to cancer cells.

This stops the growth of those cancer cells which need oestrogen, a natural female sex hormone, to grow.

Ask your doctor if you have any questions about why AROMASIN has been prescribed for you.

Your doctor may have prescribed it for another purpose.

AROMASIN is only available with a doctor's prescription. It is not addictive.

Before you take AROMASIN

When you must not take it

Do not take AROMASIN and talk to your doctor if you think you may have an allergy to:

- * exemestane, the active ingredient in AROMASIN
- * any of the other ingredients in AROMASIN listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take AROMASIN if you are pregnant or intend to become pregnant.

AROMASIN may affect your developing baby if you take it during pregnancy.

Do not breastfeed while taking AROMASIN.

There is a possibility that your baby may be affected.

AROMASIN is not recommended for use in children.

Do not take AROMASIN after the expiry date printed on the pack.

Do not take AROMASIN if the packaging is torn or shows signs of tampering.

If your AROMASIN has expired or is damaged return it to your pharmacist for disposal.

If you are not sure whether you should start taking AROMASIN, talk to your doctor.

Before you start to take it

Tell your doctor if you have an allergy to:

- * any medicine
- * other substances, such as foods, preservatives or dyes.

Tell your doctor if you:

- * are still having your monthly period
- * have or have had kidney problems
- * have or have had liver problems
- * have osteoporosis (disease which causes bones to be more brittle and likely to break)

If you have not told your doctor about any of the above, tell your doctor before you start taking AROMASIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines

that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines should not be used with AROMASIN. These include:

- * medicines which contain oestrogen, such as hormone replacement therapy (HRT)
- * oral contraceptives

Some health food products for menopausal symptoms contain natural oestrogens.

Tell your doctor or pharmacist if you are taking any medicines or health food products containing oestrogens.

Talk to your doctor or pharmacist if you have any concerns or questions about taking AROMASIN.

How to take AROMASIN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The recommended dose is one 25 mg tablet taken once daily.

When to take it

Take the tablet once daily after a meal at approximately the same time each day.

How long to take it

Your doctor or pharmacist will tell you how long to take AROMASIN.

Do not stop taking AROMASIN unless your doctor tells you to, even if you feel better.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking AROMASIN as you would normally.

Do not take a double dose to make up for the one that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Phone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much AROMASIN.

Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

While you are using AROMASIN

Things you must do

Use AROMASIN exactly as your doctor has prescribed.

Be sure to keep all your doctor's appointments so your progress can be checked.

If you feel that your medicine is not helping your condition, talk to your doctor.

Tell all doctors, dentists and pharmacists who are treating you that you are taking AROMASIN.

If you go into hospital whilst taking AROMASIN, let the medical staff know that you are taking AROMASIN.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking AROMASIN.

Things you must not do

Do not give AROMASIN to anyone else, even if they have the same condition as you.

Do not take AROMASIN to treat any other complaints unless your doctor tells you to.

Do not stop taking AROMASIN or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery, until you know how AROMASIN affects you.

AROMASIN may cause tiredness or dizziness in some people.

If you experience these effects whilst taking AROMASIN, you should not attempt to drive or operate machinery.

If AROMASIN makes you feel dizzy, be careful when getting up from a sitting or lying position.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AROMASIN.

AROMASIN, like other medicines, may cause unwanted side effects in some people. Many women can take AROMASIN without any problems, but some women may have mild to moderate side effects.

Tell your doctor or pharmacist as soon as possible if you have any of the following side effects or other effects that you think may be related to your treatment:

- * hot flushes
- * nausea, vomiting, loss of appetite, indigestion, pain (including stomach ache)

- * constipation
- * diarrhoea
- * tiredness
- * swelling in your legs
- * dizziness and headache
- * increased sweating
- * difficulty sleeping
- * depression
- * disturbed vision such as blurriness
- * pain in your muscle or joints
- * increase in weight
- * skin rash
- * hair loss
- * bleeding or bruising more easily than normal
- * pain and/or numbness of hands, loss of feeling in fingers/thumb
- * frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- * symptoms of gastric ulcer such as blood in stools, black tarry stools or vomiting of blood.
- * abnormal vaginal bleeding
- * hepatitis, yellowing of the skin or eyes, also called jaundice.

Other side effects not listed above may occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using AROMASIN

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep AROMASIN in a cool dry place where the temperature stays below 30 degrees C.

Do not leave AROMASIN or any other medicine in the car or on window sills.

Do not store AROMASIN or any other medicines in a bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep AROMASIN where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking AROMASIN or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

AROMASIN is available as 25 mg tablets. The tablets are round and off-white to slightly greyish in colour marked with '7663' on one side in black ink.

AROMASIN 25 mg tablets are available in blister packs of 30 tablets.

Ingredients

Active Ingredient

AROMASIN tablets contain 25 mg of exemestane as the active ingredient.

Other Ingredients

The tablets also contain:

- * silicon dioxide
- * crospovidone
- * hypromellose
- * light magnesium carbonate
- * magnesium stearate
- * mannitol

- * microcrystalline cellulose
- * methyl hydroxybenzoate
- * macrogol 6000
- * polysorbate 80
- * polyvinyl alcohol
- * simethicone emulsion
- * sodium starch glycollate
- * sucrose
- * titanium dioxide
- * cetyl esters wax
- * purified talc
- * carnauba wax
- * black printing ink.

Supplier

AROMASIN is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll Free Number 1800 675 229

It is supplied in New Zealand by:

Pfizer New Zealand Ltd

PO Box 3998

Auckland

Toll Free Number 0800 736 363

Australian Registration Number

AROMASIN 25 mg tablets can be identified by the Australian Register Number on the box:

AUST R 76369

Date of preparation

This leaflet was revised on 30 January 2009.

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(R)= Registered trademark