

# AROMASIN®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using AROMASIN?

AROMASIN contains the active ingredient exemestane. 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 also 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.

For more information, see Section [1. Why am I using AROMASIN?](#) in the full CMI.

### 2. What should I know before I use AROMASIN?

Do not use if you have ever had an allergic reaction to exemestane or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use AROMASIN?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with AROMASIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use AROMASIN?**

- The recommended dose is one 25 mg tablet taken once daily after meals, however, follow all directions given to you by your doctor or pharmacist carefully as they may differ from the information contained in this leaflet.
- Your doctor or pharmacist will tell you how long to take AROMASIN.

More instructions can be found in Section [4. How do I use AROMASIN?](#) in the full CMI.

### **5. What should I know while using AROMASIN?**

|                             |  |
|-----------------------------|--|
| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul> |
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|   |  |
|---|--|
|   | <p>you visit that you are using AROMASIN.</p>  |
| <p><b>Things you should not do</b></p>  | <ul style="list-style-type: none"> <li>● Do not give AROMASIN to anyone else, even if they have the same condition as you.</li> <li>● Do not take AROMASIN to treat any other complaints unless your doctor tells you to.</li> <li>● Do not stop taking AROMASIN or change the dosage without checking with your doctor.</li> <li>● Do not take AROMASIN after the expiry date printed on the pack.</li> </ul> |
| <p><b>Driving or using machines</b></p> | <ul style="list-style-type: none"> <li>● AROMASIN may cause tiredness in some people.</li> <li>● If AROMASIN makes you feel dizzy, be careful when getting up from a sitting or lying position.</li> <li>● If you experience these effects whilst taking AROMASIN, you should not attempt to drive or operate machinery.</li> </ul>  |

|                                    |  |
|------------------------------------|--|
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• Store it in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 30°C.</li></ul> |
|------------------------------------|--|



For more information, see Section [5. What should I know while using AROMASIN?](#) in the full CMI.

## **6. Are there any side effects?**

More common side effects may include headache, nausea, constipation or diarrhoea, tiredness or difficulty sleeping. More serious side effects include swelling in legs or feet, abnormal bleeding, skin changes or infections.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# AROMASIN®

**Active ingredient(s):** *Exemestane*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using AROMASIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AROMASIN.**

**Where to find information in this leaflet:**

- [1. Why am I using AROMASIN?](#)
- [2. What should I know before I use AROMASIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use AROMASIN?](#)
- [5. What should I know while using AROMASIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using AROMASIN?

**AROMASIN contains the active ingredient exemestane.** AROMASIN is an aromatase inactivator. It works by significantly reducing the supply of estrogen (a natural female sex hormone) to cancer cells.

This stops the growth of those cancer cells which normally need estrogen to grow.

**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 also 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.

## **2. What should I know before I use AROMASIN?**

### **Warnings**

#### **Do not use AROMASIN if:**

- You are allergic to exemestane, or any of the ingredients 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
  - Always check the ingredients to make sure you can use this medicine
- You are pregnant or intend to become pregnant, or are breastfeeding – see ‘Pregnancy and Breastfeeding’ in next column

**AROMASIN is not recommended for use in children.**

## Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

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.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

Some health food products for menopausal symptoms contain natural estrogens.

Tell your doctor before you start taking AROMASIN 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)
- Have a vitamin D deficiency

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

- Medicines which contain estrogen, such as hormone replacement therapy (HRT).
- Oral contraceptives.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AROMASIN.**

## **4. How do I use AROMASIN?**

### **How much to take**

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



## **When to take AROMASIN**

- Take the tablet once daily after a meal at approximately the same time each day.
- Your doctor or pharmacist will tell you how long to take AROMASIN.

## **If you forget to use AROMASIN**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

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

## **If you use too much AROMASIN**

If you think that you have used too much AROMASIN, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia, or 0800 POISON or 0800 764 766 in New Zealand**),
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using AROMASIN?**

### **Things you should 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.

### **Call your doctor straight away if you:**

Notice any unusual, severe or worrying symptoms.

Remind any doctor, dentist or pharmacist you visit that you are using AROMASIN.

### **Things you should 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, even if you feel better.

- 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how AROMASIN affects you.**

AROMASIN may cause tiredness in some people.

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

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

## **Looking after your medicine**

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Store it in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 30°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

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.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## More common side effects

| <b>More common side effects</b>   | <b>What to do</b>  |
|---|--|
| <p data-bbox="204 488 671 591"><b>Gastrointestinal and weight related:</b></p> <ul data-bbox="204 629 762 1137" style="list-style-type: none"><li data-bbox="204 629 416 674">• Nausea</li><li data-bbox="204 696 437 741">• Vomiting</li><li data-bbox="204 763 592 808">• Loss of appetite</li><li data-bbox="204 831 485 875">• Indigestion</li><li data-bbox="204 898 762 1003">• Pain (including stomach ache)</li><li data-bbox="204 1025 517 1070">• Constipation</li><li data-bbox="204 1093 464 1137">• Diarrhoea</li></ul> <p data-bbox="204 1167 603 1270"><b>Aches, pains and swelling related:</b></p> <ul data-bbox="204 1308 756 1480" style="list-style-type: none"><li data-bbox="204 1308 469 1352">• Headache</li><li data-bbox="204 1375 756 1480">• Trigger finger (gets stuck in a bent position)</li></ul> <p data-bbox="204 1509 676 1612"><b>Alertness, sleep and mood related:</b></p> <ul data-bbox="204 1650 628 1823" style="list-style-type: none"><li data-bbox="204 1650 453 1695">• Dizziness</li><li data-bbox="204 1718 464 1762">• Tiredness</li><li data-bbox="204 1785 628 1830">• Difficulty sleeping</li></ul> <p data-bbox="204 1852 735 1955"><b>Bleeding, hair and skin related:</b></p> | <p data-bbox="810 488 1374 703"><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

| <b>More common side effects</b>  | <b>What to do</b> |
|--|-------------------|
| <ul style="list-style-type: none"> <li>● Hot flushes</li> <li>● Skin rash or itching</li> <li>● Hair loss</li> </ul> |                   |

## **Serious side effects**

| <b>Serious side effects</b>  | <b>What to do</b>  |
|--|--|
| <p><b>Gastrointestinal and weight related:</b></p> <ul style="list-style-type: none"> <li>● Symptoms of gastric ulcer such as blood in stools, black tarry stools or vomiting of blood</li> <li>● Increase in weight</li> </ul> <p><b>Aches, pains and swelling related:</b></p> <ul style="list-style-type: none"> <li>● Swelling in your legs</li> <li>● Pain and/or numbness of hands, loss of feeling in fingers/thumb</li> <li>● Pain in your muscle or joints</li> <li>● Tendon pain and swelling</li> </ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

| <b>Serious side effects</b>  | <b>What to do</b> |
|--|-------------------|
| <p><b>Alertness, sleep and mood related:</b></p> <ul style="list-style-type: none"> <li>• Depression</li> <li>• Disturbed vision such as blurriness</li> </ul> <p><b>Bleeding, hair and skin related:</b></p> <ul style="list-style-type: none"> <li>• Bleeding or bruising more easily than normal</li> <li>• Abnormal vaginal bleeding</li> <li>• Infection of the liver (hepatitis) with symptoms such as yellowing of the skin or eyes (jaundice).</li> <li>• Skin rash or itching</li> </ul> <p><b>Infection:</b></p> <ul style="list-style-type: none"> <li>• Frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul> |                   |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What AROMASIN contains

|   |   |
|---|---|
| <b>Active ingredient<br/>(main ingredient)</b>      | Exemestane  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <ul style="list-style-type: none"><li>• Silicon dioxide</li><li>• Crospovidone</li><li>• Hypromellose</li><li>• Iron oxide black</li><li>• Magnesium carbonate hydrate</li><li>• Magnesium stearate</li></ul> |



|                            |   |
|----------------------------|---|
|                            | <ul style="list-style-type: none"> <li>• Mannitol</li> <li>• Microcrystalline cellulose</li> <li>• Methyl hydroxybenzoate</li> <li>• Macrogol 6000</li> <li>• Polysorbate 80</li> <li>• polyvinyl alcohol</li> <li>• shellac</li> <li>• simethicone emulsion</li> <li>• sodium starch glycollate</li> <li>• sucrose</li> <li>• titanium dioxide</li> <li>• cetyl esters wax</li> <li>• purified talc</li> <li>• carnauba wax</li> <li>• black printing ink</li> </ul> |
| <b>Potential allergens</b> | Contains hydroxybenzoates   |

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What AROMASIN looks like**

AROMASIN is available as 25 mg tablets (Aust R 76369). 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.

## **Who distributes AROMASIN**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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