EXEMESTANE PFIZER®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using EXEMESTANE PFIZER?

EXEMESTANE PFIZER contains the active ingredient exemestane. EXEMESTANE PFIZER 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.

EXEMESTANE PFIZER 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 <u>1. Why am I using EXEMESTANE PFIZER?</u> in the full CMI.

2. What should I know before I use EXEMESTANE PFIZER?

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 EXEMESTANE PFIZER? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EXEMESTANE PFIZER and affect how it works.

A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How do I use EXEMESTANE PFIZER?

- 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 EXEMESTANE PFIZER.

More instructions can be found in Section 4. How do I use EXEMESTANE PFIZER? in the full CMI.

5. What should I know while using EXEMESTANE PFIZER?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using EXEMESTANE PFIZER.	
Things you should not do	 Do not give EXEMESTANE PFIZER to anyone else, even if they have the same condition as you. Do not take EXEMESTANE PFIZER to treat any other complaints unless your doctor tells you to. Do not stop taking EXEMESTANE PFIZER or change the dosage without checking with your doctor. Do not take EXEMESTANE PFIZER after the expiry date printed on the pack. 	
Driving or using machines	If EXEMESTANE PFIZER makes you feel dizzy, be careful when getting up from a sitting or lying position	
Looking after your medicine	• Store it in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 30°C.	

For more information, see Section 5. What should I know while using EXEMESTANE PFIZER? 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 <u>6. Are there any side effects?</u> in the full CMI.

EXEMESTANE PFIZER®

Active ingredient(s): Exemestane

Consumer Medicine Information (CMI)

This leaflet provides important information about using EXEMESTANE PFIZER. 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 EXEMESTANE PFIZER.

Where to find information in this leaflet:

1. Why am I using EXEMESTANE PFIZER?

2. What should I know before I use EXEMESTANE PFIZER?

- 3. What if I am taking other medicines?
- 4. How do I use EXEMESTANE PFIZER?
- 5. What should I know while using EXEMESTANE

PFIZER?

- 6. Are there any side effects?
- 7. Product details

1. Why am I using EXEMESTANE PFIZER?

EXEMESTANE PFIZER contains the active ingredient exemestane. EXEMESTANE PFIZER 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.

EXEMESTANE PFIZER 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.

EXEMESTANE PFIZER 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 EXEMESTANE PFIZER?

Warnings

Do not use EXEMESTANE PFIZER 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

EXEMESTANE PFIZER 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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

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

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

Do not breastfeed while taking EXEMESTANE PFIZER.

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 EXEMESTANE PFIZER 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 EXEMESTANE PFIZER. 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 EXEMESTANE PFIZER.

4. How do I use EXEMESTANE PFIZER?

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 EXEMESTANE PFIZER

- 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 EXEMESTANE PFIZER.

If you forget to use EXEMESTANE PFIZER

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 EXEMESTANE PFIZER

If you think that you have used too much EXEMESTANE PFIZER, 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), or
- 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 EXEMESTANE PFIZER?

Things you should do

- Use EXEMESTANE PFIZER 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 EXEMESTANE PFIZER.

Things you should not do

- Do not give EXEMESTANE PFIZER to anyone else, even if they have the same condition as you.
- Do not take EXEMESTANE PFIZER to treat any other complaints unless your doctor tells you to.
- Do not stop taking EXEMESTANE PFIZER or change the dosage without checking with your doctor, even if you feel better.

- Do not take EXEMESTANE PFIZER after the expiry date printed on the pack.
- Do not take EXEMESTANE PFIZER if the packaging is torn or shows signs of tampering. If your EXEMESTANE PFIZER 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 EXEMESTANE PFIZER affects you.

EXEMESTANE PFIZER may cause tiredness in some people.

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

If you experience these effects whilst taking EXEMESTANE PFIZER, 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 EXEMESTANE PFIZER 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

More common side effects	What to do
Gastrointestinal and weight related:	Speak to your
 Nausea Vomiting Loss of appetite Indigestion 	doctor if you have any of these less serious side

•	Pain (including stomach ache) Constipation Diarrhoea	effects and they worry you.	
Acl	nes, pains and swelling related:		
•	Headache		
Ale	rtness, sleep and mood related:		
• •	Dizziness Tiredness Difficulty sleeping		
Ble	Bleeding, hair and skin related:		
•	Hot flushes Skin rash or itching Hair loss		

Serious side effects

Ser	ious side effects	What to do		
Gastrointestinal and weight related:		Call your doctor		
•	Symptoms of gastric ulcer such as blood in stools, black tarry stools or vomiting of blood Increase in weight	straight away, or go straight to the Emergency Department at		
Act	nes, pains and swelling related:	your nearest hospital if you notice any of these serious side effects.		
•	Swelling in your legs Pain and/or numbness of hands, loss of feeling in fingers/thumb Pain in your muscle or joints			
Ale	Alertness, sleep and mood related:			
•	Depression Disturbed vision such as blurriness			
Ble	Bleeding, hair and skin related:			
•	Bleeding or bruising more easily than normal Abnormal vaginal bleeding Infection of the liver (hepatitis) with symptoms such as yellowing of the skin or eyes (jaundice). Skin rash or itching			
Inf	Infection:			
•	Frequent infections such as fever, severe chills, sore throat or mouth ulcers			

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 Medsafe

online at <u>https://www.medsafe.govt.nz/safety/report-a-problem.asp</u>. 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 EXEMESTANE PFIZER contains

Active ingredient	Exemestane	
(main ingredient)		
Other ingredients	Silicon dioxide	
•		
(inactive ingredients)	Crospovidone	
	Hypromellose	
	 Iron oxide black 	
	 Magnesium carbonate 	
	hydrate	
	 Magnesium stearate 	
	 Mannitol 	
	Microcrystalline cellulose	
	 Methyl hydroxybenzoate 	
	Macrogol 6000	
	 Polysorbate 80 	
	 Polyvinyl alcohol 	
	• Shellac	
	Simethicone emulsion	
	 Sodium starch glycollate 	
	Sucrose	
	Titanium dioxide	
	Cetyl esters wax	
	Purified talc	
	Carnauba wax	
	Black printing ink	
Potential allergens	Contains hydroxybenzoates	

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

What EXEMESTANE PFIZER looks like

EXEMESTANE PFIZER 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.

EXEMESTANE PFIZER 25 mg tablets are available in blister packs of 30 tablets.

Who distributes EXEMESTANE PFIZER

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.au

This leaflet was prepared in March 2024.

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