# **Exaccord Tablets 25 mg**

Exemestane Tablets 25 mg

#### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about Exaccord Tablets. 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 Exaccord Tablets 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 Exaccord Tablets is used for

Exaccord Tablets are 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.

Exaccord Tablets are 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 Exaccord Tablets works

Exaccord Tablets 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 Exaccord Tablets have been prescribed for you.

Your doctor may have prescribed it for another purpose.

Exaccord Tablets are only available with a doctor's prescription. It is not addictive.

### Before you take Exaccord Tablets

When you must not take it

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

- exemestane, the active ingredient in Exaccord Tablets
- any of the other ingredients in Exaccord Tablets 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 Exaccord Tablets if you are pregnant or intend to become pregnant.

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

Do not breastfeed while taking Exaccord Tablets.

There is a possibility that your baby may be affected.

Exaccord Tablets is not recommended for use in children.

Do not take Exaccord Tablets after the expiry date printed on the pack.

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

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

If you are not sure whether you should start taking Exaccord Tablets, 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 Exaccord Tablets.

### Taking other medicines

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

Some medicines should not be used with Exaccord Tablets. 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 Exaccord Tablets.

### How to Take Exaccord Tablets

Follow all directions given to you by your doctor and 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 Exaccord Tablets.

Do not stop taking Exaccord Tablets 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 Exaccord Tablets 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 (13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Exaccord Tablets.

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

Keep the telephone numbers for these places handy.

## While you are using Exaccord Tablets

Things you must do

Use Exaccord Tablets 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 Exaccord Tablets.

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

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

Things you must not do

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

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

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

Things to be careful of

Be careful driving or operating machinery, until you know how Exaccord Tablets affect you.

Exaccord Tablets may cause tiredness or dizziness in some people.

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

If Exaccord Tablets 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 Exaccord Tablets.

Exaccord Tablets, like other medicines, may cause unwanted side effects in some people. Many women can take Exaccord Tablets 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 Exaccord Tablets

### 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 Exaccord Tablets in a dry place where the temperature stays below 25°C.

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

### Do not store Exaccord Tablets or any other medicines in a bathroom or near a sink.

Heat and dampness can destroy some medicines.

### Keep Exaccord Tablets where children cannot reach it.

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

### Disposal

If your doctor tells you to stop taking Exaccord Tablets 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

Exaccord Tablets 25 mg - White to off-white, round, biconvex film-coated tablets debossed with 'E25' on one side and plain on the other.

Exaccord Tablets 25 mg tablets are available in blister packs of 15, 30 and 90 tablets.

### Ingredients

### **Active ingredient(s):**

Exaccord Tablets 25 mg - contain 25 mg of exemestane as the active ingredient.

#### Other ingredients:

Mannitol, Cellulose Microcrystalline, Crospovidone, Sodium starch Glycollate (Type A), Hypromellose, Polysorbate 80, Silica-colloidal anhydrous, Magnesium stearate and Opadry Complete Film Coating System 03B58900 White.

Name and Address of the Sponsor

#### **Accord Healthcare Pty Ltd.**

Unit 702/23, Queens Road, Melbourne, Victoria, 3004 Australia

Name and Address of the Distributor

### Ranbaxy Australia Pty Ltd

Suite 4.02, Building D, Level 4 12-24 Talavera Road North Ryde, NSW 2113 Australia

### **Exaccord Tablets 25 mg:**

AUST R No. 167856

### **Date of Approval**

TGA approval: 7th February 2011

This leaflet was prepared in April 2011.