

# EVISTA®

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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 taking EVISTA?

EVISTA contains the active ingredient raloxifene hydrochloride. EVISTA is used to prevent and treat osteoporosis in women after menopause. EVISTA is also used to reduce the risk of invasive breast cancer in women with osteoporosis after menopause and reduce the risk of invasive breast cancer in women at high risk of invasive breast cancer after menopause.

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

### 2. What should I know before I take EVISTA?

Do not use if you have ever had an allergic reaction to EVISTA 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 EVISTA?](#) in the full CMI.

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

Some medicines may interfere with EVISTA 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 take EVISTA?**

- The usual dose is one tablet per day, which can be taken at any time of the day.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking EVISTA.</li></ul>
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	<ul style="list-style-type: none"> <li>● It is important that you remember to take EVISTA daily and at the dose prescribed by your doctor.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not take EVISTA if you have not been through menopause.</li> <li>● Do not stop using this medicine without first checking with your doctor.</li> <li>● Do not give EVISTA to anyone else, your doctor has prescribed it specifically for you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● EVISTA has no known effect on driving or the ability to use machinery.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>● Keep your tablets in a cool, dry place where the temperature stays below 30°C.</li> <li>● Keep your tablets in the blister pack until it is time to take them.</li> <li>● Keep your medicine where young children cannot reach it.</li> </ul>

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

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

EVISTA may cause hot flushes, leg cramps, muscle spasms, swelling of hands, feet and legs, flu like symptoms. Serious side effects may be: severe pain or swelling in your legs, severe stomach pain, shortness of breath or pain on breathing, gall stones, blood clots, problems with your eyesight.

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.

# EVISTA®

**Active ingredient:** *raloxifene hydrochloride*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using EVISTA. **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 EVISTA.**

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

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

## 1. Why am I taking EVISTA?

**EVISTA contains the active ingredient raloxifene hydrochloride.** EVISTA belongs to a group of medicines called Selective Estrogen Receptor Modulators (SERMS). When a woman reaches menopause, the level of female sex hormone,

oestrogen, goes down. EVISTA mimics some of the beneficial effects of oestrogen after menopause.

**EVISTA is used to prevent and treat osteoporosis in women after menopause. It is also used to reduce the risk of invasive breast cancer in women with osteoporosis after menopause and reduce the risk of invasive breast cancer in women at high risk of invasive breast cancer after menopause.**

## **2. What should I know before I take EVISTA?**

### **Warnings**

#### **Do not use EVISTA if:**

- you are allergic to raloxifene hydrochloride, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine
- you have not been through menopause. EVISTA is only for use by women after menopause and must not be taken by women who could still have a baby
- you are being treated or have been treated for blood clots
- you are a male. EVISTA is not intended for use in men.

#### **Check with your doctor if you:**

- have any unexplained vaginal bleeding

- are at risk of blood clots
- are, or know you will be immobilised for some time, e.g., being wheelchair bound or having to stay in bed while recovering from an operation or illness
- have liver disease
- are intolerant to lactose. EVISTA contains a small amount of lactose (150 mg)
- have menopausal symptoms, such as hot flushes. EVISTA does not treat hot flushes
- are on oestrogen or hormone replacement therapy (HRT)
- have or have had high blood fats (triglycerides) caused by oestrogen
- have previously had a stroke, or if you have ever had other risk factors for stroke such as a mini-stroke (transient ischaemic attack) or a type of irregular heartbeat called atrial fibrillation
- have had breast cancer. EVISTA has not been fully studied in women who have a history of breast cancer. Before starting and while taking EVISTA you should have breast examinations and mammograms, as directed by your doctor. EVISTA does not eliminate the chance of developing breast cancers, you need these examinations to find any breast cancers as early as possible.

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**

EVISTA is only for use by women after menopause and must not be taken by women who could still have a baby.

Check with your doctor if you are pregnant or intend to become pregnant.

You **must** tell your doctor if you are breastfeeding or intend to breastfeed.

## **Impaired liver function**

The use of EVISTA is not recommended in this patient population.

## **Use in men**

EVISTA is not intended for use in men.

## **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.

Some medicines may interfere with EVISTA and affect how it works. These include:

- medicines for your heart such as digitalis drugs (e.g. digoxin) or blood thinning drugs such as warfarin.



Your doctor may need to adjust the dose of these medicines.

- hormone replacement therapy (HRT) or oestrogens.
- lipid-lowering drugs including cholestyramine.

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

## **4. How do I take EVISTA?**

### **How much to take**

- The usual dose of EVISTA is one tablet per day.
- For maximum benefit, EVISTA is intended for long-term use.
- Follow the instructions provided and use EVISTA until your doctor tells you to stop.

### **When to take EVISTA**

- It does not matter what time of day you take your tablet. However, it is best to take it at the same time each day as this will help you remember to take it.
- The days of the week are printed on the blister foil to help you remember to take your tablet each day.

### **How to take EVISTA**

- EVISTA tablets should be swallowed whole with a glass of water.

- When prescribed for the treatment or prevention of osteoporosis, EVISTA should be taken in conjunction with supplementary calcium if daily calcium intake is inadequate.
- You may take EVISTA with or without food.

## **If you forget to take EVISTA**

Evista should be used regularly at the same time each day.

**If you miss your dose at the usual time, and 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, then go back to taking EVISTA as you would normally.**

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

## **If you take too much EVISTA**

If you think that you have taken too much EVISTA, you may need urgent medical attention.

### **You should immediately:**

- phone the Australian Poisons Information Centre (**by calling 13 11 26**) or the New Zealand National Poisons Centre (**by calling 0800 POISON or 0800 764 766**), 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 taking EVISTA?**

### **Things you should do**

- It is important that you remember to take EVISTA daily and at the dose prescribed by your doctor.
- If you become pregnant while taking EVISTA, tell your doctor.

Tell your doctor if you are immobilized for some time, e.g., being wheelchair bound or having to stay in bed while recovering from an operation or illness.

If you are going on a long plane or car trip, you should move about periodically.

Tell your doctor if you have any vaginal bleeding.

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

- have severe pain or swelling in your legs
- have severe stomach pain
- have shortness of breath or pain on breathing
- have problems with your eyesight.

Remind any doctor, dentist or pharmacist you visit that you are taking EVISTA.

## **Things you should not do**

Do not stop using this medicine without first talking to your doctor.

Do not give EVISTA to anyone else, your doctor has prescribed it specifically for you.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how EVISTA affects you.** EVISTA has no known effect on driving or the ability to use machinery.

## **Looking after your medicine**

- Store below 30°C.
- Keep your tablets in the blister until it is time to take them.

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

Store it in a cool, dry place away from moisture, heat or sunlight; 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

There will be an expiry date (month, year) on your EVISTA pack.

The medicine should not be taken after this date because it may have lost some of its strength.

## Getting rid of any unwanted medicine

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

## 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>General symptoms:</b></p> <ul style="list-style-type: none"><li>• leg cramps</li><li>• swelling of hands, feet and legs</li><li>• flu-like symptoms</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● infection</li> <li>● headache</li> <li>● fever</li> <li>● chest pain</li> <li>● breast pain</li> </ul> <p><b>Cardiovascular:</b></p> <ul style="list-style-type: none"> <li>● hot flushes</li> <li>● migraine</li> <li>● passing out</li> <li>● twisted or enlarged veins</li> </ul> <p><b>Digestive system:</b></p> <ul style="list-style-type: none"> <li>● nausea</li> <li>● diarrhoea</li> <li>● upset stomach</li> <li>● vomiting</li> <li>● flatulence</li> </ul> <p><b>Metabolic and nutritional:</b></p> <ul style="list-style-type: none"> <li>● weight gain</li> </ul> <p><b>Musculoskeletal:</b></p> <ul style="list-style-type: none"> <li>● muscle ache</li> <li>● muscle spasms</li> <li>● joint pain and/or swelling</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Inflammation or irritation of tendon</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>● depression</li> <li>● difficulty sleeping</li> <li>● vertigo</li> <li>● severe pain anywhere in body</li> <li>● reduced sensibility to touch</li> </ul> <p><b>Respiratory system:</b></p> <ul style="list-style-type: none"> <li>● congested nose, runny nose, sneezing and itching</li> <li>● sore throat, wheezing and wet cough</li> <li>● hoarseness</li> </ul> <p><b>Skin and appendages:</b></p> <ul style="list-style-type: none"> <li>● rash</li> <li>● sweating</li> </ul> <p><b>Eye-related:</b></p> <ul style="list-style-type: none"> <li>● eye inflammation (including redness, swelling and itching)</li> </ul> <p><b>Urinary system:</b></p>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● inflammation of the vagina</li> <li>● urinary tract infection (UTI)</li> <li>● bladder infection</li> <li>● yellowish/greenish discharge from vagina</li> <li>● pain while urinating or passing stool</li> <li>● uterine disorder</li> </ul> vaginal bleeding	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>General symptoms:</b></p> <ul style="list-style-type: none"> <li>● severe pain or swelling in your legs</li> <li>● severe stomach pain</li> <li>● shortness of breath or pain on breathing, fever chills (symptoms of pneumonia)</li> </ul> <p><b>Cardiovascular:</b></p> <ul style="list-style-type: none"> <li>● blood clots</li> </ul> <p><b>Digestive system:</b></p>	<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>
<ul style="list-style-type: none"> <li>● gall stones</li> </ul> <p><b>Eye-related:</b></p> <ul style="list-style-type: none"> <li>● problems with your eyesight</li> <li>● pain or redness of the eyes</li> </ul>	

In clinical trials of EVISTA, some women experienced blood clots in the veins (venous thromboembolic events). This occurred in less than 1% of EVISTA patients. This is a serious side effect. You may need urgent medical attention or hospitalization.

**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 EVISTA contains

<b>Active ingredient (main ingredient)</b>	raloxifene hydrochloride
<b>Other ingredients (inactive ingredients)</b>	lactose lactose monohydrate povidone polysorbate 80 crospovidone magnesium stearate colour mixture white YS-1-18027-A carnauba wax trace amounts of Edible Blue Ink: Opacode Blue S-1-10537G (PI 3536) and Opacode S-1-10537G (PI 3535)
<b>Potential allergens</b>	contains sugars as lactose

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

## **What EVISTA looks like**

EVISTA is a white film coated oval tablet. Each EVISTA tablet has the identicode number '4165' printed on it in blue ink (Aust R 64709).

In Australia EVISTA tablets are available in blister packs containing 7 (sample pack) and 28 tablets.

In New Zealand EVISTA tablets are available in blister packs containing 28 tablets.

## **Who distributes EVISTA**

EVISTA is distributed in Australia by:

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney, NSW 2000

AUSTRALIA

Phone: 1800 454 559

EVISTA is distributed in New Zealand by:

Eli Lilly and Company (NZ) Limited

PO Box 109 197, Newmarket

Auckland

NEW ZEALAND

Phone: 0800 500 056

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