

# APO-Letrozole

Contains the active ingredient letrozole

## Consumer Medicine Information

For a copy of a large print leaflet,  
Ph: 1800 195 055

### What is in this leaflet

#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about letrozole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

### What this medicine is used for

The name of your medicine is APO-Letrozole. It contains the active ingredient letrozole.

It is used to treat breast cancer in women who are post-menopausal - that is, women who no longer have periods, either naturally due to their age or after surgery or chemotherapy.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

#### How it works

Letrozole belongs to a family of medicines called aromatase inhibitors. They are also called "antioestrogens" because they act by reducing the production of oestrogen in your body.

Oestrogen stimulates the growth of certain types of breast cancer. These cancers are called "oestrogen-dependant." Reducing the production of oestrogen may help keep the cancer from growing. This may be the first time you are taking an "antioestrogen" or you may have taken another "antioestrogen" such as Tamoxifen in the past.

There is no evidence that this medicine is addictive.

#### Use in children

This medicine should not be used in children.

### Before you take this medicine

#### When you must not take it

#### Do not take this medicine if:

- **You are pregnant.**  
Letrozole may affect your developing baby if you take it during pregnancy.
- **You are breast-feeding.**  
Letrozole may pass into human breast milk.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to Letrozole or any of the ingredients listed at the end of this leaflet.**  
Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting or hayfever-like symptoms.
- **If you think you are having an allergic reaction do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **Do not take letrozole if you are still having periods. This medicine is only used in women who are no longer having periods.**

- **Women of child-bearing age who recently became postmenopausal or perimenopausal should use a proven method of birth control to avoid pregnancy, until your postmenopausal status is fully established.**

### *Before you start to take it*

#### **Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - kidney disease
  - liver disease
 Your doctor may want to take special precautions while you are taking this medicine.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breast-feeding or you plan to breastfeed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with letrozole. These include:

- Medicines dependant on cytochrome P450 2A6 and 2C19 isoenzymes.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with letrozole.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

### *How much to take*

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

### *How to take it*

The recommended dose of letrozole is one tablet daily.

### *When to take it*

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

### *How long to take it for*

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

### *If you forget to take it*

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

#### **Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

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

### *If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## While you are taking this medicine

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### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### *Things you must not do*

#### **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

### *Things to be careful of*

Be careful when driving or operating machinery until you know how this medicine affects you.

Letrozole may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

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## **Possible side effects**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking letrozole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Tell your doctor or pharmacist if you notice any of the following and they worry you.**

This list includes the more common side effects. Mostly, these are mild:

- Headache

- Dizziness
- Nausea
- Vomiting
- Constipation
- Diarrhoea
- Fatigue
- Indigestion
- Cough
- Mood changes such as depression, anxiety, irritability, drowsiness
- High blood cholesterol
- Hair loss
- Muscle and bone pain
- Osteoporosis
- Bone fractures
- Constant "flu-like" symptoms
- Increased sweating
- Hot flushes
- Vaginal discharge or bleeding
- Anorexia
- Appetite increase
- Weight increase or loss
- Abdominal pain
- Needing to urinate more often
- Urinary tract infection
- Breast pain
- Tumour pain (in metastatic setting only)
- Low white cell count
- General swelling
- Unpleasant or abnormal sense of touch e.g. pins and needles, numbness, burning sensation
- Taste disturbance
- Insomnia
- Memory impairment
- Cataract
- Eye irritation
- Blurred vision
- Fast or irregular heartbeat
- High blood pressure
- Shortness of breath
- Increased liver enzymes
- Mucosal dryness
- Inflamed sore mouth
- Dry mouth
- Thirst
- Dry skin
- Itchiness

- Hives or rash
- Joint pain
- Arthritis

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- Severe allergic reaction
- Yellow skin and eyes, nausea, loss of appetite, dark coloured urine (signs of hepatitis)
- Swelling of the feet, ankles or other parts of the body due to fluid build-up
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder)
- Signs a blood clot may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood, rapid heartbeat, bluish skin discoloration, fainting.
- Crushing chest pain or sudden arm or leg (foot) pain (signs of a heart attack)

Other side effects not listed above may occur in some patients.

### *Allergic reactions*

**If you think you are having an allergic reaction to letrozole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and disposal

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### Storage

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 25°C.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.** Heat and dampness can destroy some medicines.

**Keep this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### *What APO-Letrozole tablets look like*

- **2.5mg Tablet:**  
Dark yellow, round, biconvex, film-coated tablets. Engraved "APO" on one side, "LET" over "2.5" on the other side.

They are available in blister packs of 10 or 30 tablets and bottles of 30, 100 or 500 tablets.

\* Not all strengths, pack types and/or pack sizes may be available.

### *Ingredients*

Each tablet contains 2.5mg of letrozole as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- cellulose microcrystalline
- sodium starch glycolate
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide yellow

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

### *Australian Registration Numbers*

- APO-Letrozole 2.5mg tablets (blister pack):  
AUST R 163826
- APO-Letrozole 2.5mg tablets (bottle):  
AUST R 163830

### *Sponsor*

**Apotex Pty Ltd**  
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