

APO-TIBOLONE

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.

1. Why am I using APO-TIBOLONE?

APO-TIBOLONE contains the active ingredient tibolone, which is a synthetic steroid medicine, used for Hormone Replacement Therapy (HRT). APO-TIBOLONE is used to help relieve symptoms occurring after menopause and for the prevention of osteoporosis.

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

2. What should I know before I use APO-TIBOLONE?

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

3. What if I am taking other medicines?

Some medicines may interfere with APO-TIBOLONE 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 APO-TIBOLONE?

- Take APO-Tibolone as directed by your doctor. You should also read the instructions given in this leaflet for your medicine.
- Take one tablet daily, at about the same time each day. Swallow the tablet with some water or other non-alcoholic drink.

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

5. What should I know while using APO-TIBOLONE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-TIBOLONE.• See your doctor for regular check-ups (at least once a year) and go for regular breast screening, as recommended by your doctor.• If you notice any changes in your own health, or any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist as soon as possible.
Things you should not do	<ul style="list-style-type: none">• APO-Tibolone should not be taken until 12 months after your last natural menstrual bleeding, as the chance of irregular bleeding may be increased• Do not take APO-TIBOLONE if you are pregnant or think you may be pregnant, or breast-feeding.
Driving or using machines	<ul style="list-style-type: none">• As far as is known, APO-TIBOLONE has no effect on alertness and concentration.
Looking after your medicine	<ul style="list-style-type: none">• Store APO-TIBOLONE in the original packaging, below 25°C, in a cool, dry place and protect from light and moisture.• Keep APO-TIBOLONE in a safe place out of the reach of children.

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

6. Are there any side effects?

The most common side effects are vaginal bleeding or spotting, abdominal pain, weight gain, breast pain, unnatural hair growth, vaginal symptoms such as discharge, itching and irritation. Serious side effects include ovarian and breast cancer, increased cell growth or cancer in the lining of the womb, blood clots in the veins or lungs and heart disease.

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.

APO-TIBOLONE

Active ingredient: *tibolone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-TIBOLONE. **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 APO-TIBOLONE.**

Where to find information in this leaflet:

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

1. Why am I using APO-TIBOLONE?

APO-TIBOLONE contains the active ingredient tibolone, which is a synthetic steroid medicine used for hormone replacement therapy (HRT). It mimics the activity of the female sex hormones in the body.

APO-TIBOLONE contains tibolone, a substance that has favourable effects on different tissues in the body, such as brain, vagina and bone.

APO-TIBOLONE is used in postmenopausal women at least 12 months since their last natural period.

APO-TIBOLONE is used for:

- Relief of symptoms occurring after menopause**

During the menopause, the amount of estrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). APO-TIBOLONE alleviates these symptoms after menopause. You will only be prescribed APO-TIBOLONE if your symptoms seriously hinder your daily life.

- Prevention of osteoporosis**

After the menopause some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor.

If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can take APO-TIBOLONE to prevent osteoporosis after menopause.

APO-TIBOLONE is not a contraceptive.

A doctor's prescription is required to obtain this medicine.

2. What should I know before I use APO-TIBOLONE?

Warnings

Do not use APO-TIBOLONE if:

- you are pregnant or think you may be pregnant
- you are breastfeeding
- you have or have ever had breast cancer, or if you are suspected of having it
- you have cancer which is sensitive to estrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- you have any unexplained vaginal bleeding
- you have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- you have or have ever had a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency)
- you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- you have or have ever had liver disease and your liver function tests have not returned to normal
- you have a rare blood problem called porphyria which is passed down in families (inherited)
- you are allergic (hypersensitive) to tibolone or any of the ingredients of APO-TIBOLONE listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or troubled breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If any of the above conditions appear for the first time while taking APO-TIBOLONE, stop taking it at once and consult your doctor immediately.

Check with your doctor if you:

- have ever had any of the following conditions before you start the treatment, as these may return or become worse during treatment with APO-TIBOLONE. If so, you should see your doctor more often for check-ups:
 - fibroids inside your womb
 - growth of the womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)

- increased risk of developing blood clots (see Section [5. What should I know while using APO-TIBOLONE?](#), "Blood clots in a vein (thrombosis)")
- increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems

Tell your doctor if you react badly to lactose or milk before you start taking APO-TIBOLONE.

APO-TIBOLONE contains lactose.

Tell your doctor if you notice any change in your condition whilst using APO-TIBOLONE.

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

Talk to your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

APO-TIBOLONE is for use in postmenopausal women only. If you are pregnant or breast-feeding or think you may be pregnant, do not take APO-TIBOLONE.

Medical history and regular check-ups

As well as benefits, HRT or APO-TIBOLONE has some risks which need to be considered when deciding whether to starting taking it, or whether to carry on taking it.

The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT or APO-TIBOLONE may be different. Please talk to your doctor.

Before you start (or restart) HRT or APO-TIBOLONE, your doctor will ask you about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Once you have started on APO-TIBOLONE, you should see your doctor for regular check-ups (at least once a year). At

these check-ups, discuss with your doctor the benefits and risks of continuing with APO-TIBOLONE.

Go for regular breast screening, as recommended by your doctor.

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 APO-TIBOLONE and affect how it works.

This applies to the following medicines:

- medicines against blood clotting (such as warfarin)
- medicines for epilepsy (such as phenobarbitone, phenytoin and carbamazepine)
- medicines for tuberculosis (such as rifampicin)
- herbal remedies containing St John's Wort (*hypericum perforatum*)

Your doctor may need to adjust the dose of these medicines. Ask your doctor or pharmacist for advice before taking any medicine.

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

4. How do I use APO-TIBOLONE?

When to start it

- APO-TIBOLONE should not be taken until 12 months after your last natural menstrual bleed. If APO-TIBOLONE is taken sooner than this, the chance of irregular vaginal bleeding may be increased.
- Women who have undergone premature menopause (surgical removal of ovaries) can start taking APO-TIBOLONE immediately.
- If you are already using a different type of HRT, your doctor will advise you when to switch to APO-TIBOLONE.

How to take it

- **Take APO-TIBOLONE as directed by your doctor. You should also read the instructions given in this leaflet for your medicine. If you are not sure how to take APO-TIBOLONE ask your doctor or pharmacist.**
- Take one tablet daily, at about the same time each day. Swallow the tablet with some water or other non-alcoholic drink.
- The APO-TIBOLONE pack contains 28 white tablets. The strips with APO-TIBOLONE are marked with the days of the week. Start by taking the tablet marked with that day. For example, if it is a Monday, take a tablet marked Monday on the upper row of the strip. Follow the days of the week until the strip is empty. Start the next strip the next day.
- **Do not leave a break between strips or packs.**

How long to take APO-TIBOLONE

- HRT should be prescribed at the lowest effective dose and for the shortest duration necessary. Your doctor can advise you how long you may need to take APO-TIBOLONE.

If you forget to use APO-TIBOLONE

If you forget to take a tablet, take it as soon as you remember, unless you are more than 12 hours late. If you are more than 12 hours late, 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 forgotten dose.

If you use too much APO-TIBOLONE (overdose)

If you think that you have used too much APO-TIBOLONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

Signs of an overdose may include feeling sick or vomiting. Vaginal bleeding may also occur after a few days.

5. What should I know while using APO-TIBOLONE?

Things you should do

- **Tell your doctor and your surgeon that you are taking APO-TIBOLONE if you are going to have surgery.**

You may need to stop taking APO-TIBOLONE, about 4-6 weeks before the operation to reduce the risk of a blood clot (see section below "Blood clots in a vein"). Ask your doctor when you can start taking APO-TIBOLONE again.

Stop taking APO-TIBOLONE and see a doctor immediately if you notice any of the following when taking HRT or APO-TIBOLONE:

- Any of the conditions mentioned in [Section 2. What should I know before I use APO-TIBOLONE?](#) "Do not take APO-TIBOLONE if".
- Yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
 - painful swelling and redness of the legs
 - sudden chest pain
 - difficulty in breathing
 - For more information, see section below "Blood clots in a vein (thrombosis)"

HRT and Cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer).

There have been reports and studies of an increased cell growth or cancer of the lining of the womb in women using APO-TIBOLONE. The risk of cancer of the lining of the womb increases with the duration of use.

Irregular bleeding

You may have irregular bleeding or drops of blood (spotting) during the first 3-6 months of taking APO-TIBOLONE. However, if the irregular bleeding:

- carries on for more than the first 6 months
- starts after you have been taking APO-TIBOLONE for more than 6 months
- carries on after you have stopped taking APO-TIBOLONE **see your doctor as soon as possible.**

Breast Cancer

Taking estrogen, estrogen-progesterone combined HRT or APO-TIBOLONE for several years increases the risk of breast cancer. The risk increases with the duration of HRT use and returns to normal within about 5 years after stopping HRT.

Women taking APO-TIBOLONE have a lower risk than women using combined HRT and a comparable risk with estrogen-only HRT.

Regularly check your breasts. See your doctor if you notice any changes such as:

- dimpling or sinking of the skin
- changes in the nipple
- any lumps you can see or feel

Ovarian Cancer

Ovarian cancer is rare. An increased risk of ovarian cancer has been reported in women taking HRT after 5 years of use.

For women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be 1 extra case per 2000 users. With use of APO-TIBOLONE, the increased risk of ovarian cancer for women taking APO-TIBOLONE for 5 years is 1 extra case per 2500 users.

Effects of HRT on heart or circulation

Heart disease (heart attack)

There is no evidence that HRT or APO-TIBOLONE will prevent a heart attack.

Women over the age of 60 who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT. As the risk of heart disease strongly depends on age, the number of extra cases of heart disease due to use of estrogen-progestogen HRT is

very low in healthy women close to menopause, but will rise with more advanced age.

There is no evidence to suggest that the risk of myocardial infarction with APO-TIBOLONE is different to the risk of other HRT.

See a doctor as soon as possible and do not take any more APO-TIBOLONE if you get a pain in your chest that spreads to your arm or neck.

This pain could be a sign of heart disease.

Stroke

Recent research suggests that HRT and APO-TIBOLONE increases the risk of having a stroke. This increased risk has mainly been observed in elderly postmenopausal women above 60 years of age.

Looking at women in their 50s who are not taking APO-TIBOLONE - on average, over a 5-year period, 3 in 1000 would be expected to have a stroke. For women in their 50s who are taking APO-TIBOLONE, the figure would be 7 in 1000 (i.e. an extra 4 cases).

Looking at women in their 60s who are not taking APO-TIBOLONE - on average, over a 5-year period, 11 in 1000 would be expected to have a stroke. For women in their 60s who are taking APO-TIBOLONE, the figure would be 24 in 1000 (i.e. an extra 13 cases).

If you are worried about any of these things, or if you have had a stroke in the past, talk to your doctor to see if you should take APO-TIBOLONE.

See a doctor as soon as possible and do not take any more APO-TIBOLONE until your doctor says you can if you get any unexplained migraine-type headaches with or without disturbed vision.

These headaches may be an early warning sign of a stroke.

Blood clots in a vein (Thrombosis)

Estrogen and estrogen-progestogen combined HRT may increase the risk of blood clots in the veins (also called deep vein thrombosis, or DVT), especially during the 1st year of taking it. It is unknown if APO-TIBOLONE increases the risk in the same way.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death. You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations apply to you:

- you are pregnant or recently had a baby
- you use estrogens
- you are unable to walk for a long time because of major surgery, injury or illness (see also above "Tell your doctor... if you are going to have surgery")
- you are seriously overweight (BMI greater than 30kg per square metre)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ

- you have systemic lupus erythematosus (SLE, a disease of your immune system)
- you have cancer

If any of these apply to you, talk to your doctor about whether you should use APO-TIBOLONE.

For signs of a blood clot, see section above "Stop taking APO-TIBOLONE and see a doctor immediately if...".

Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.

For women in their 50s who have been taking estrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

With use of APO-TIBOLONE, the increased risk of getting a blood clot in a vein is lower than with other types of HRT.

Other conditions

HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Driving or using machines

APO-TIBOLONE has no effect on alertness and concentration as far as is known.

Looking after your medicine

- Keep your APO-TIBOLONE tablets in the original package in a cool dry place where the temperature stays below 25°C.
- Do not use after the expiry date stated on the blister and outer box.

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.

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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-TIBOLONE.

APO-TIBOLONE helps most women with menopausal symptoms, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<p>Common side effects observed in clinical studies (occurring in 1-10% of using APO-TIBOLONE) were:</p> <ul style="list-style-type: none"> • Vaginal bleeding or spotting • Abdominal pain • Weight gain • Breast pain • Unnatural hair growth • Vaginal symptoms, such as discharge, itching, and irritation <p>Uncommon side effects (occurring in 0.1-1% of the women using APO-TIBOLONE) were:</p> <ul style="list-style-type: none"> • Acne <p>Other side effects observed with APO-TIBOLONE in market use were:</p> <ul style="list-style-type: none"> • Dizziness, headache, migraine, depression • Rash or itching • Visual disturbances • Gastro-intestinal upset • Fluid retention • Joint pain, muscle pain • Changes in liver function 	<p>Speak to your doctor if vaginal bleeding or spotting occurs or if any of these side effects worry you or continue.</p>

Serious side effects

Serious side effects	What to do
<p>Please see Section 5. What should I know while using APO-TIBOLONE?, for conditions where APO-TIBOLONE should be stopped.</p>	<p>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.</p>

There have been reports of breast cancer and of an increased cell growth or cancer of the lining of the womb in women using APO-TIBOLONE.

The following diseases are reported more often in women using HRT compared to women not using HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke

- probable memory loss if HRT is started over the age of 65

The following side effects have been reported with other HRT's:

- gall bladder disease
- various skin disorders:
 - discolouration of the skin especially of the face or neck known as "pregnancy patches" (chloasma)
 - painful reddish skin nodules (erythema nodosum)
 - rash with target-shaped reddening or sores (erythema multiforme)

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. 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 APO-TIBOLONE contains

Active ingredient (main ingredient)	Tibolone 2.5mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • potato starch • lactose monohydrate • ascorbyl palmitate • lactose anhydrous • magnesium stearate
Potential allergens	lactose

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

Do not use the product if the blister pack or tablets are damaged or appear unusual.

What APO-TIBOLONE looks like

Packs contain 28 white round flat tablets with bevelled edges. The tablets are debossed with 'TO' above '2' on one side and plain on other side (Aust R 283952).

Who distributes APO-TIBOLONE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street Cremorne,
VIC 3121
www.arrotex.com.au

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