

TIBOLONE SANDOZ

contains the active ingredient tibolone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TIBOLONE SANDOZ.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TIBOLONE SANDOZ against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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

What TIBOLONE SANDOZ is used for

TIBOLONE SANDOZ tablets contain 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.

TIBOLONE SANDOZ contains tibolone, a substance that has a favourable effects on different tissues in the body, such as brain, vagina and bone. TIBOLONE SANDOZ is used in postmenopausal women at least 12 months since their last natural period.

TIBOLONE SANDOZ 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"). Tibolone alleviates these symptoms after menopause. You will only be prescribed TIBOLONE SANDOZ 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 TIBOLONE SANDOZ to prevent osteoporosis after menopause.

TIBOLONE SANDOZ is not a contraceptive.

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

TIBOLONE SANDOZ is available only with a doctor's prescription.

Before you use TIBOLONE SANDOZ

When you must not take it

Do not take TIBOLONE SANDOZ if you have:

- 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 TIBOLONE SANDOZ 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 TIBOLONE SANDOZ stop taking it at once and consult your doctor immediately.

Do not take TIBOLONE SANDOZ if the expiry date (Exp.) printed on the pack has passed.

Do not take TIBOLONE SANDOZ if the packaging is torn or shows signs of tampering.

Medical history and regular check-ups

As well as benefits, HRT or TIBOLONE SANDOZ has some risks which need to be considered when deciding whether to start 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 TIBOLONE SANDOZ may be different. Please talk to your doctor.

Before you start (or restart) HRT or TIBOLONE SANDOZ, 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 TIBOLONE SANDOZ, 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 TIBOLONE SANDOZ.

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

When to take special care with TIBOLONE SANDOZ

Tell 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 TIBOLONE SANDOZ. 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 "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 notice any change in your condition whilst using TIBOLONE SANDOZ.

- Any of the conditions mentioned in the "Don not take TIBOLONE SANDOZ" section
- 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 headiness 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, "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 TIBOLONE SCP. 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 TIBOLONE SANDOZ.

However, if the irregular bleeding:

- carries on for more than the first 6 months
- starts after you have been taking TIBOLONE SANDOZ for more than 6 months
- carries on after you have stopped taking TIBOLONE SANDOZ

see your doctor as soon as possible.

Breast Cancer

Taking estrogen, estrogen-progesterone combined HRT or TIBOLONE SANDOZ for several years slightly 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 TIBOLONE SANDOZ 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. A slightly increased risk of ovarian cancer has been reported in women taking HRT for at least 5 to 10 years.

For women aged 50 to 69 who are not taking HRT, on average about 2 women in 1000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be between 2 and 3 cases per 1000 users (i.e. up to 1 extra case).

With use of TIBOLONE SANDOZ, the increased risk of ovarian cancer is similar to other types of HRT.

Effects of HRT on heart or circulation

Heart disease (heart attack)

There is no evidence that HRT or TIBOLONE SANDOZ 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 TIBOLONE SANDOZ is different to the risk of other HRT.

See a doctor as soon as possible and do not take any more TIBOLONE SANDOZ 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 TIBOLONE SANDOZ 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 TIBOLONE SANDOZ - 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 TIBOLONE SANDOZ, the figure would be 7 in 1000 (i.e. an extra 4 cases).

Looking at women in their 60s who are not taking TIBOLONE SANDOZ - 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 TIBOLONE SANDOZ, 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 TIBOLONE SANDOZ.

See a doctor as soon as possible and do not take any more TIBOLONE SANDOZ 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 TIBOLONE SANDOZ 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 "If you need 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 TIBOLONE SANDOZ.

For signs of a blood clot, see "Stop taking TIBOLONE SANDOZ and see a doctor immediately".

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 TIBOLONE SANDOZ, 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.

Tell your doctor if you become pregnant or are breast-feeding.

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

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

TIBOLONE SANDOZ tablets contain lactose.

Taking other medicines

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

Some medicines may be affected by TIBOLONE SANDOZ, or may affect how well it works. These include:

- 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 can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking TIBOLONE SANDOZ.

How to take TIBOLONE SANDOZ

When to start it

TIBOLONE SANDOZ should not be taken until 12 months after your last natural menstrual bleed. If TIBOLONE SANDOZ 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 TIBOLONE SANDOZ immediately.

If you are already using a different type of HRT, your doctor will advise you when to switch to TIBOLONE SANDOZ.

How much to take

Take one tablet daily, at about the same time each day.

Your doctor may advise you to take a different dose. This depends on your condition and whether or not you are taking any other medicines.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take TIBOLONE SANDOZ

Swallow the tablets with a glass of water or other non-alcoholic drink.

Do not crush or chew the tablets. If you crush or chew TIBOLONE SANDOZ tablets, they will not work as well.

If you forget to take TIBOLONE SANDOZ

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 are not sure what to do, ask your doctor or pharmacist.

How long to take TIBOLONE SANDOZ for

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 TIBOLONE SANDOZ.

If you take too much TIBOLONE SANDOZ (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much TIBOLONE SANDOZ. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

If you need to have surgery

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

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

Side effects

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

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

TIBOLONE SANDOZ 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 lists of side effects. You may not experience any of them.

Common side effects observed in clinical studies (occurring in 1-10% of the women using TIBOLONE SANDOZ) were:

- vaginal bleeding or spotting
- abdominal pain
- weight gain
- breast pain
- unnatural hair growth
- vaginal symptoms, such as discharge, itching, and irritation

Uncommon side effects observed in clinical studies (occurring in 1-10% of the women using TIBOLONE SANDOZ) were:

- acne

Other side effects observed with TIBOLONE SANDOZ in market use were:

- dizziness, headache, migraine, depression
- rash or itching
- visual disturbances
- gastro-intestinal upset
- fluid retention
- joint pain, muscle pain
- changes in liver function

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

Tell your doctor if vaginal bleeding or spotting occurs or if any of the above mentioned side effects worry you or continue.

Please see "Medical history and regular check-ups" for conditions where Livial should be stopped.

The following side effects have been reported with other HRTs:

- 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)

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using TIBOLONE SANDOZ

Storage

Keep TIBOLONE SANDOZ 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.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store TIBOLONE SANDOZ or any other medicine in the bathroom or near a sink.

Do not leave TIBOLONE SANDOZ in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking TIBOLONE SANDOZ, or your tablets have passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

TIBOLONE SANDOZ is a white to off-white round tablet without any markings.

Each blister pack contains 28 tablets.

Ingredients

The active ingredient in TIBOLONE SANDOZ is tibolone. Each TIBOLONE SANDOZ tablet contains 2.5 mg of tibolone.

The tablet also contains:

- lactose monohydrate
- mannitol
- potato starch
- magnesium stearate
- ascorbyl palmitate.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Southern Cross Pharma Pty Ltd
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Hawthorn, Victoria 3122
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Distributor

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Australian registration numbers:

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