

PACKAGE LEAFLET

Package leaflet: Information for the patient

Tibelia 2.5 mg tablets

tibolone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [(Invented) name] is and what it is used for
2. What you need to know before you take [(Invented) name]
3. How to take [(Invented) name]
4. Possible side effects
5. How to store [(Invented) name]
6. Contents of the pack and other information

1. What [(Invented) name] is and what it is used for

This medicine is a Hormone Replacement Therapy (HRT). It contains tibolone, a substance that has favourable effects on different tissues in the body, such as brain, vagina and bone.

This medicine is used in postmenopausal women with at least 12 months since their last natural period.

This medicine is used for:

Relief of symptoms occurring after menopause

During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). [(Invented) name] alleviates these symptoms after menopause. You will only be prescribed [(Invented) name] 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 use [(Invented) name] to prevent osteoporosis after menopause.

There are three different kinds of HRT:

- Oestrogen-only HRT
- Combined HRT, containing two kinds of female hormone, an oestrogen and a progestogen.
- [(Invented) name], which contains a substance called tibolone

[(Invented) name] is different from other HRT. Instead of actual hormones (such as oestrogen and progestogen) it contains tibolone. Your body breaks down tibolone to make hormones.

Its effects and benefits are similar to combined HRT.

2. What you need to know before you take [(Invented) name]

Medical history and regular check-ups

The use of HRT carries 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 may be different. Please talk to your doctor.

Before you start (or restart) HRT, your doctor will ask 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.

Tell your doctor if you have any medical problems or illnesses.

Regular check-ups

Once you have started on [(Invented) name] 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 [(Invented) name].

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

Be sure to:

- go for regular breast screening and cervical smear tests
- regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

Do not take [(Invented) name]:

- If you have or have ever had **breast cancer**, or if you are suspected of having it;
- If you have **cancer which is sensitive to oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it;
- If you have any **unexplained vaginal bleeding**;
- If you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated;
- If 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);
- If you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency);
- If you have or recently have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke or angina**;
- If you have or have ever had a **liver disease** and your liver function tests have not returned to normal;
- If you have a **rare blood problem** called "porphyria" which is passed down in families (inherited);
- If you are **allergic** to tibolone or any of the other ingredients of [(Invented) name] (listed in section 6);

If you are not sure about any of the points above, **talk to your doctor** before taking [(Invented) name].

If any of the above conditions appears for the first time while taking [(Invented) name], stop taking it at once and consult your doctor immediately.

Warnings and precautions

Talk to your doctor or pharmacist before taking tibolone.

As well as benefits, HRT has some risks which you need to consider when you are deciding whether to take it, or whether to carry on taking it.

Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with [(Invented) name]. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb;
- growth of 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 a oestrogen-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;

Stop taking [(Invented) name] and see a doctor immediately

If you notice any of the following when taking HRT:

- any of the conditions mentioned in the 'DO NOT take [(Invented) name] ' 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 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 'Blood clots in a vein (thrombosis)'.

Note: Tibolone is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

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 of an increased cell growth or cancer of the lining of the womb in women using tibolone. The risk of cancer of the lining of the womb increases the longer you take the medicine.

Irregular bleeding

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

- carries on for more than the first 6 months;
- starts after you have been taking [(Invented) name] for more than 6 months;
- carries on after you have stopped taking [(Invented) name];

→ **see your doctor as soon as possible.**

Breast cancer

Evidence shows that taking tibolone increases the risk of breast cancer. The extra risk depends on how long you use tibolone. In studies with HRT, after stopping HRT the extra risk decreased with time, but the risk may persist for 10 years or more when women have used HRT for more than 5 years.. No data for persistence of risk after stopping are available for tibolone, but a similar pattern cannot be ruled out.

Compare

Looking at women aged 50 to 79 who are not taking HRT, on average, 9 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 to 79 who are taking oestrogen-progestogen HRT over 5 years, there will be 13 to 23 cases in 1000 users (i.e. an extra 4 to 6 cases).

Women taking tibolone have a lower risk than women using combined oestrogen-progestogen HRT and a comparable risk with oestrogen-only HRT.

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

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

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer

Ovarian cancer is rare - much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in 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 about 3 cases per 2000 users (i.e. about 1 extra case).

With use of [Invented name], the increased risk of ovarian cancer is similar to other types of HRT.

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.

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 applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, if you need to have surgery);
- you are seriously overweight (BMI >30 kg/m²);
- 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);
- you have cancer;

For signs of a blood clot, see “Stop taking [(Invented) name] and see a doctor immediately”.

Compare

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

Heart disease (heart attack)

There is no evidence that HRT or tibolone will prevent a heart attack.

Women over the age of 60 years who use oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

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

Stroke

The risk of getting stroke is about 1.5 times higher in HRT and tibolone users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Other things that can increase the risk of stroke include:

- High blood pressure
- Smoking
- Drinking too much alcohol
- An irregular heartbeat

If you are worried about any of these things, talk to your doctor to see if you should take HRT.

Compare

Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

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.

[(Invented) name] is not intended for contraceptive use.

Oestrogens may cause fluid retention, and therefore patients with cardiac or renal dysfunction should be carefully observed.

Women with pre-existing hypertriglyceridaemia should be followed closely during oestrogen replacement or Hormone replacement therapy, since rare cases of large increases of plasma triglycerides leading to pancreatitis have been reported with oestrogen therapy in this condition.

Other medicines and [(Invented) name]

Some medicines may interfere with the effect of [(Invented) name]. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine);
- Medicines for **tuberculosis** (such as rifampicin, rifabutin);
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir);
- Medicines against **blood clotting** (such as warfarin);
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*);

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or other natural products.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking [(Invented) name], because this medicine can affect the results of some tests.

Tibolone with food and drink

You can eat or drink normally while you are taking [(Invented) name].

Pregnancy, breast-feeding and fertility

[(Invented) name] is for use in postmenopausal women only. If you become pregnant, stop taking [(Invented) name] and contact your doctor.

Driving and using machines

Tibolone is not known to have any effects on alertness and concentration.

[(Invented) name] contains lactose

The tablet contains 43.2 mg of lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take [(Invented) name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet every day.

Tibolone should be swallowed without chewing with some water.

Take your tablet at the same time every day.

The strips of tablets are marked with the days of the week. Start by taking a tablet marked with the current day. For example, if it is Monday, take a tablet marked “Mo” on the top row of the strip. Follow the arrows until the strip is empty. Start the next strip the next day. Do not leave a break between strips or packs.

Your doctor will aim to prescribe the lowest dose to treat your symptom for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.

You should not take tibolone until at least 12 months after your last natural menstrual bleed (period).

If you have had your womb and ovaries removed or are being treated with drugs known as gonadotrophin releasing hormone (GnRH) analogues, for conditions such as endometriosis, you can start taking tibolone immediately.

If you have never used HRT before, you can start taking tibolone straight away.

If you are changing over from another type of HRT

There are several different types of HRT, such as tablets, patches and gels. Most contain either oestrogen or an oestrogen and a progestogen. With some you have a period, and with some you do not (period-free HRT).

If you are changing over from another type of HRT where you have a period, start taking Tibolone as soon as your period ends.

If you are changing over from a period-free HRT you can start taking tibolone straight away. You can also start straight away if you are being treated for endometriosis.

Use in children and adolescents

Tibolone should not be taken by children.

If you take more [(Invented) name] than you should

It is unlikely that taking more than one tablet will do you any harm, but you may feel sick, be sick or have some vaginal bleeding.

If you forget to take 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, just skip the missed tablet and take your next tablet at the usual time.

Do not take a double dose.

If you need to have surgery

If you are going to have surgery, tell the surgeon that you are taking [(Invented) name]. You may need to stop taking [(Invented) name] about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2, Blood clots in a vein). Ask your doctor when you can start taking [(Invented) name] again.

If you stop taking tibolone

Do not stop taking tibolone because you feel better without first talking to your doctor. It is important to take the medicine for as long as the doctor has told you to. Otherwise the problem might come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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;

For more information about these side effects, see Section 2.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most side effects are mild.

Serious side effects – see a doctor straight away

If you think you may have signs of a serious side effect, see a doctor straight away.

You may need to stop taking [(Invented) name]:

- If your **blood pressure** rises
- If your skin or the whites of your eyes go yellow (**jaundice**)
- If you suddenly have **migraine**-type headaches (see section 2 above)
- If you have signs of a **blood clot** (see section 2 above)
- If you get any of the problems listed in section 2 (Do not take [(Invented) name])

Other side effects

Common (affect up to 1 in 10 women):

- breast pain
- stomach or pelvic pain
- unusual hair growth
- vaginal bleeding or spotting.

This is usually nothing to worry about in the first few months of taking HRT. If bleeding continues, or starts after you have been on HRT for a while, see Section 2 “Irregular Bleeding”.

- vaginal problems such as more secretions, itching, irritation
- inflammation of the vulva and vagina (vulvovaginitis)
- thrush (i. e. Candidiasis)
- thickening of the lining of the womb or the lining of the cervix
- Tissue changes in the cervix
- Abnormal cervical smear
- weight gain.

Uncommon (affects up to 1 in 100 women):

- swollen hands, ankles or feet – a sign of fluid retention
- stomach upset
- acne
- painful nipples or breasts feeling uncomfortable
- vaginal infections (mycosis)
- fungal infection

Rare (affects up to 1 in 1000 women):

- itchy skin

Some women taking [(Invented) name] have also reported:

- depression, dizziness, headache
- joint pain or muscle pain
- skin problems such as rash or itching
- loss of vision or blurred vision
- changes in liver tests

There have been reports of breast cancer and of an increased cell growth or cancer of the lining of the womb in women using [(Invented) name].

➔ Tell your doctor if any of the above mentioned side effects continues or becomes troublesome.

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).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V*](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [(Invented) name]

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the blister and carton after “Exp.:”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [(Invented) name] contains

- The active substance is tibolone.
the other ingredients are: lactose monohydrate (see section 2 “[(Invented) name] contains lactose”), mannitol, potato starch, ascorbyl palmitate and magnesium stearate.

What [(Invented) name] looks like and contents of the pack

[(Invented) name] are white to off-white round tablets of 6 mm diameter with beveled edge without any marking. They come in packs of 1, 3 and 6 blisters of 28 or 30 tablets.

Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

Cenexi

17, rue de Pontoise

95520 OSNY

FRANCE

This medicinal product is authorised in the Member States of the EEA under the following names:

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