

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TANILIVE 100 mg VAGINAL CAPSULES soft gelatin capsules

TANILIVE 200 mg VAGINAL CAPSULES soft gelatin capsules

Progesterone

TANILIVE VAGINAL CAPSULES are sugar-free.

Ingredients with known effect: Soy Lecithin.

Read all of this leaflet carefully before you start taking TANILIVE VAGINAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TANILIVE VAGINAL CAPSULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TANILIVE VAGINAL CAPSULES is and what it is used for
2. What you need to know before you take TANILIVE VAGINAL CAPSULES
3. How to take TANILIVE VAGINAL CAPSULES
4. Possible side effects
5. How to store TANILIVE VAGINAL CAPSULES

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6. Contents of the pack and other information

1. What TANILIVE VAGINAL CAPSULES is and what it is used for

TANILIVE VAGINAL CAPSULES contains a female hormone called progesterone.

TANILIVE VAGINAL CAPSULES are used:

- when your ovaries are not functioning normally
- during *in vitro* fertilisation cycles (IVF)
- in cases of threatened miscarriage or prevention of repeated miscarriages.

2. What you need to know before you take TANILIVE VAGINAL CAPSULES

Do not take TANILIVE VAGINAL CAPSULES:

- if you are hypersensitive (allergic) to progesterone, or to any of the ingredients of TANILIVE VAGINAL CAPSULES (see section 6)
- if you have or have ever had a severe liver disease and your liver function tests have not returned to normal
- if you have any undiagnosed vaginal bleeding
- if you suffer from any of the following disorders: herpes gestationis (a type of skin rash with sores that starts during pregnancy), jaundice of pregnancy (yellowing of the skin), otosclerosis (an abnormal growth of bone near the middle ear, causing impaired hearing), severe itching, or porphyria (a condition that affects your blood)
- if you or any of your family members have or had breast cancer
- 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)

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- if you have ever suffered from inflammation of the wall of a vein with associated thrombosis, often occurring in the legs during pregnancy (thrombophlebitis)
- 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 bleeding on the brain (cerebral haemorrhage)
- if you have been told by a doctor that you have inherited genetic mutation of the Breast cancer genes (BRCA 1 and BRCA 2)
- if you had an early onset of menstrual periods (before the age of 12 years)
- if you have a history of non-cancerous breast diseases such as atypical hyperplasia (Abnormal cells found during a breast biopsy) and lobular carcinoma *in situ* (a rare condition where you have abnormal cells in your lobules—the glands that produce breast milk)
- if you've had treatment using radiation therapy to the chest or breast
- if you have previously used medicines containing diethylstilbestrol (DES), which is a female hormone estrogen prescribed to pregnant women to prevent miscarriage, premature labor, and related complications of pregnancy
- if you are breastfeeding your baby.

Warnings and precautions

Take special care with TANILIVE VAGINAL CAPSULES:

- treatment with TANILIVE VAGINAL CAPSULES should be stopped if your liver function test indicates any abnormalities or if you develop cholestatic jaundice (yellowing of the eyes and/or skin)

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- before starting TANILIVE VAGINAL CAPSULES treatment you should undergo a thorough examination and special care should be given to the breasts, pelvic organs and a “pap” smear should be conducted
- TANILIVE VAGINAL CAPSULES should not be used as a contraceptive medicine as the dosage is not sufficient
- TANILIVE VAGINAL CAPSULES is only for use in the first trimester of pregnancy
- TANILIVE VAGINAL CAPSULES is not a treatment for the threat of premature birth
- TANILIVE VAGINAL CAPSULES can cause depressed mood, depression and the risk of having suicidal thoughts.

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

- abnormal tumours/growths (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
- increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- liver problems such as benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches

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- 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)
- depression
- your skin is sensitive to light (photosensitivity).

Stop taking TANILIVE VAGINAL CAPSULES and see a doctor immediately if you notice any of the following:

- any of the conditions mentioned in the Do not take TANILIVE VAGINAL CAPSULES 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
- pregnancy
- sudden or gradual, partial or complete loss of vision
- forward displacement of the eye (proptosis) or double vision (diplopia)
- swelling of the optic nerve (papilledema)
- eye diseases (retinal vascular lesions).

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

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Taking estrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer). The progestogen in TANILIVE VAGINAL CAPSULES protects you from this extra risk.

Unexpected bleeding:

You will have a bleed once a month (so-called withdrawal bleed) while taking TANILIVE VAGINAL. If you experience unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which carries on for more than the first 6 months which either starts after you have been taking TANILIVE VAGINAL CAPSULES for more than 6 months, or carries on after you have stopped taking TANILIVE VAGINAL CAPSULES, see your doctor or healthcare provider as soon as possible.

Breast cancer:

The use of combined estrogen and progesterone or estrogen only which, on prolonged use, may increase your risk of developing breast cancer. Studies show a significant increase in the risk of developing breast cancer in women 40 – 59 years of age who used menopausal hormone therapy (MHT). There was no risk of developing breast cancer in women who started MHT at 60 years of age.

All women on TANILIVE VAGINAL CAPSULES should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations.

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.

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Ovarian cancer:

Ovarian cancer is rare much rarer than breast cancer. The use of estrogen-only or combined estrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer. The combination of TANILIVE VAGINAL CAPSULES and estrogen reduces the risk slightly.

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.

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
- 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.

Heart disease (heart attack)

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

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Healthy women close to menopause age who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke:

The risk of getting stroke is about 1,5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.

Other conditions:

HRT will not improve your mental/brain function, e.g. memory, decision making, language abilities. There is some evidence of a higher risk of dementia in women who start using HRT after the age of 65. Speak to your doctor or healthcare provider for advice.

Other medicines and TANILIVE VAGINAL CAPSULES

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

The effect of TANILIVE VAGINAL CAPSULES may be decreased when taken with medicines such as:

- carbamazepine, phenobarbital or phenytoin (to treat epilepsy)
- rifabutin or rifampicin (to treat tuberculosis)
- griseofulvin (used in the treatment of fungal infections)
- ampicillin, tetracyclines (antibiotics to treat infections)
- phenylbutazone (for treating pain and fever)
- bromocriptine (to treat menstrual disorders, stop production of breastmilk, Parkinson's disease)

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- spironolactone (to treat heart conditions and high blood pressure)
- herbal medicines containing St. John's Wort.

The effect of the other medicines may be increased when taken with TANILIVE VAGINAL CAPSULES such as:

- ciclosporin (used to suppress the immune system)
- theophylline (used to treat symptoms of asthma, bronchitis, emphysema, and other breathing problems)
- troleandomycin (to treat many different types of bacterial infections, such as tonsillitis, bronchitis, sinusitis, and pneumonia)
- diazepam (to treat anxiety, alcohol withdrawal, and seizures)
- tizanidine (used to relieve the spasms and increased muscle tone caused by multiple sclerosis)
- terbinafine (to treat skin fungal infections).

Medicines that affect the way TANILIVE VAGINAL CAPSULES works include:

- ritonavir and nelfinavir (medicines for HIV infection)
- ketoconazole (to treat fungal infections)
- aminoglutethimide (to treat seizures, Cushing's syndrome, breast cancer)
- warfarin, phenindione (medicines to prevent blood clots)
- ulipristal acetate (emergency contraceptive).

Diabetic medicine, e.g. metformin, glibenclamide - dosage may need to be adjusted when taking TANILIVE VAGINAL CAPSULES.

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Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking HRT, because HRT can affect the results of some tests.

TANILIVE VAGINAL CAPSULES with food and drink

Vaginal route:

Food and drink have no effect on the treatment.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using TANILIVE VAGINAL CAPSULES.

Do not take TANILIVE VAGINAL CAPSULES if you are pregnant or might become pregnant as safety in pregnancy has not been established.

TANILIVE VAGINAL CAPSULES are contraindicated in women who are breastfeeding (see Do not take TANILIVE VAGINAL CAPSULES).

Driving and using machines:

You may feel sleepy or dizzy while taking TANILIVE VAGINAL CAPSULES. If this happens, do not drive or use any tools or machines.

Taking TANILIVE VAGINAL CAPSULES at bedtime can reduce these effects.

It is not always possible to predict to what extent TANILIVE VAGINAL CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage

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in the above activities until they are aware of the measure to which TANILIVE VAGINAL CAPSULES affects them.

TANILIVE VAGINAL CAPSULES contains Soy lecithin

If you are allergic to peanut or soya, do not take TANILIVE VAGINAL CAPSULES.

3. How to take TANILIVE VAGINAL CAPSULES

Do not share medicines prescribed for you with any other person. Always use TANILIVE VAGINAL CAPSULES exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Your doctor will aim to prescribe the lowest dose to treat your symptoms as short as necessary.

Vaginal route:

The usual daily dose is as follows (in addition to estrogen):

- 100 mg TANILIVE VAGINAL CAPSULES per day on days 13 and 14 of the transfer cycle, then
- 200 mg of TANILIVE VAGINAL CAPSULES per day on days 15 and 25 of the transfer cycle, split over one or two doses per day, then
- from day 26 of the cycle, and in cases of an early pregnancy, the dose may be increased up to a maximum of 600 mg per day, split over three doses.

This dosage should be followed upto day 60, or until week 12 of pregnancy at the latest.

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Children

TANILIVE VAGINAL CAPSULES are not indicated for use in children.

Your doctor will tell you how long your treatment with TANILIVE VAGINAL CAPSULES will last.

If you have the impression that the effect of TANILIVE VAGINAL CAPSULES is too strong or too weak, tell your doctor or pharmacist.

Method of administration:

Insert the capsule(s) deep into the vagina.

If you take more TANILIVE VAGINAL CAPSULES than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- nausea, vomiting, sleepiness, dizziness, fatigue, a feeling or state of intense excitement and happiness, painful menstruation, typically involving abdominal cramps.

If you forget to take TANILIVE VAGINAL CAPSULES:

If you forget to take TANILIVE VAGINAL CAPSULES, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

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If you stop taking TANILIVE VAGINAL CAPSULES

Do not stop taking TANILIVE VAGINAL CAPSULES without first discussing with your doctor or healthcare provider.

4. Possible side effects

You may feel sleepy and dizzy within 1 to 3 hours of using TANILIVE VAGINAL CAPSULES. The information given below is based on extensive post marketing experience from vaginal administration of progesterone.

- itchy skin is often caused by dry skin (pruritus)
- abnormal vaginal bleeding (vaginal haemorrhage)
- vaginal discharge
- changes in your weight
- difficulty sleeping (insomnia), depression, dementia (characterized by, loss of memory, confusion, disorientation, difficulty handling tasks)
- gall bladder diseases
- skin rash, blisters (urticaria), dark patches (chloasma/melasma), hair loss (alopecia), redness of the skin (erythema), blood spots on the skin (vascular purpura)
- change in menstruation, absence of menstruation, breast pain and swelling, change in sex drive
- fever (pyrexia), water retention and swelling.

Not all side effects reported for TANILIVE VAGINAL CAPSULES are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using TANILIVE VAGINAL CAPSULES, please consult your healthcare provider for advice.

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Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of TANILIVE VAGINAL CAPSULES.

5. How to store TANILIVE VAGINAL CAPSULES

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from excessive moisture.

Do not remove from outer carton until required for use.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TANILIVE VAGINAL CAPSULES contains

Each soft gelatin capsule contains 100 or 200 mg progesterone.

The other ingredients are:

Grapeseed oil, soy lecithin

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Soft gelatine capsule:

Gelatine, glycerol, titanium dioxide.

What TANILIVE VAGINAL CAPSULES looks like and contents of the pack

TANILIVE 100 mg VAGINAL CAPSULES are ovoid soft gelatin capsules off-white coloured, approximately 12 mm long and 8 mm wide

TANILIVE 200 mg VAGINAL CAPSULES are ovoid soft gelatin capsules off-white coloured, approximately 16 mm long and 9,6 mm wide

TANILIVE VAGINAL CAPSULES tablets are available in transparent
PVC/PE/PVDC/Aluminum blister.

TANILIVE 100 mg VAGINAL CAPSULES: Each carton contains 30 capsules.

TANILIVE 200 mg VAGINAL CAPSULES: Each carton contains 15 capsules.

Holder of Certificate of Registration

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Tanilive 100 & 200 mg Vaginal Capsules
Pharma Dynamics (Pty) Ltd.

Each soft capsule contains 100 or 200 mg
progesterone

Date of registration: 17 June 2025

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17 June 2025

Registration numbers

TANILIVE 100 mg VAGINAL CAPSULES: 58/21.8.2/0036

TANILIVE 200 mg VAGINAL CAPSULES: 58/21.8.2/0037