PATIENT INFORMATION LEAFLET

TANILIVE ORAL CAPSULES RANGE

SCHEDULING STATUS

S4

TANILIVE 100 mg ORAL CAPSULES soft gelatin capsules

TANILIVE 200 mg ORAL CAPSULES soft gelatin capsules

Progesterone

TANILIVE ORAL CAPSULES are sugar free

Read all of this leaflet carefully before you start taking TANILIVE ORAL CAPSULES

- 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 ORAL CAPSULES have 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 ORAL CAPSULES are and what it is used for
2. What you need to know before you take TANILIVE ORAL CAPSULES
3. How to take TANILIVE ORAL CAPSULES
4. Possible side effects
5. How to store TANILIVE ORAL CAPSULES
6. Contents of the pack and other information

1. What TANILIVE ORAL CAPSULES are and what it is used for

TANILIVE ORAL CAPSULES contain a female hormone called progesterone.

TANILIVE ORAL CAPSULES are used for:

- premenstrual syndrome (PMS)
- menstrual irregularities
- breast disorders (such as pain, nodules, swellings or cysts, especially during the menstrual cycle)
- perimenopause (the time leading up to menopause or your last menstrual cycle)
- hormone replacement therapy (HRT) to relieve symptoms of menopause.

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

Do not take TANILIVE ORAL CAPSULES:

- if you are hypersensitive (allergic) to progesterone, or to any of the ingredients of TANILIVE ORAL 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 unexplained 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)
- 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 have early onset of 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 labour, and related complications of pregnancy
- if you are breastfeeding your baby.

Warnings and precautions

Take special care with TANILIVE ORAL CAPSULES:

- treatment with TANILIVE ORAL 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)
- before starting TANILIVE ORAL 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
- once you have started on TANILIVE ORAL CAPSULES, you should see your doctor for regular check-ups (at least once a year) and go for regular breast screening, as recommended by your doctor
- TANILIVE ORAL CAPSULES should not be used as a contraceptive medicine as the dosage is not sufficient
- TANILIVE ORAL CAPSULES are not a treatment for the threat of premature birth
- TANILIVE ORAL 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 ORAL 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
- 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 ORAL CAPSULES and see a doctor immediately if you notice any of the following:

- any of the conditions mentioned in the (Do not take TANILIVE ORAL 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):

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 ORAL CAPSULES protects you from this extra risk.

Unexpected bleeding:

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

Breast cancer:

The use of combined estrogen-progesterone or estrogen-only which, with 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 ORAL 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.

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 ORAL 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 - 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/m^2)
- 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.

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

Stroke:

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

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 or healthcare provider for advice.

Other medicines and TANILIVE ORAL CAPSULES

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

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

- anti-epileptic medicine containing carbamazepine, phenobarbital or phenytoin
- tuberculosis treatment containing rifabutin or rifampicin
- griseofulvin (used in the treatment of fungal infections)
- some antibiotics (ampicillin, tetracycline)
- phenylbutazone (for treating pain and fever)
- bromocriptine (to treat menstrual disorders, stop production of breastmilk, Parkinson’s disease)
- 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 ORAL 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 ORAL CAPSULES work include:

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

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

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.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using TANILIVE ORAL CAPSULES.

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

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

Driving and using machines

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

Taking TANILIVE ORAL CAPSULES at bedtime can reduce these effects.

It is not always possible to predict to what extent TANILIVE ORAL CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TANILIVE ORAL CAPSULES affect them.

TANILIVE ORAL CAPSULES contains soy lecithin

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

3. How to take TANILIVE ORAL CAPSULES

Do not share medicines prescribed for you with any other person. Always use TANILIVE ORAL 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 for as short as necessary.

Premenstrual syndrome, mastopathy, irregular menstruation and perimenopause:

The usual recommended dose is 200 mg – 300 mg daily.

The recommended dose is 200 mg capsule to 300 mg (one 100 mg capsule and one 200 mg capsule) taken at two intakes, daily at bedtime, for ten days in the last half of each therapeutic cycle (beginning on Day 17 of the cycle and ending on Day 26).

Hormone replacement therapy (HRT) to relieve symptoms of the menopause:

Estrogen should be taken with 200 mg per day TANILIVE ORAL CAPSULES as follows:

- two doses of 100 mg capsule each, or
- one dose of 200 mg capsule taken before bed in the evening, from day 12 to day 14 of the month, or during the last two weeks of each treatment course.

After this treatment, your dose will be stopped for approximately one week. You will usually have a few days withdrawal bleeding (like a period) after this time.

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

TANILIVE ORAL CAPSULES should be taken after food, preferably after the evening meal upon retiring.

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

If you take more TANILIVE ORAL 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 ORAL CAPSULES:

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

If you stop taking TANILIVE ORAL CAPSULES

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

4. Possible side effects

TANILIVE ORAL CAPSULES can have side effects.

Not all side effects reported for TANILIVE ORAL CAPSULES are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using TANILIVE ORAL CAPSULES, please consult your healthcare provider for advice.

If any of the following happens, stop using TANILIVE ORAL CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TANILIVE ORAL CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- pain in one leg (usually the calf or inner thigh), warmth, swelling and tenderness in the leg or arm, chest pain, numbness or weakness on one side of the body, sudden change in your mental state (symptoms of thromboembolism)
- yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- high blood sugar (hyperglycaemia)
- unusual or rapid weight gain
- dizziness, drowsiness, fatigue, mild headache, mood changes, nervousness, unusual tiredness or weakness, sensation of whirling and loss of balance (vertigo), sleepiness
- general swelling due to build-up of fluid
- stomach pain, cramping or bloating, diarrhoea, nausea
- joint pain
- bladder problems
- vaginal discharge, abnormal absence of menstruation, breakthrough menstrual bleeding, spotting, abnormally heavy bleeding menstruation.

Less frequent side effects:

- low blood pressure (light-headedness, dizziness, blurred vision, feeling sick, weakness)
- abnormally high levels of the hormone cortisol in the body (Crushing's syndrome) or decreased cortisol levels (adrenal suppression)
- mental depression, insomnia
- hot flushes

- skin rash, acne, loss or gain of body, facial or scalp hair, skin discolouration (brown patches), itchy skin
- milky breast discharge not related to breastfeeding, breast pain or tenderness, decreased libido.

The following side effects have been reported but the frequency for them to occur is not known:

- suicidal thoughts
- loss of bone mineral density, osteoporosis (bones become brittle and fragile) fractures
- vaginal haemorrhage
- fatigue (extreme tiredness).

When TANILIVE ORAL CAPSULES are taken together with estrogen, the following side effects have been reported:

- breast cancer
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, 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 ORAL CAPSULES.

5. How to store TANILIVE ORAL CAPSULES

Store all medicines out of reach of children.

Store at or below 30 ºC. 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 ORAL CAPSULES contains

Each soft gelatin capsule contains 100 or 200 mg progesterone.

The other ingredients are:

Grapeseed oil, soy lecithin

Soft gelatine capsule:

Gelatin, glycerol, titanium dioxide (E171).

What TANILIVE ORAL CAPSULES looks like and contents of the pack

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

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

TANILIVE ORAL CAPSULES are available in transparent PVC/PE/PVDC/Aluminium blister packed in an outer carton.

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

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

Holder of Certificate of Registration

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