PROFESSIONAL INFORMATION

TANILIVE ORAL CAPSULES RANGE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

TANILIVE 100 mg ORAL CAPSULES soft gelatin capsules

TANILIVE 200 mg ORAL CAPSULES soft gelatin capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin capsule contains progesterone 100 mg.

Each soft gelatin capsule contains progesterone 200 mg.

Ingredients with known effect: Soy Lecithin.

TANILIVE ORAL CAPSULES are sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft gelatin capsules.

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

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TANILIVE ORAL CAPSULES are indicated in patients with disorders associated with progesterone deficiency, in particular:

- premenstrual syndrome
- menstrual irregularities due to dysovulation or anovulation
- mastopathy

- perimenopause
- hormone replacement therapy (HRT) for menopause (in addition to estrogen therapy).

4.2 Posology and method of administration

It is important to adhere strictly to the recommended dosages for all therapeutic indications.

The dosage must not exceed 200 mg per dose.

Posology

For progesterone deficiency, an average dose of 200 mg – 300 mg TANILIVE ORAL CAPSULES per day is recommended.

Luteal phase insufficiency (premenstrual syndrome, mastopathy, irregular menstruation and perimenopause):

The usual therapeutic regimen is 200 mg – 300 mg per day:

- a single dose of 200 mg in the evening, upon retiring, or 300 mg split over two doses
- ten days per cycle, usually from day 17 to day 26 inclusive.

Hormone replacement therapy for menopause:

Estrogen therapy alone is not advised (due to the risk of endometrial hyperplasia). Instead, TANILIVE ORAL CAPSULES should be incorporated at a dose of 200 mg per day:

- split over two 100 mg doses, or
- as a single 200 mg dose in the evening, upon retiring, either from day 12 to day 14 of the month, or during the last two weeks of each treatment course.

Following this treatment, all replacement therapies should be suspended for approximately one week, during which time it is normal to observe withdrawal bleeding.

Method of administration

For oral use.

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

Missed dose:

Medical practitioners should advise patients who forget to take TANILIVE ORAL CAPSULES to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications

TANILIVE ORAL CAPSULES are contraindicated in:

- patients with hypersensitivity to progesterone or to any of the ingredients of TANILIVE ORAL CAPSULES (see section 6.1)
- severe liver disease such as cholestatic jaundice, or hepatitis, or a history of severe liver disease, hepatic cell tumours, Rotor syndrome, or Dubin-Johnson syndrome
- known or suspected estrogen dependent malignant tumours (e.g. genital tract carcinoma)
- undiagnosed vaginal bleeding
- conditions of rare occurrence known to be affected by sex steroids i.e. herpes gestationis, jaundice of pregnancy, otosclerosis, severe pruritus, or porphyria
- personal and family history of breast cancer
- previous or current thromboembolism disorders (e.g. deep venous thrombosis, pulmonary embolism) or thrombophlebitis
- known thrombophilic disorders
- cerebral haemorrhage
- patients known with inherited genetic mutation: BRCA 1 and BRCA 2 genes
- early menstrual periods (before the age of 12 years)
- history of non-cancerous breast diseases (atypical hyperplasia or lobular carcinoma in situ)
- previous treatment using radiation therapy to the chest or breast
- previous exposure to diethylstilbestrol (DES)

- breastfeeding (see section 4.6).

4.4 Special warnings and precautions for use

In the event that results of liver function tests become abnormal or if cholestatic jaundice appears, therapy with TANILIVE ORAL CAPSULES should be discontinued.

More than half of early spontaneous abortions are due to genetic defects. Moreover, infections and mechanical disorders may cause early miscarriages. In these cases, the only effect of progesterone administration will be to delay the expulsion of the dead egg (or interruption of a terminated pregnancy).
Upon diagnosis of a missed abortion, therapy should be discontinued.

A pre-treatment physical examination, including a complete personal and family medical history, prior to the initiation of hormone replacement treatment should include special attention to breast and pelvic organs as well as Papanicolaou smear and by the contraindications and warnings for use.
During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual woman. Women should be advised what changes in their breasts should be reported to their medical practitioner or nurse (see 'Breast cancer' below). Investigations, including appropriate imaging tools, e.g. mammography, should be carried out in accordance with currently accepted screening practices, modified to the clinical needs of the individual.

The use of TANILIVE ORAL CAPSULES must be reserved for cases with insufficient secretion of the corpus luteum.

TANILIVE ORAL CAPSULES have no contraceptive effect when taken under the recommended conditions of use.

The use of progesterone during pregnancy is restricted to the first trimester and only via the vaginal route. TANILIVE ORAL CAPSULES are not a treatment for the threat of preterm birth.

During the second and third trimesters of pregnancy, exceptional cases of cytolytic hepatitis and intrahepatic cholestasis of pregnancy have been reported in patients taking progesterone as in TANILIVE ORAL CAPSULES.

For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. In all cases, a careful appraisal of the risks and benefits should be undertaken at least annually, and HRT should only be continued as long as the benefit outweighs the risk.

Evidence regarding the risks associated with HRT in the treatment of premature menopause is limited. Due to the low level of absolute risk in younger women, however, the balance of benefits and risks for these women may be more favourable than in older women.

Conditions requiring supervision

If any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment, the patient should be closely supervised. It should be taken into account that these conditions may recur or be aggravated during treatment with TANILIVE ORAL CAPSULES, in particular:

- leiomyoma (uterine fibroids) or endometriosis
- risk factors for thromboembolic disorders (see below)
- risk factors for estrogen dependent tumours, e.g. 1st degree heredity for breast cancer
- hypertension
- liver disorders (e.g. liver adenoma)
- diabetes mellitus with or without vascular involvement
- cholelithiasis
- migraine or (severe) headache

- systemic lupus erythematosus
- a history of endometrial hyperplasia (see below)
- epilepsy
- asthma
- otosclerosis
- depression
- photosensitivity.

Reasons for immediate withdrawal of therapy

Therapy should be discontinued in case a contraindication is discovered and in the following situations:

- jaundice or deterioration in liver function
- significant increase in blood pressure
- new onset of migraine-type headache
- pregnancy
- sudden or gradual, partial or complete loss of vision
- proptosis or diplopia
- papilloedema
- retinal vascular lesions.

Endometrial hyperplasia and carcinoma

In women with an intact uterus the risk of endometrial hyperplasia and carcinoma is increased when estrogens are administered alone for prolonged periods. The reported increase in endometrial cancer risk among estrogen-only users varies from 2- to 12-fold greater compared with non-users, depending on the duration of treatment and estrogen

dose (see section 4.8). After stopping treatment the risk may remain elevated for at least 10 years.

The addition of progesterone for at least 12 days per month/28-day cycle or continuous combined estrogen-progestogen therapy in non-hysterectomised women prevents the excess risk associated with estrogen-only HRT.

Breakthrough bleeding and spotting may occur during the first months of treatment. If breakthrough bleeding persists, a lower dose of TANILIVE ORAL CAPSULES for 25 days per cycle could be considered (see section 4.2).

Breakthrough bleeding or spotting appears after some time on therapy or continuously after discontinuation or during treatment, it may be an indication for endometrial assessment, which may include a biopsy to exclude endometrial malignancy.

Breast cancer

Combined estrogen and progesterone or estrogen only which, on prolonged use, may increase the risk of developing breast cancer. A meta-analysis of prospective epidemiological studies from 1992 to 2018 reported a significant increase in the risk of developing breast cancer in 55 575 women 40 – 59 years of age who used menopausal hormone therapy (MHT). The risk increased steadily with duration of use and was slightly greater for estrogen-progestogen than estrogen only preparations, and the risk persisted for more than 10 years after stopping the treatment. The relative risk (RR) to develop breast cancer for estrogen-progestogen preparations was 1,60 at 1-4 years and RR=2,08 at 5-14 years, while that for oestrogen only preparations was 1,17 at 1-4 years and 1,33 at 5-14 years. 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. Mammography evaluations should be done based on patient age, risk factors, and prior mammogram results.

Ovarian cancer

Ovarian cancer is much rarer than breast cancer. Epidemiological evidence from a large meta-analysis suggests a slightly increased risk in women taking estrogen-only or combined estrogen-progestogen HRT, which becomes apparent within 5 years of use and diminishes over time after stopping. Some other studies, including the WHI trial, suggest that use of combined HRTs may be associated with a similar or slightly smaller risk (see section 4.8).

Venous thromboembolism

HRT is associated with a 1,3- to 3- fold risk of developing venous thromboembolism (VTE), i.e. deep vein thrombosis or pulmonary embolism. The occurrence of such an event is more likely in the first year of HRT than later (see section 4.8).

Patients with known thrombophilic states have an increased risk of VTE and HRT may add to this risk. HRT is therefore contraindicated in these patients (see section 4.3).

Generally recognised risk factors for VTE include, use of estrogens, older age, major surgery, prolonged immobilisation, obesity (BMI > 30 kg/m^2), pregnancy/postpartum period, systemic lupus erythematosus (SLE), and cancer. There is no consensus about the possible role of varicose veins in VTE.

As in all postoperative patients, prophylactic measures need be considered to prevent VTE following surgery. If prolonged immobilisation is to follow elective surgery, temporarily stopping HRT 4 - 6 weeks earlier is recommended. Treatment should not be restarted until the woman is completely mobilised.

In women with no personal history of VTE but with a first degree relative with a history of thrombosis at young age, screening may be offered after careful counselling regarding its limitations (only a proportion of thrombophilic defects are identified by screening).

If a thrombophilic defect is identified which segregates with thrombosis in family members or if the defect is severe (e.g. anti-thrombin, protein S, or protein C deficiencies or a combination of defects) HRT is contraindicated.

Women already on chronic anticoagulant treatment require careful consideration of the benefit-risk of use of HRT.

If VTE develops after initiating therapy, TANILIVE ORAL CAPSULES should be discontinued. Patients should be told to contact their medical practitioners immediately when they are aware of a potential thromboembolic symptom (e.g. painful swelling of a leg, sudden pain in the chest, dyspnoea).

Coronary artery disease (CAD)

There is no evidence from randomised controlled trials of protection against myocardial infarction in women with or without existing CAD who received combined estrogen-progestogen or estrogen-only HRT.

Combined estrogen-progestogen therapy:

The relative risk of CAD during use of combined estrogen + progestogen HRT is slightly increased. As the baseline absolute risk of CAD is strongly dependent on age, the number of extra cases of CAD due to estrogen + progestogen use is very low in healthy women close to menopause, but will rise with more advanced age.

Ischaemic stroke

Combined estrogen-progestogen and estrogen-only therapy are associated with an up to 1,5-fold increase in risk of ischaemic stroke. The relative risk does not change with age or time since menopause. However, as the baseline risk of stroke is strongly age-dependent, the overall risk of stroke in women who use HRT will increase with age (see section 4.8).

Depression

Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use (see section 4.8). Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their medical practitioner in case of mood changes and depressive symptoms, including shortly after initiating the treatment.

Other conditions

HRT use does not improve cognitive function. There is some evidence of increased risk of probable dementia in women who start using continuous combined or estrogen-only HRT after the age of 65.

Excipients with known effect

TANILIVE ORAL CAPSULES contain soy lecithin and may cause hypersensitivity reactions (urticarial and anaphylactic shock in hypersensitive patients). As there is a possible relationship between allergy to soya and allergy to peanut, patients with peanut allergy
should avoid taking TANILIVE ORAL CAPSULES.

4.5 Interaction with other medicines and other forms of interaction

Enzyme inducers

The efficacy of TANILIVE ORAL CAPSULES may be decreased due to an enhanced metabolism of progesterone by hepatic enzyme inducing-medicines, such as carbamazepine, phenobarbital, phenytoin, rifabutin or rifampicin, griseofulvin, some antibiotics (ampicillin, tetracyclines), phenylbutazone, bromocriptine, spironolactone and also herbal products containing St. John's wort (*Hypericum perforatum*).

Enzyme inhibitors

The bioavailability of TANILIVE ORAL CAPSULES may be increased by hepatic metabolic enzyme inhibitors such as ketoconazole, ritonavir and nelfinavir. The metabolism of progesterone by human liver microsomes was inhibited by ketoconazole (IC50 < 0,1 micromolar).

Immunosuppressants

TANILIVE ORAL CAPSULES may raise the plasma concentration of ciclosporin.

Xanthines

TANILIVE ORAL CAPSULES may raise the plasma concentration of theophylline.

Macrolide antibiotics

TANILIVE ORAL CAPSULES may raise the plasma concentration of troleandomycin.

Anti-steroidal medicines

Aminoglutethimide markedly reduces the plasma concentrations of medroxyprogesterone acetate and megestrol, possibly through a hepatic enzyme-inducing effect.

Anticoagulants

TANILIVE ORAL CAPSULES may enhance or reduce the anticoagulant effect of coumarins.

TANILIVE ORAL CAPSULES antagonise the anticoagulant effect of phenindione.

Diabetic medicines

An adjustment in anti-diabetic dosage may be required for women being treated concomitantly with TANILIVE ORAL CAPSULES.

Emergency contraceptives

The concomitant use of ulipristal acetate with progesterone may result in reduced efficacy of TANILIVE ORAL CAPSULES.

Diazepam

TANILIVE ORAL CAPSULES may increase the plasma concentration of diazepam.

Tizanidine

TANILIVE ORAL CAPSULES may increase the plasma concentration of tizanidine.

Terbinafine

There have been occasional reports of breakthrough bleeding when terbinafine is used concomitantly with TANILIVE ORAL CAPSULES.

Laboratory tests

TANILIVE ORAL CAPSULES may affect the results of laboratory tests of hepatic and/or endocrine functions.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established. The use of progesterone during pregnancy is restricted to the first trimester via the vaginal route.

Cases of hepatic cytolysis and cases of cholestasis of pregnancy have been reported during administration of micronised progesterone during the 2nd and 3rd trimesters of pregnancy.

If pregnancy occurs whilst on therapy, TANILIVE ORAL CAPSULES should be withdrawn immediately.

Therapy with TANILIVE ORAL CAPSULES beyond the first trimester of pregnancy may reveal gravidic cholestasis.

Breastfeeding

TANILIVE ORAL CAPSULES are contraindicated when breastfeeding (see section 4.3).

Fertility

TANILIVE ORAL CAPSULES are indicated to support luteal deficiency in sub-fertile or infertile women.

4.7 Effects on ability to drive and use machines:

Drowsiness, dizziness, somnolence and vertigo are possible side effects of TANILIVE ORAL CAPSULES. Patients should be warned to avoid driving or using machines until they know how TANILIVE ORAL CAPSULES affect them.

4.8 Undesirable effects

a). Tabulated summary of adverse reactions

System Organ Class	**Frequency**	**Side effects**
Blood and lymphatic system disorders	Frequent Less frequent	Hyperglycaemia Thromboembolism or thrombus formation
Immune system disorders	Frequency unknown	Anaphylaxis or anaphylactoid reaction
Endocrine disorders	Less frequent	Cushing's syndrome, adrenal suppression or insufficiency
Metabolism and nutrition disorders	Frequent	Unusual or rapid weight gain
Psychiatric disorders	Less frequent Frequency unknown	Mental depression, insomnia Risk of suicidality
Nervous system disorders	Frequent	Dizziness, drowsiness, fatigue, mild headache, mood changes, nervousness, unusual tiredness or weakness, vertigo, somnolence,
Vascular disorders	Frequent Less frequent	Oedema Hypotension, hot flushes

Gastrointestinal disorders	Frequent	Abdominal cramping or pain, abdominal bloating, diarrhoea, nausea
Hepatobiliary disorders	Frequency unknown	Jaundice
Skin and subcutaneous tissue disorders	Less frequent	Skin rash, acne, loss or gain of body, facial or scalp hair, melasma, chloasma, pruritus
Musculoskeletal, connective tissue and bone disorders	Frequent Frequency unknown	Joint pain Loss of bone mineral density, osteoporosis, osteoporotic fracture
Renal and urinary disorders	Frequent	Urinary problems
Reproductive system and breast disorders	Frequent Less frequent Frequency unknown	Amenorrhoea, breakthrough menstrual bleeding or metro menorrhagia, menorrhagia, spotting, vaginal discharge Galactorrhoea, breast pain or tenderness, libido decrease Vaginal haemorrhage
General disorders and administrative site conditions	Frequency unknown	Fatigue

c). Description of selected adverse reactions

Somnolence or transient dizziness may occur 1 - 3 hours after intake of TANILIVE ORAL

CAPSULES. Dosing upon retiring and dose reduction may reduce these effects.

The following risks apply in relation to systemic estrogen/progestogen therapy:

Breast cancer risk

There is an up to 2-fold increased risk of having breast cancer diagnosed, reported in women taking combined estrogen-progestogen therapy for more than 5 years.

Any increased risk in users of estrogen-only therapy is substantially lower than that seen in users of estrogen-progestogen combinations.

The level of risk is dependent on the duration of use (see section 4.4).

Endometrial cancer risk

Postmenopausal women with a uterus

Approximately 5 in every 1 000 women with a uterus, not using hormone replacement therapy (HRT), are at risk of endometrial cancer.

Administration of estrogen-only HRT is not recommended in women with a uterus, as it increases the risk of endometrial cancer (see section 4.4).

Depending on the duration of estrogen-only use and estrogen dose, the increase in risk of endometrial cancer.

The increased risk can be prevented by adding progesterone to estrogen-only therapy for at least 12 days per cycle. In a clinical study the use of five years of combined (sequential or continuous) HRT did not increase risk of endometrial cancer.

Ovarian cancer

Use of estrogen-only and combined estrogen-progestogen HRT has been associated with a slightly increased risk of having ovarian cancer diagnosed (see section 4.4).

A meta-analysis from epidemiological studies reported an increased risk of ovarian cancer in women currently using HRT compared to women who have never used HRT. For women aged 50 to 54 years

taking 5 years of HRT, the results indicated about 1 extra case per 2 000 users. In women aged 50 to 54 who are not taking HRT, about 2 women in 2 000 will be diagnosed with ovarian cancer over a 5-year period.

Risk of venous thromboembolism

HRT is associated with a 1,3 - 3-fold increased relative risk of developing venous thromboembolism (VTE), i.e. deep vein thrombosis or pulmonary embolism. The occurrence of such an event is more likely in the first year of using HRT (see section 4.4).

Risk of coronary artery disease

Patients over the age of 60, using combined estrogen-progestogen HRT, are at a slightly higher risk of coronary artery disease (see section 4.4).

Risk of ischaemic stroke

There is an up to 1,5-fold increase in relative risk of ischaemic stroke during estrogen-only and estrogen + progestogen therapy. The risk of haemorrhagic stroke is not increased during use of HRT. This relative risk is not dependent on age or on duration of use, but as the baseline risk is strongly age-dependent, the overall risk of stroke in women who use HRT will increase with age (see section 4.4).

The following adverse reactions have also been reported in association with systemic estrogen/progestogen treatment:

- rash
- urticaria
- chloasma/melasma
- pyrexia
- insomnia
- alopecia

- irregular menstruation
- amenorrhoea
- breast pain/oedema
- fluid retention/oedema
- weight changes
- changes in libido
- depression
- gall bladder disease
- probable dementia over the age of 65 (see section 4.4)
- skin and subcutaneous disorders: erythema multiforme, erythema nodosum, vascular purpura.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse drug reactions 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.

4.9 Overdose

Signs and symptoms:

Symptoms of overdosage may include nausea, vomiting, somnolence, dizziness, fatigue, euphoria or dysmenorrhoea.

Management of overdose:

Treatment of overdosage consists of discontinuation of TANILIVE ORAL CAPSULES and institution of appropriate symptomatic and supportive care.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic groups: Genitourinary system and sex hormones, sex hormones and modulators of the genital system - Progesterones

ATC code: G03DA04

Pharmacological classification: A 21.8.2 Progesterones with or without estrogens

The properties of progesterone are comparable to those of natural progesterone, in particular being a progestogen, estrogen antagonist, mild androgen antagonist, and aldosterone antagonist.

Mechanism of action

Progesterone is a natural progestogen, the main hormone of the corpus luteum and the placenta. It acts on the endometrium by converting the proliferating phase to the secretory phase.
This medicine has all the properties of endogenous progesterone, in particular gestagenic, antiestrogenic, slightly anti-androgenic and anti-aldosterone effects.

Clinical efficacy and safety

As estrogens promote the growth of the endometrium, unopposed estrogens increase the risk of endometrial hyperplasia and cancer. The addition of progesterone greatly reduces the estrogen-induced risk of endometrial hyperplasia in non-hysterectomised women.

5.2 Pharmacokinetic properties

Absorption:

Micronised progesterone is absorbed by the digestive tract.
Blood progesterone levels begin to rise within the first hour, and plasma levels reach the highest levels within one to three hours of a dose.
Pharmacokinetic studies conducted in volunteers have shown that, after simultaneously consuming two capsules of progesterone 100 mg, on average, blood progesterone levels rise from 0,13 ng/mL to

4,25 ng/mL after one hour, to 11,75 ng/mL after two hours, to 8,37 ng/mL after four hours, to 2 ng/mL after six hours, and to 1,64 ng/mL after eight hours.

Given the hormone retention time by tissues, in order to ensure infusion for a full 24 hours, it seems necessary to split the dosage over two doses, spaced approximately 12 hours apart.

There are discernible individual variations, although a given individual will exhibit the same pharmacokinetic characteristics for several months, thus allowing individuals to adapt to the dosage.

Distribution:

Progesterone is approximately 96 % - 99 % bound to serum proteins, primarily to serum albumin (50 % - 54 %) and transcortin (43 % - 48 %).

Biotransformation:

Progesterone is metabolised primarily by the liver. The main plasma metabolites are 20α-hydroxyprogesterone, Δ4α-prenolone and 5α-dihydroprogesterone.

Elimination:

Ninety-five per cent is eliminated via the urine in the form of glucuronide-conjugated metabolites, of which the principal metabolite is 3α, 5β-pregnanediol (pregnanediol). These plasma and urine metabolites are identical to those physiologically secreted from the corpus luteum in the ovaries.

Linearity/non-linearity:

The pharmacokinetics of micronised progesterone is independent of the dose administered. Although there were some inter-individual's variations, the same individual pharmacokinetic characteristics were maintained over several months permitting appropriate individual adaptation of the posology and indicating predictable responses to the medicine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Grapeseed oil

Soy Lecithin

Soft gelatin capsule:

Gelatin

Glycerol

Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 30 ºC.

Protect from excessive moisture.

Do not remove from outer carton until required for use.

6.5 Nature and contents of container

Transparent thermoformed PVC/PE/PVDC/Aluminium blister packed in an outer carton.

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

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

6.6 Special precautions for disposal

No special precautions.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharma Dynamics (Pty) Ltd

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8. REGISTRATION NUMBERS

TANILIVE 100 mg ORAL CAPSULES: A57/21.8.2/0422

TANILIVE 200 mg ORAL CAPSULES: A57/21.8.2/0423

9. DATE OF FIRST AUTHORISATION

August 2025