PATIENT INFORMATION LEAFLET

ORAL ROUTE

SCHEDULING STATUS

S4

UTROGESTAN, 100 mg and 200 mg, capsules

Micronised progesterone

Sugar free

Read all of this leaflet carefully before you start taking UTROGESTAN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- UTROGESTAN 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 UTROGESTAN is and what it is used for
2. What you need to know before you take UTROGESTAN
3. How to take UTROGESTAN
4. Possible side effects
5. How to store UTROGESTAN
6. Contents of the pack and other information

1. What UTROGESTAN is and what it is used for

UTROGESTAN is a progesterone hormone treatment and is prescribed for disorders where you have too little progesterone:

- as an addition to postmenopausal oestrogen replacement therapy;

- a condition called dysovulation or anovulation (where you have irregularity in your menstrual cycle (period), which might even occur two times in a single month);
- a condition called premenstrual syndrome (complex of symptoms, including emotional tension, experienced by some women in the day immediately before menstruation (your period);
- a condition called mastopathy (a painful disorder of the breast);
- a condition called perimenopause (the time during which your body makes the natural transition to menopause, marking the end of your reproductive years.

2. What you need to know before you take UTROGESTAN

Do not take UTROGESTAN:

- If you are hypersensitive (allergic) to progesterone or any of the other ingredients of UTROGESTAN listed in section 6).
- If you suffer from a severe liver disorder.
- If you experience any vaginal bleeding which a doctor has not diagnosed.
- If you have any mammary (breast) or genital cancer.
- If you suffer from any of the following disorders: herpes gestations (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 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 thrombophlebitis (inflammation of your veins due to blood clot formation).
- If you have a blood clotting disorders (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 bleeding on the brain (cerebral haemorrhage).
- If you are breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with UTROGESTAN:

- Treatment with UTROGESTAN 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 UTROGESTAN 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.
- UTROGESTAN should not be used as a contraceptive agent as the dosage is not sufficient.
- UTROGESTAN is not a treatment for the threat of premature birth.

Other medicines and UTROGESTAN:

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

Tell your doctor or pharmacist if you are currently taking:

- Griseofulvin (used in the treatment of fungal infections).
- Activated charcoal (usually used in the treatment of overdosing).
- Anti-epileptic medicines containing carbamazepine, phenobarbital or phenytoin.
- Tuberculosis treatment containing rifabutin or rifampicin.
- Ciclosporin used in cancer treatment.
- Theophylline (used in the treatment of asthma).
- Antibiotics such as ampicillins and tetracyclines (used to treat bacterial infections).
- Herbal remedies containing St John’s Wort (*Hypericum perforatum*) (used to assist with symptoms of depression).

UTROGESTAN with food and drink:

UTROGESTAN should be taken after food and preferably in the evening before going to bed.

Pregnancy, breastfeeding and fertility:

The use of UTROGESTAN is not recommended during pregnancy and breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking UTROGESTAN.

Driving and using machines:

UTROGESTAN may cause dizziness or drowsiness. Take care when driving a vehicle or using machines that requires concentration while you are being treated with UTROGESTAN.

UTROGESTAN contains soybean lecithin:

If you are allergic to peanut or soya, do not use UTROGESTAN.

3. How to take UTROGESTAN

Do not share medicines prescribed for you with any other person.

Always take UTROGESTAN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual daily dose is 200 mg to 300 mg divided into one or two intakes.

The dose of UTROGESTAN and duration of treatment will be determined by your doctor for your specific condition.

Swallow the capsule whole with a glass of water. You should take UTROGESTAN sometime after eating, preferably in the evenings upon going to bed.

If you have the impression that the effect of UTROGESTAN is too strong or too weak, talk to your doctor or pharmacist.

If you take more UTROGESTAN than you should:

In the event of overdosage, consult your doctor or pharmacist immediately. If he/she is unavailable, seek help at the nearest hospital or poison control centre.

If you forget to take UTROGESTAN:

If you have been prescribed the 300 mg daily dosage and forget to take a morning or evening dose, do not take the missed dose. Continue to take the next dosage as prescribed.

If you forget to take the 200 mg daily dose, skip the missed dose and carry on as before. Do not take more than one 200 mg dose daily.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you stop taking UTROGESTAN:

Do not stop taking UTROGESTAN unless instructed by your doctor.

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

4. Possible side effects

UTROGESTAN can have side effects.

Not all side effects reported for UTROGESTAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking UTROGESTAN, please consult your health care provider for advice. If any of the following happens, stop taking UTROGESTAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your 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 UTROGESTAN. You may need urgent medical attention.

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

Frequent:

- Passing more or less urine than is normal for you or if you experince pain while passing urine.

Less frequent:

- Unexplainded shortness of breath, rapid breathing, chest pain, fast heart rate.

Frequency unknown:

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Dry mouth, frequent urination, loss of appetite, unusual thirst.
- Unusual or rapid weight gain.
- Dizziness, drowsiness, tiredness, headache, mood changes, nervousness.
- Unusual tiredness, or weakness, vertigo (sensation of spinning or swaying), sleeplessness.
- Abdominal pain or cramping, bloating of the stomach, nausea (feeling sick).
- Stopping of menstrual periods, medium to heavy uterine bleeding between your periods, increase amount of menstrual bleeding occurring at regular monthly periods.
- Joint pain.

Less frequent:

- Thin skin that bruises easily.
- Filling or rounding out of the face.
- Mental depression, sleeplessness.
- Hot flushes, low blood pressure.
- Skin rash, acne, darker patches of skin on the face, itching, loss or gain of body, facial or scalp hair.
- Unexpected or increased flow of breast milk.
- Breast pain or tenderness, loss of sexual desire.

Frequency unknown:

- Pain in back, pain that gets worse when you stand or walk, a curved, stooped shape of your spine, a bone that breaks much more easily than expected.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/health-products-vigilance/. By reporting side effects, you can help provide more information on the safety of UTROGESTAN.

5. How to store UTROGESTAN

- Store at or below 25 °C.
- Protect from light and excessive moisture.
- Do not remove from outer carton until use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the capsules after the expiry date printed on the blisters. Decomposed products may be toxic.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

The active substance per soft gelatine capsule contains 100 mg or 200 mg micronised progesterone, respectively.

The other ingredients are gelatine, glycerol, soybean lecithin, sunflower oil and titanium dioxide (E171).

What UTROGESTAN looks like and contents of the pack:

UTROGESTAN:

Round-shaped, slightly yellow, soft gelatine capsule containing an oily whitish suspension (paste).

PVC/aluminium or PVC/PVDC/aluminium blisters with 15 capsules, each carton containing 30 capsules.

UTROGESTAN 200 mg:

Ovoid-shaped, slightly yellow, soft gelatine capsule containing an oily whitish suspension (paste).

PVC/aluminium or PVC/PVDC/aluminium blisters with 15 capsules, each carton containing 15 capsules.

Holder of Certificate of Registration:

Medi Challenge (Pty) Ltd

493 De Jonge Street

Elardus Park

Pretoria

0181

Tel: 011 462 5491

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Registration numbers:

UTROGESTAN: 29/21.8.2/0215

UTROGESTAN 200 mg: A40//21.8.2/0771

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VAGINAL ROUTE

SCHEDULING STATUS

S4

UTROGESTAN, 100 mg and 200 mg, capsules

Micronised progesterone

Sugar free

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- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- UTROGESTAN 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.

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6. Contents of the pack and other information

1. What UTROGESTAN is and what it is used for

UTROGESTAN is a progesterone hormone treatment and is used:

- when your ovaries are not functioning normally;

- during *in vitro* fertilisation cycles (IVF);
- in cases of threatened miscarriage or prevention of recurrent miscarriages;
- to prevent preterm birth if you are pregnant with one baby, you have a short cervix and/or you have a history of preterm birth.

2. What you need to know before you use UTROGESTAN

Do not use UTROGESTAN:

- If you are hypersensitive (allergic) to progesterone or any of the other ingredients of UTROGESTAN (listed in section 6).
- If you suffer from a severe liver disorder.
- If you experience any vaginal bleeding which a doctor has not diagnosed.
- If you have any mammary (breast) or genital cancer.

  If you suffer from any of the following disorders: herpes gestations (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 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 thrombophlebitis (inflammation of your veins due to blood clot formation).
- 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).

Warnings and precautions

Take special care with UTROGESTAN:

- Treatment with UTROGESTAN 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 UTROGESTAN 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.

- UTROGESTAN should not be used as a contraceptive agent as the dosage is not sufficient.
- UTROGESTAN should only be used during the first trimester (12 weeks) of pregnancy.

Other medicines and UTROGESTAN:

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

Tell your doctor or pharmacist if you are currently taking:

- Griseofulvin (used in the treatment of fungal infections).
- Anti-epileptic medicine containing carbamazepine, phenobarbital or phenytoin.
- Tuberculosis treatment containing rifabutin or rifampicin.
- Ciclosporin used in cancer treatment.
- Theophylline (used in the treatment of asthma).

UTROGESTAN with food and drink:

UTROGESTAN is used intravaginally. Food and drink have no effect on the treatment.

Pregnancy, breastfeeding and fertility:

UTROGESTAN can be used during pregnancy to support and maintain pregnancy. Do not use UTROGESTAN if you are breastfeeding your baby.

Driving and using machines:

UTROGESTAN may cause dizziness or drowsiness. Take care when driving a vehicle or using machines that requires concentration while you are being treated with UTROGESTAN.

UTROGESTAN contains soybean lecithin:

If you are allergic to peanut or soya, do not use UTROGESTAN.

3. How to use UTROGESTAN

Do not share medicines prescribed for you with any other person.

Always use UTROGESTAN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How much to use:

The usual daily dose is 100 mg to 600 mg divided into one, two or three intakes.

The dose of UTROGESTAN and duration of treatment will be determined by your doctor for your specific condition.

Insert the capsule(s) deep into the vagina.

If you have the impression that the effect of UTROGESTAN is too strong or too weak, talk to your doctor or pharmacist.

If you use more UTROGESTAN than you should:

In the event of overdosage, consult your doctor or pharmacist immediately. If he/she is unavailable, seek help at the nearest hospital or poison control centre.

If you missed a dose of UTROGESTAN:

If you forget a dose, insert it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not insert a double dose to make up for a forgotten dose.

If you have trouble remembering when to use UTROGESTAN, ask your pharmacist for some hints.

If you stop using UTROGESTAN:

Do not stop using UTROGESTAN unless instructed by your doctor.

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

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- swelling of your 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 UTROGESTAN. You may need urgent medical attention.

The following side effects may occur with UTROGESTAN:

- vaginal discharge
- vaginal haemorrhage
- itching.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/health-products-vigilance/. By reporting side effects, you can help provide more information on the safety of UTROGESTAN.

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- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
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- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UTROGESTAN contains:

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Round-shaped, slightly yellow, soft gelatine capsule containing an oily whitish suspension (paste).

PVC/aluminium or PVC/PVDC/aluminium blisters with 15 capsules, each carton containing 30 capsules.

UTROGESTAN 200 mg:

Ovoid-shaped, slightly yellow, soft gelatine capsule containing an oily whitish suspension (paste).

PVC/aluminium or PVC/PVDC/aluminium blisters with 15 capsules,

each carton containing 15 capsules.

Holder of certificate of registration:

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Tel: 011 462 5491

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