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APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

DUPHASTON 10 mg film-coated tablets

Dydrogesterone

Contains sugar (111,1 mg lactose monohydrate per tablet).

Read all of this leaflet carefully before you start taking DUPHASTON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DUPHASTON 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 DUPHASTON is and what it is used for

DUPHASTON is used in the treatment of deficiencies of a hormone called progesterone.

DUPHASTON is used:

- *For problems you may get when your body does not produce enough progesterone:*
  - to control irregular menstrual cycle;
  - by growth of the womb lining outside the womb (endometriosis);
  - painful menstruation;

- infertility due to low level of progesterone;
- luteal support as part of induced cycles during fertility treatments;
- to limit the risk of a threatened miscarriage;
- if you have had repeated miscarriages (habitual miscarriage);

- *Hormone Replacement Therapy (HRT)*

  DUPHASTON is also used in combination with oestrogen:
  - to prevent abnormalities in the lining of the womb during treatment of menopausal symptoms;
  - if you have stopped having periods before the menopause;
  - for unusually heavy and/or irregular periods.

  This medicine is not a contraceptive.

Your body normally balances the amount of the natural hormones progesterone and oestrogen (the other female hormone). If your body does not produce enough progesterone, DUPHASTON compensates and restores the balance.

Your doctor may also ask you to use oestrogen in addition to DUPHASTON. This depends on what you are using DUPHASTON for.

For some women using hormone replacement therapy (HRT), taking only an oestrogen can cause an abnormal thickening of the womb lining. This may also be the case if you do not have your womb and have a history of endometriosis (womb tissue outside the womb). Taking DUPHASTON for part of your monthly cycle helps to prevent a build up of your womb lining.

2. What you need to know before you take DUPHASTON

Do not take DUPHASTON:

- If you are allergic (hypersensitive) to dydrogesterone or any of the other ingredients in DUPHASTON tablets (listed in section 6);
- If you have or have ever had tumours that grow in response to sex hormones or if you are suspected of having tumours that grow in response to sex hormones;
- If you have unexplained vaginal bleeding;

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- If you suffer from or have a history of blood clots;
- If you suffer from a condition where the lining of the womb have grown extensively (also called endometrial hyperplasia) and you are taking a hormone called oestrogen for it;
- If you have or have ever had breast cancer, or if you are suspected of having it, or have a family history of 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 a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency);
- If you have or have ever had a liver disease and your liver function tests have not returned to normal;
- If you have inherited genetic mutations: BRCA1 and BRCA 2 genes;
- If you have experienced early menstrual periods (before the age of 12 years);
- If you have a history of non-cancerous breast diseases (atypical hyperplasia or lobular carcinoma in situ);
- If you have had previous treatment using radiation therapy to the chest or breast;
- If you have had previous exposure to diethylstilbestrol (DES);
- If you have or have ever had a serious liver disorder and your liver function has not as yet fully recovered.

Warnings and precautions

If you need to take DUPHASTON for abnormal monthly bleeding, your doctor will find the cause of the bleeding before you start taking this medicine.

If you get unexpected vaginal bleeding or spotting, it is usually nothing to worry about. It is especially likely during the first months of taking DUPHASTON. However, make an appointment to see your doctor straight away if bleeding or spotting:

- carries on for more than a few months,
- starts after you have been on treatment for a few months,
- carries on even after you have stopped treatment.
- If you use DUPHASTON for luteal support as part of induced cycles during fertility treatments and

your doctor diagnoses an abortion or miscarriage, treatment should be discontinued;

This may be a sign that your womb lining has become thicker. Your doctor will look into the cause of the bleeding or spotting and may do a test to find out if you have cancer of the womb lining.

Take special care with DUPHASTON:

- If you suffer from migraine or get migraine-like headaches while using DUPHASTON if you have never had these before.
- If you get severe headaches or migraines more often than normal.
- If your blood pressure suddenly increases significantly.
- If you have a stroke.
- If you get blood clotting (thrombosis).
- If you have abnormal vaginal bleeding.
- If you use DUPHASTON to limit the risk of miscarriage, the condition of the mother and foetus must be closely monitored during treatment.
- If you suffer from depressed mood.
- If you have rare disorders, known to be influenced by sex hormones, such as: severe itching, jaundice due to blockage of the bile ducts, herpes during pregnancy, a certain metabolic disorder (porphyria) and otosclerosis (which causes abnormal growth of the bone in the middle ear resulting in hearing loss).
- If you have previously had a growth or tumour that has reacted to the use of hormones;
- If you have conditions of the gastro-intestinal tract, such as galactose intolerance, Lapp lactase deficiency and glucose-galactose malabsorption;
- If you suffer from heart disease;
- If you suffer from kidney or liver impairment;
- If you suffer from diabetes;
- If you suffer from asthma;
- If you suffer from epilepsy;

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist. It is particularly

important to tell them if the problems above have ever got worse during pregnancy or previous hormone therapy. Your doctor may want to monitor you more closely during treatment. If they get worse or reappear while taking DUPHASTON, your doctor may stop treatment with DUPHASTON.

DUPHASTON and hormone replacement therapy (HRT)

HRT has some risks which you and your doctor need to consider when you are deciding whether to take these medicines. If you are taking DUPHASTON with an oestrogen as part of HRT, the following information is important. Please also read the information leaflet that comes with your oestrogen medicine.

Early menopause

There is limited evidence about the risks of HRT when it is used to treat early menopause. There is a low level of risk in younger women. This means that the balance of benefits and risks for younger women using HRT for early menopause may be better than in older women.

Medical check-ups

Before you start taking HRT, a complete personal or family medical history will be taken. A physical (including pelvic and breast) examination will be performed. You are also required to have periodic check-ups, including a breast examination, during treatment with DUPHASTON. You should examine your breasts regularly for any changes. If any changes occur, you must contact your doctor immediately.

You may need to be regularly monitored by your doctor while you are using DUPHASTON.

Cancer of the lining of the womb (endometrial cancer)

Women who have womb and take oestrogen-only HRT for a long time have a higher risk of cancer and abnormal thickening of the womb lining. Taking progestogen tablets as well as an oestrogen for at least 12 days per month can prevent this extra risk.

HRT and breast cancer

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Research has shown that women who take oestrogen-only HRT or oestrogen-progestogen HRT for a few years have a higher risk of breast cancer. The risk increases with the duration of HRT and seems to increase to baseline over the five-year period after the woman has stopped HRT. You must inform your doctor immediately if any changes in your breasts occur.

HRT and ovarian cancer

Ovarian cancer is rare.

The use of oestrogen-only or combined oestrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

HRT and thrombosis

A blood clot can be serious and if it finds its way into the lungs, it can lead to chest pains, shortness of breath, fainting or even death.

You are more likely to develop deep vein thrombosis if:

- you are older
- you have cancer
- you are very overweight
- you are taking an oestrogen
- you are pregnant or recently had a baby
- if you have ever had deep vein thrombosis or have another blood clotting disorder or any of your direct family members have had deep vein thrombosis
- you have been off your feet for a long time because of surgery, injury or illness (see information under "Surgery")
- you have systemic lupus erythematosus (a disease affecting the immune system).

If any of these things apply to you (or you are not sure), talk to your doctor to see if you should take HRT. If you get deep vein thrombosis or pulmonary embolism while using HRT, you should immediately stop taking HRT. Immediately tell your doctor about any symptoms that may indicate deep vein thrombosis or

pulmonary embolism, such as painful swelling of one of your legs, sudden chest pain, or shortness of breath.

Tell your doctor or pharmacist if you are taking anti-coagulants, such as warfarin. Your doctor will pay special attention to the benefits and risks of you taking HRT.

Surgery

If you are going to have surgery, tell your doctor before the operation that you are taking HRT. Do this well before the operation. You may need to stop taking HRT several weeks before the scheduled operation. Your doctor will tell you when you can start taking HRT again.

HRT and coronary disorders

Two large studies have shown that the risk of cardiovascular diseases may have been higher during the first year of HRT. It is yet unclear whether this also applies to other types of HRT.

If you get a pain in your chest that spreads to your arm or neck:

- see a doctor as soon as possible
- do not take any more HRT until your doctor says you can.

This pain could be a sign of heart disease.

HRT and stroke

The risk of a stroke is about 1,5 times higher in women on HRT than in women not on HRT. The number of additional cases of stroke as a result of HRT increases with age.

The comparable risk for users, versus non-users, does not change with age or time since menopause. The risk of stroke increases with age. This means that the general risk of stroke in women who use HRT will increase with age.

If you get an unexplained headache or migraine (which can include disturbed vision):

- see a doctor as soon as possible
- do not take any more HRT until your doctor says you can.

This may be an early warning sign of a stroke.

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Children and adolescents

DUPHASTON is not recommended for use in children before their first menstrual bleed. It is not known how safe or effective DUPHASTON is in children below 18 years of age.

Other medicines and DUPHASTON

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

Tell your doctor if you have used or are taking any of the following medicines. These medicines may lower the effect of DUPHASTON and lead to irregular bleeding:

- herbal medicines containing St John's Wort (Hypericum perforatum),
- medicines for epilepsy (such as phenobarbital, phenytoin, carbamazepine, primidone),
- medicines for infection (such as rifampicin),
- medicines for HIV infection (AIDS) (such as ritonavir, nevirapine, efavirenz),
- medicines for hepatitis-C virus.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking DUPHASTON.

DUPHASTON with food, drink and alcohol

DUPHASTON must be taken with food.

Do not take DUPHASTON with alcohol.

Pregnancy, breastfeeding and fertility

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 this medicine.

There may be an increased risk of a birth defect of the penis involving the urinary opening (hypospadias) in children whose mothers have taken certain progestogens. However, this increased risk is not yet certain.

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Do not take DUPHASTON if you are breastfeeding.

There is no evidence that DUPHASTON decreases your fertility, if taken as recommended by your doctor.

Driving and using machines

You may feel slightly sleepy or dizzy after taking DUPHASTON. This is more likely in the first few hours after taking it. If this happens, do not drive or use any tools or machines. Do not drive or operate machines until you know how DUPHASTON affects you.

DUPHASTON contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DUPHASTON.

3. How to take DUPHASTON

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

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

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

Swallow the tablet with water.

You can take the tablets with or without food.

If you have to take more than one tablet, spread them evenly over the day. For example, take one tablet in the morning and one in the evening.

Try to take the tablets at the same time each day. This will make sure that there is a constant amount of the medicine in your body. This will also help you remember to take your tablets.

The score line on each tablet is only to help break the tablets so they are easier to swallow.

It should not be used in order to take half a tablet.

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How much DUPHASTON to take

The number of tablets you take and the days you take them on will depend on what you are being treated for. If you are still having natural periods, day 1 of your cycle is when you start bleeding. If you are not having natural periods, your doctor will decide with you when to start day 1 of the cycle and when to start taking your tablets.

If you are prescribed 2 per day, take one tablet every 12 hours. If you are prescribed 3 tablets per day, take one tablet every 8 hours.

To regulate your menstrual cycle:

- Take 1 tablet a day.
- Do this from the second half of your cycle until the first day of your next cycle.
- The starting day and number of days you take your tablets for will depend on the length of your cycle.

To treat endometriosis (presence of womb lining outside the womb):

- Take 1 to 3 tablets a day.
- You will either be asked to take your tablets:
  - on every day of your cycle or
  - only on cycle days 5 to 25.

For period pain:

- Take 1 or 2 tablets a day.
- Do this only on cycle days 5 to 25.

For unusually heavy or irregular periods:

- To stop bleeding:
  - Take 2 tablets a day.
  - Do this for 5 to 7 days. You will get severe withdrawal bleeding after this.

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- For continuous treatment:
  - Take 1 tablet a day.
  - Do this during the second half of your cycle.

The starting day and number of days you take your tablets for will depend on the length of your cycle. You will generally have withdrawal bleeding a few days after your last DUPHASTON tablet.

To treat infertility due to low levels of progesterone:

- Take 1 tablet a day.
- Do this from the second half of your cycle until the first day of your next cycle.
- The starting day and number of days you take your tablets for will depend on the length of your cycle.
- Continue treatment for at least 3 cycles in a row.

Luteal support as part of induced cycles during fertility treatments:

- Take 1 tablet three times a day, starting at the day of egg retrieval, and continuing for 10 weeks if pregnancy is confirmed.

To limit the risk of a threatened miscarriage:

- Start by taking 4 tablets and then take 1 tablet every 8 hours. Take 2 tablets every 8 hours after this if the symptoms do not disappear or return.
- Treatment should be continued for one week after the symptoms have disappeared. The dose can be tapered down slowly after this.

If you have had repeated miscarriages:

- 1 tablet per day until the 12th week of pregnancy. The dose can be tapered down slowly after this. Treatment should preferably be started before conception.

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To prevent abnormalities in the lining of your womb while treating menopausal symptoms:

- If you are using a hormone called oestrogen, that you are taking every day (continuous therapy):1 to 2 tablets of DUPHASTON per day for 14 days per cycle. You will generally have withdrawal bleeding a few days after your last DUPHASTON tablet.
- If you are using a hormone called oestrogen, that you are taking only certain times of the month (cyclic therapy):

  One tablet of DUPHASTON twice daily during the last 12 to 14 days of the treatment.

If you take more DUPHASTON 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.

If you forget to take DUPHASTON

Take your missed dose as soon as you remember.

Take your next dose at the normal time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DUPHASTON

If you have stopped taking DUPHASTON for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting.

4. Possible side effects

DUPHASTON can have side-effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

If any of the following happens, stop taking DUPHASTON and tell your doctor immediately or go to the casualty department at your nearest hospital:

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- swelling of the hands, feet, angkles, facte, lips and mouth or throat, which may cause diffuculty 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 reaction to DUPHASTON. 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:

- alterations in liver function (with yellowing of the skin).

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

Tell your doctor if you notice any of the following:

The following side-effects may occur more frequently:

- migraines/headache,
- vaginal bleeding,
- irregular, heavy or painful periods,
- nausea (feeling sick), vomiting (being sick), pain in your stomach area.
- breakthrough bleedings.

The following side-effects may occur less frequently:

- feeling weak or unwell,
- and stomach pain,
- feeling depressed,
- allergic skin reactions (e.g. rash, itching, nettle rash),
- heavy and painful menstrual bleeding,
- increased weight,
- breast pain, breast tenderness,

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- iron deficiency in the blood,
- sleepiness,
- dizziness,
- water retention in or around the face, water retention under the skin.

The following side-effects may occur with an unknown frequency:

- increase in the size of tumours affected by progestogens (such as meningioma),
- anaemia by too strong destruction of red blood cells (haemolytic anemia),
- swelling due to fluid retention, often in the lower legs or ankles,

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

Side effects of taking DUPHASTON with an estradiol (oestrogen-progestogen HRT)

If you are taking DUPHASTON together with an oestrogen, please also read the information leaflet that comes with your oestrogen medicine. See section 2 "What you need to know before you take this medicine" for more information on the side effects below.

Stop taking DUPHASTON and see a doctor straight away, if you notice any of the following side effects:

- Painful swelling in your leg, sudden chest pain or difficulty breathing. These could be signs of a blood clot.
- Pain in your chest that spreads to your arm or neck. This could be a sign of a heart attack.
- Severe, unexplained headache or migraine (with or without vision problems). These could be signs of a stroke.

Stop taking DUPHASTON straight away, if you notice any of the side effects above.

Make an appointment to see a doctor straight away if you notice:

- dimpling of the skin in your breast, changes in the nipple or lumps you can see or feel. These could be signs of breast cancer.

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Other side effects of taking DUPHASTON with an oestrogen include abnormal thickening or cancer of the lining of the womb and ovarian cancer.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more information on the safety of DUPHASTON.

5. How to store DUPHASTON

- Do not take the tablets after the expiry date printed on the pack.
- Keep the tablets in their original packs and store at room temperature (below 25 °C) in a dark place.
- If you don't need to take this medicine anymore, take it to your doctor or nearest pharmacy who will dispose of it.
- **Store all medicines out of reach of children.**

6. Contents of the pack and other information

What DUPHASTON contains

The active substance is: 10 mg dydrogesterone per film-coated tablet.

The other ingredients arecolloidal anhydrous silica, hypromellose, lactose, magnesium stearate, maize starch, Opadry Y-1-7000 white, consisting of hypromellose, macrogol 400 and titanium dioxide (E 171).

What DUPHASTON looks like and contents of the pack

A round, biconvex, scored white film-coated tablet, one side with inscription '155' on either side of the score.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Clear PVC/aluminium blister strips placed in an outer carton.

Available in packs of 30 tablets.

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Holder of certificate of registration

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

Constantia Kloof 1709

South Africa

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