APPROVED PATIENT INFORMATION LEAFLET

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 or your pharmacist.
- **DUPHASTON** 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

DUPHASTON 10 mg TABLETS

Film-coated tablets

WHAT DUPHASTON CONTAINS:

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

The inactive ingredients are:

Lactose , hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate, Opadry Y-1-7000 white, consisting of hypromellose, macrogol 400 and titanium dioxide (E 171)

WHAT DUPHASTON IS USED FOR:

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

These deficiencies may be:

- Irregular duration of menstrual cycles and irregular occurrence and duration of periods;
- Duphaston is also used in combination with another hormone, called oestrogen in:

- Treatment of the condition when no menstrual bleeding occurs (amenorrhoea);
- Treatment of bleeding of the womb or uterus;
- Complaints or symptoms that may occur after women have gone through the change of life (post-menopausal).

This medicine is not a contraceptive.

BEFORE YOU TAKE DUPHASTON:

Do not take DUPHASTON:

- If you are allergic to dydrogesterone or any other ingredient in Duphaston tablets;
- If you have undiagnosed vaginal bleeding;
- If you suffer from or have a history of blood clots;
- If your doctor suspects that you have or are developing any tumours that may be dependent on hormone production;
- 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.

Take special care with DUPHASTON:

- 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 you suffer from migraine;
- If you suffer from porphyria;
- If you have a history of depression.

Before you start treatment with **DUPHASTON** in combination with another hormone called oestrogen for menopausal complaints, 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 during treatment with **DUPHASTON**. You must inform your doctor immediately if any changes in your breasts occur. Breakthrough bleeding and spotting may sometimes occur during the first months of treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continue after treatment has been discontinued, you must inform your doctor immediately.

You should examine your breasts regularly for any changes. If any changes occur, you must contact your doctor immediately. You should also go for regular breast examinations (called a mammography), while you are taking **DUPHASTON.**

Taking DUPHASTON with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DUPHASTON** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

If you are pregnant or breastfeeding your baby while taking **DUPHASTON** ***please consult your doctor, pharmacist or other health care professional for advice.***

HOW TO TAKE DUPHASTON:

Always take **DUPHASTON** exactly as your doctor 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, talk to your doctor or pharmacist.

In irregular duration of menstrual cycles and irregular occurrence and duration of periods, treatment should be repeated for several cycles.

Treatment of the condition when no menstrual bleeding occurs (amenorrhoea):

0,05 mg of a different product containing ethinylestradiol is administered each day from the 1st to the 25th day of the cycle, and one tablet of Duphaston 10 mg is added twice daily from the 11th to the 25th day. Five days after bleeding starts, the same dosage is repeated. Your natural cycle should then start again.

Treatment of bleeding of the womb or uterus:

- To stop bleeding:

  One tablet of Duphaston 10 mg together with 0,10 mg of a different product containing ethinylestradiol twice daily for 5 to 7 days.

- To prevent heavy bleedings:

  One tablet of Duphaston 10 mg twice daily from day 11 to day 25 of the cycle, if necessary, combined with a different product containing an oestrogen during the first half of the cycle.

Complaints or symptoms that may occur after women have gone through the change of life (post-menopausal):

If you are using a hormone called oestrogen, that you are taking every day (continuous therapy):

One tablet of Duphaston 10 mg twice daily during the first 12 to 14 days of each calendar month.

If you are using a hormone called oestrogen, that you are taking only certain times of the month (cyclic therapy):

One tablet of Duphaston 10 mg twice daily during the last 12 to 14 days of the treatment.

Duphaston is not recommended for use in children below 18 years of age.

If you take more DUPHASTON than you should:

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

If you forget to take a tablet, take it 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.

POSSIBLE SIDE EFFECTS:

DUPHASTON can have side-effects.

The following side-effects may occur more frequently:

Migraines/headache, breakthrough bleedings

The following side-effects may occur less frequently:

Alterations in liver function (with yellowing of the skin), 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. Iron deficiency in the blood, hypersensitivity reactions, water retention in or around the face and water retention under the skin may also occur.

APPROVED PATIENT INFORMATION LEAFLET

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

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.

PRESENTATION:

Available in packs of 30 tablets.

IDENTIFICATION:

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.

REGISTRATION NUMBER:

S/21.8.2/165

APPROVED PATIENT INFORMATION LEAFLET

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

Constantia Kloof

1709

South Africa

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

20 April 2012

The Patient Information Leaflet has been checked and is free of typographical and grammatical errors Initials:___