

DUPHASTON® TABLET

Dydrogesterone (10mg)

What is in this leaflet

1. What Duphaston® is used for
2. How Duphaston® works
3. Before you use Duphaston®
4. How to use Duphaston®
5. While you are using it
6. Side effects
7. Storage and disposal of Duphaston®
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

What Duphaston® is used for

Duphaston® is used for problems you may get when your body does not produce enough progesterone:

- painful periods
- endometriosis, where tissue from the lining of the womb grows outside the womb.
- unusual menstrual bleeding
- periods that have stopped before the menopause
- pre-menstrual syndrome (PMS)
- irregular periods
- to reduce the risk of miscarriage (threatened and recurrent)
- infertility due to low levels of progesterone.
- as part of Assisted Reproductive Technology (ART) treatment

Duphaston® is also used to treat the symptoms of menopause in women with intact womb.

How Duphaston® works

The body normally balances the amount of the natural hormone progesterone with estrogen (the other major female hormone). If your body does not produce enough

progesterone, Duphaston® makes up for this and restores the balance.

Before you use Duphaston®

- When you must not use it

Do not take Duphaston® if:

- if you are allergic (hypersensitive) to dydrogesterone or to any of the other ingredients of Duphaston®.
- You have, or might have a tumour that is made worse by progesterone - such as a brain tumour called a 'meningioma'
- You have vaginal bleeding and the cause is not known.

If you are not sure, talk to your doctor or pharmacist before taking it.

Duphaston® is not recommended for use in children below age 18 due to insufficient safety information

- Before you start to use it

Talk to your doctor or pharmacist before taking Duphaston® if you suffer from any medical conditions or illnesses, in particular if you have:

- depression
- liver problem
- a rare inherited blood problem called "porphyria"
- increased tendency to form blood clots (e.g. major surgery, prolonged immobilization, obesity, pregnancy/after delivery period, and cancer)

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without

a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- herbal medicines containing St John's wort, sage, or ginkgo biloba.
- medicines for fits (epilepsy) such as phenobarbital, carbamazepine, phenytoin
- medicines for infections such as rifampicin, rifabutin, nevirapine, efavirenz
- medicines for HIV infection (AIDS) such as ritonavir, nelfinavir.

How to use Duphaston®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

For painful periods

Take one tablet twice daily from day 5 to day 25 of your cycle.

For endometriosis

Take one tablet two or three times daily. You will either be asked to take your tablets:

- On every day of your cycle
- On days 5 to 25 of your cycle.

For unusual menstrual bleeding

When treatment is started to stop bleeding:

- Take one tablet twice daily for 5 to 7 days

When treatment is started to prevent bleeding:

- Take one tablet twice daily from day 11 to 25 of your cycle

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For periods that have stopped before the menopause

Your doctor should prescribe a hormone oestrogen along with Duphaston®. Then take the oestrogen once daily from day 1 to day 25 of the cycle, together with one tablet of Duphaston® twice daily from day 11 to day 25 of the cycle.

For pre-menstrual syndrome (PMS)

Take one tablet twice daily from day 11 to day 25 of your cycle.

For irregular periods

Take one tablet twice daily from day 11 to day 25 of the cycle

For threatened abortion due to low levels of progesterone

Take four tablets at once, then one tablet every eight hours until symptoms resolved.

For recurrent abortion due to low levels of progesterone

Take one tablet twice daily until the twentieth week of pregnancy.

For infertility due to low levels of progesterone

Take one tablet once a day from day 14 to 25 of the cycle. Continue treatment for at least six cycles in a row.

To reduce the risk of miscarriage (ART)

Take one tablet three times daily starting at the day of oocyte retrieval and continuing for 10 weeks if pregnancy is confirmed.

- When to use it

Use as directed by your doctor or pharmacist.

Swallow each 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 steady amount of the medicine in your body. This will also help you remember to take your tablets.

- How long to use it

Continue taking Duphaston® for as long as your doctor or pharmacist recommends.

- If you forget to use it

Do not take a double dose to make up for the forgotten dose. Take the next dose at your regular time. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more Duphaston® than you should stop taking Duphaston® and talk to a doctor or pharmacist.

While you are using it

- Things you must do

Tell your doctor immediately if you become pregnant while taking this medication

- Things to be careful of

The following diseases are reported more often in women using hormone replacement therapy(HRT) compared to women not using HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb
- ovarian cancer
- blood clots in the veins of the legs or lungs
- heart disease
- stroke

If you experience any symptoms of blood clot, such as painful swelling in leg, shortness of breath or sudden pain in chest, please contact your doctor immediately.

Breakthrough bleeding and spotting may occur during the first month of treatment. Consult your doctor or pharmacist if this problem persists.

Pregnancy and breast feeding

Do not take Duphaston® if you are breast feeding or plan to breastfeed your baby, because the medicine passes into breast milk in small quantity.

Duphaston® may be used in pregnancy if indicated.

Driving and use of machines

Duphaston® may cause mild sleepiness and/or dizziness, especially within the first few hours after intake. Therefore, care should be taken when driving or using machines.

Important information about some of the ingredients of Duphaston®

Duphaston® contain lactose sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

DUPHASTON® TABLET

Dydrogesterone (10mg)

Side effects

Like all medicines, Duphaston® can cause side effects, although not everybody gets them.

Very common (affects more than 1 in 10 people):

- vaginal bleeding

Common (affects less than 1 in 10 people):

- abdominal pain
- migraine, headache
- nausea and vomiting
- tender or painful breasts
- irregular, heavy or painful periods
- no periods or periods happening less often than normal.

Uncommon (affects less than 1 in 100 people):

- weight gain
- feeling dizzy
- feeling depressed
- allergic skin reactions - such as rash, severe itching or hives.

During treatment, periodic checkups are recommended. If you notice any changes in your breast, please consult your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of

Duphaston®

- Storage

Keep this medicine out of the sight and reach of children. Do not use Duphaston® after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the blister in the outer carton, in order to protect from moisture.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Duphaston® tablets are round, biconvex and have 155 marked on one side of the score line.

Duphaston® is available in cartons of 10's, 14's and 20's tablets. Not all pack sizes may be marketed.

- Ingredients

- Active ingredient(s)

Dydrogesterone

- Inactive ingredients

Lactose monohydrate, hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate, hypromellose, macrogol 400, titanium dioxide (E171)

- MAL number:

Duphaston® Tablet 10mg:
MAL19920643AZ

Manufacturer

Abbott Biologicals B.V.,
Veerweg 12, 8121
The Netherlands

Product Registration Holder

Abbott Laboratories (M) Sdn. Bhd.
27-02, Level 27, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor
Darul Ehsan, Malaysia

Date of revision

- 27/04/2022

Serial Number

NPRA (R1/1) 26042022/105