Package Leaflet: Information for the user

Duphaston® 10mg film-coated tablets

dydrogesterone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor, pharmacist or nurse.
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1 What Duphaston is and what it is used for
2 What you need to know before you take Duphaston
3 How to take Duphaston
4 Possible side effects
5 How to store Duphaston
6 Contents of the pack and other information

1. What Duphaston is and what it is used for

What Duphaston is
Duphaston contains a medicine called “dydrogesterone”. Dydrogesterone is a man-made hormone. It is very similar to the hormone “progesterone” made by your body. Medicines like Duphaston are called “progestogens”

What Duphaston is used for
Duphaston can be used alone or with an estrogen. Whether you take an estrogen as well, depends on what you are taking the medicine for.

Duphaston is used:
For problems you may get when your body does not produce enough progesterone:
to relieve painful periods
to relieve the symptoms of endometriosis (a problem caused by growth of the womb lining outside the womb)
to treat infertility due to low level of progesterone
to control irregular periods (that come at the wrong time or not at all)
to relieve the symptoms of premenstrual syndrome (PMS).
to re-start periods that have stopped before the menopause (amenorrhoea)
to stop or prevent unusually heavy or long periods (often due to the start of the menopause).

To treat the signs of your menopause – this treatment is called Hormone Replacement Therapy or ‘HRT’.
Duphaston is used with an estrogen to treat the signs of your menopause. These signs vary from woman to woman.

How Duphaston works
Duphaston is used to treat problems which you may get when your body is not making enough of its own progestogen hormone. This is normally produced in your ovaries from puberty until your menopause. The progestogen (dydrogesterone) in Duphaston replaces this missing hormone. In your body, progestogen is normally balanced against the major female hormone estrogen. Your doctor may also have prescribed an estrogen medicine for you so that you get the right balance of hormones. For some women using HRT, taking only an estrogen 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. Taking dydrogesterone 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

If you are just taking Duphaston
Before taking your medicine, you should make sure it is safe for you to do so.

Do not take Duphaston if:
• you have a tumour that is made worse by progestogens (such as meningioma)
• you have irregular or unusually heavy periods that your doctor does not already know about
• you are allergic (hypersensitive) to any of the ingredients of this medicine listed in Section 6
Do not take Duphaston if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Duphaston.
If you are **taking Duphaston together with an estrogen for example part of a HRT**, please also read the “Do not take” section on the information leaflet that comes with your estrogen medicine.
Before taking your medicine you should also make sure that it is safe for you to take the estrogen product at the same time.

Warnings and Precautions
If you need to take Duphaston for abnormal 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 while
• carries on even after you have stopped treatment
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.

Check with your doctor or pharmacist before taking Duphaston if you have any of the following:
• depression
• liver problems
• a rare blood problem passed down in families (inherited) called “porphyria”.
If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Duphaston. 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.

Duphaston and HRT
As well as benefits, 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 estrogen as part of HRT, the following information is important. Please also read the information leaflet that comes with your estrogen 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, your doctor should ask about you and your family’s medical history. Your doctor may decide to examine your breasts or your tummy (abdomen) and may do an internal examination.
They will only do this if it is necessary for you or if you have any special concerns.
Once you have started on HRT, see your doctor for regular check-ups (at least once a year), he may do screening tests such as a mammogram (an X-ray of the breasts). At these check-ups, your doctor may discuss the benefits and risks of continuing to take HRT.
Make sure that you:
• go for regular breast screening and cervical smear tests
• regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Heart disease
HRT will not help to prevent heart disease. HRT is not recommended for women who have heart disease or have had heart disease recently.
The risk of heart disease also increases with age. The number of extra cases of heart disease due to use of estrogen-progestogen HRT is very low in healthy women close to menopause. The number of extra cases increases with age. If you have ever had heart disease, talk to your doctor to see if you should take 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.

Stroke
Taking estrogen-progesterone HRT and estrogen only HRT increases the risk of having a stroke. The risk is up to one and a half times that of people not taking HRT. 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.

Blood clots
HRT increases the risk of blood clots in the veins (a deep vein thrombosis or DVT) the risk is up to 3 times higher than that of people not taking HRT, especially during the first year of taking it.
You are more likely to get a blood clot if:
• you are older
• you have cancer
• you are very overweight
• you are taking an estrogen
• you are pregnant or have recently had a baby
• you (or close family) have had a blood clot before, including in the leg or lung
• you have been off your feet for a long time because of major surgery, injury or illness (see information under “Operations”)
• you have systemic lupus erythematosus (SLE). This is a problem that causes joint pain, skin rashes and fever.
If any of these things apply to you, talk to your doctor to see if you should take HRT.
If you get painful swelling in your leg, sudden chest pain or have difficulty breathing:
• see a doctor as soon as possible
• do not take any more HRT until your doctor says you can.
These may be signs of a blood clot.
Also, tell your doctor or pharmacist if you are taking medicines to prevent blood clots (anti-coagulants) - such as warfarin. Your doctor will pay special attention to the benefits and risks of you taking HRT.

Breast cancer
Women who take estrogen-progestogen HRT or estrogen-only HRT have a higher risk of breast cancer. The risk depends on how long you take HRT.

The extra risk of breast cancer goes up the longer you take it, after about 3 (1-4) years. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.
If you notice any changes in your breast, such as:
• dimpling of the skin
• changes in the nipple
• any lumps you can see or feel.
Make an appointment to see your doctor as soon as possible.

Endometrial cancer (cancer of the lining of the womb) and endometrial hyperplasia
Women who have womb and take estrogen-only HRT for a long time have a higher risk of cancer of the lining of the womb (the endometrium) and endometrial hyperplasia (abnormal thickening of the womb lining).
Taking Duphaston as well as an estrogen (for at least 12 days per month - or 28 day cycle) or as continuous combined estrogen-progestogen therapy can prevent this extra risk.

Ovarian cancer
Ovarian cancer is rare – much rarer than breast cancer. The use of estrogen-only or combined estrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.
The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

Other medicines and Duphaston
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription or herbal medicines.
In particular, tell your doctor or pharmacist if you are taking any of the following:
These medicines may lower the effect of Duphaston and lead to bleeding or spotting
• medicines for fits (epilepsy) such as phenobarbital, phenytoin or carbamazepine
• medicines for infection such as rifampicin, rifabutin, nevirapine, efavirenz
• medicines for HIV infection (AIDS) such as ritonavir or nelfinavir
• herbal medicines containing St John's Wort (Hypericum perforatum), sage, or ginkgo biloba
If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Duphaston.

Operations or tests
• Tell your doctor if you are going to have surgery. Do this well before the operation. You may need to stop taking HRT about 4 to 6 weeks before the operation to reduce the risk of a blood clot. Your doctor will tell you when you can start taking HRT again.
• If you visit a hospital or your family doctor for a blood or urine test, tell them that you are taking Duphaston. This is because this medicine may affect the results of these tests.

Children and young people
Duphaston is not for use in children before their first menstrual bleed. It is not known how safe or effective Duphaston is in young people aged 12-18 years.

Fertility, Pregnancy and breast-feeding
Fertility
There is no evidence that dydrogesterone decreases your fertility, if taken as recommended by your doctor.
Pregnancy
There may be an increased risk of hypospadias (a birth defect of the penis involving the urinary opening) in children whose mothers have taken certain progestogens. However, this increased risk is not yet certain. So far, there is no evidence that taking dydrogesterone during pregnancy is harmful.
More than 10 million pregnant women have taken Duphaston.
• Talk to your doctor before taking Duphaston if you are pregnant.
• If you become pregnant or think you might be pregnant see your doctor. Your doctor will discuss with you the benefits and risks of taking Duphaston while you are pregnant.
Breast-feeding
Do not take Duphaston if you are breast-feeding. It is not known if Duphaston passes into mother's milk and affects the child. Studies of other progestogens show small amounts pass into the mother's milk.

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. Wait to see how Duphaston affects you, before you drive or use any tools or machines.

Duphaston contains milk sugar (lactose). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.
This includes rare problems passed down in families that affect how the body uses lactose, such as "total lactase deficiency" or "glucose-galactose malabsorption".

3. How to take Duphaston
Always take Duphaston exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will adjust the dose to suit you.
While you are taking Duphaston, you should see your doctor regularly (at least once a year). Your doctor may wish to carry out medical checks, including breast examinations.

Taking this medicine
• Swallow the tablet with water

• You can take your tablet 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 your tablet 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.

How much to take
The number of tablets you take and the days you take them on will depend on what you are being treated for. Your doctor will decide the best time for you to take Duphaston. 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.

<u>To relieve the symptoms of pre-menstrual syndrome</u>
• Take 2 tablets 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.
• Your doctor may decide to give you a higher dose.
<u>To relieve the symptoms of endometriosis</u>
• Take 2 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.
<u>To treat infertility due to low levels of progesterone</u>
• Take 2 tablets 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 three cycles in a row.
• If you become pregnant, tell your doctor.
<u>For irregular periods</u>
• Take 2 tablets 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.
<u>To re-start periods that have stopped before the menopause</u>
• Take 2 tablets a day.
• Do this for fourteen days during the second half of your expected cycle.
<u>For menstrual bleeding that is unusually heavy or happens between periods</u>
When treatment is started to stop bleeding:
    - Take 2 tablets a day
    - Do this for five to seven days.
For continuous treatment:
    - Take 2 tablets 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.
<u>To relieve painful periods</u>
• Cycle days 5 to 25: Take 2 tablets a day.
<u>For hormone replacement therapy (HRT)</u>
• If you are on 'sequential' HRT (you take an estrogen tablet or use a patch for your whole cycle):
    - Take 1 tablet a day
    - Do this for the last fourteen days of every twenty eight day cycle.
• If you are on 'cyclic' HRT (you take an estrogen tablet or use a patch usually for 21 days, followed by a treatment-free interval of 7 days):
    - Take 1 tablet a day
    - Do this for the last fourteen days of the estrogen therapy.
• If necessary, your doctor may increase your dose to 2 tablets a day.

Children and young people
Duphaston is not for use in children before their first menstrual bleed. It is not known how safe or effective Duphaston is in young people aged 12-18 years.

Older people (over 65)
You can use this medicine for HRT. Follow the instructions above for adults.

If you take more Duphaston than you should
If you (or someone else or a child) take too many Duphaston tablets, they are unlikely to do any harm. No treatment is necessary. You may feel sick (nauseous), sleepy, dizzy or be sick (vomit). If you are worried, talk to your doctor for advice.

If you forget to take Duphaston
• If you forget to take today's tablet and it is less than 12 hours late, take it as soon as you remember. Take the next day's tablet at the normal time.
• If it is more than 12 hours since you should have taken your tablet, miss this tablet out. Take the next day's tablet at the usual time and continue taking your tablets as normal.
• Do not take a double dose to make up for a forgotten dose.
• If you miss a tablet, it is more likely that you will have irregular bleeds or spotting.

If you stop taking Duphaston
Do not stop taking Duphaston without talking to your doctor first.

4. Possible side effects

Like all medicines, Duphaston can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Side effects of taking Duphaston alone
Stop taking Duphaston and see a doctor straight away or go to hospital, if you notice or suspect any of the following. You may need urgent medical treatment:
• swelling of the skin around the face and throat which may cause difficulty breathing (angioedema) – affect less than 1 in 1,000 people).
• liver problems – the signs may include yellowing of the skin or eyes (jaundice), feeling generally unwell with abdominal pain or other liver related changes – affect less than 1 in 100 people.
• allergic reactions - the signs may include difficulty breathing or reactions involving the whole body such as feeling sick, being sick, diarrhoea or low blood pressure (affects less than 1 in 1,000 people)
If you notice or suspect any of the above, stop taking Duphaston and see a doctor straight away.

Other side effects of taking Duphaston alone:
Common (affects less than 1 in 10 people)
• headache,
• migraine
• feeling sick (nausea)
• breast pain/tender breasts
• painful, heavy or irregular periods
• no periods or periods happening less often than normal

Uncommon (affects less than 1 in 100 people)
• weight gain
• rash, severe itching or hives
• feeling depressed
• feeling dizzy
• being sick (vomiting)

Rare (affects less than 1 in 1,000 people)
• low levels of red blood cells (haemolytic anaemia)
• hypersensitivity reactions
• your body holding onto more water than usual (fluid retention)
• swelling of the breasts
• feeling sleepy
• increase in the size of tumours affected by progestogens (such as meningioma)
• worsening of a rare blood pigment disorder (porphyria).
Side effects in younger patients are expected to be similar to those seen in adults.

Side effects of taking Duphaston with an estradiol (estrogen-progestogen HRT)
If you are taking Duphaston together with an estrogen please also read the information leaflet that comes with your estrogen medicine. See Section 2 “Before you take Duphaston” 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 and see a doctor 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.
Other side effects of taking Duphaston with an estrogen include abnormal thickening or cancer of the lining of the womb and ovarian cancer.

Reporting of side effects
If any get any 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 directly via the national reporting system (details below). By reporting side effects you can help provide more information on the safety of this medicine.
In Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
In Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Duphaston

Keep out of the reach and sight of children.
Do not take the tablets after the expiry date shown on the outer carton and blister strip. The expiry date refers to the last day of that month.
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,
This medicinal product does not require any special storage condition

6. Contents of the pack and other information

What Duphaston contains

The active substance is dydrogesterone.
Each tablet contains 10mg dydrogesterone.
The other ingredients are lactose monohydrate, hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate, and macrogol 400. The colour used is titanium dioxide (E171).

What Duphaston looks like and contents of the pack

The tablets are round, biconvex, scored, film-coated and white. They are marked on one side with the inscription "155", on both sides of the score line.
Duphaston is available as a pack containing 42 or 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:
Theramex Ireland Limited, 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, D01YE64, Ireland
.
Duphaston is made by:
Abbott Biologicals BV, 8121 AA Olst, The Netherlands.
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