

DUPHASTON(TM) Tablets

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Dydrogesterone \ DAI - droh - JES - ter- roun

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions about Duphaston.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Duphaston against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

If you would like more information ask your doctor.

Keep this leaflet with your medicine. You may need to read it again.

When you must not use Duphaston

Do not use oestrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.

A study called the Women's Health Initiative indicated increased risk of heart attack, stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated oestrogens 0.625 mg and the progestogen medoxyprogesterone acetate (MPA). The researchers stopped the study after 5 years when

it was determined the risks were greater than the benefits in this group. The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged 65-79 years taking conjugated oestrogens and MPA. There are no comparable data currently available for other doses of conjugated oestrogens and MPA or other combinations of oestrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing oestrogen and progestogen combinations.

Talk regularly with your doctor about whether you still need treatment with Duphaston.

Treatment with oestrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.

What Duphaston is used for

Duphaston treats conditions where there is a lack of the female hormone progesterone. It is used for:

- * restoring bleeding in the absence of menstrual periods
- * controlling irregular bleeding which is due to hormonal imbalance
- * the treatment of endometriosis, which is a disease where fragments of the lining of the womb grow outside the womb in

the pelvic cavity

- * painful periods which do not have any specific cause such as fibroids or infection
- * a supplement for menopausal women who are taking hormone replacement therapy (HRT), in which it helps to protect the womb.

Duphaston is an artificial hormone similar to human progesterone. It belongs to a group of hormones called progestogens.

Duphaston has been approved for the uses listed above. However, your doctor may prescribe this medicine for another use. Ask your doctor for further information.

Duphaston is not addictive.

Before you take Duphaston

When you must not take it

HRT should only be used if you have been fully informed of the risks.

The decision to use HRT should be based on your particular needs and health, and made after a careful medical evaluation.

Do not take Duphaston:

- * if you have any blood clotting problems, or have had a stroke or a heart attack

- * if you have liver or gall bladder disease
- * if you have ever had jaundice (yellowing of the skin or eyes), which can occur with an intense generalised itching during pregnancy, or run in families
- * if you have, or are suspected to have, cancer of the breast or genitals, or some form of oestrogen (female hormone) dependent cancer
- * if you have had liver cancer due to taking oral contraceptives
- * if you have unusual vaginal bleeding that has not been seen by a doctor
- * if you know you have abnormal red blood cells (sickle cell anaemia)
- * if you are pregnant, or are planning to become pregnant. Duphaston may affect your developing baby if you take it during pregnancy
- * if you have ever had herpes during pregnancy
- * if you have had a certain type of miscarriage known as missed abortion
- * if you are breastfeeding. Duphaston passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected
- * if you know you are allergic to Duphaston or any of its ingredients.
(See the last section of this leaflet for a full list of ingredients).
(Signs of allergy include a rash, irritation, breathing difficulties and swollen face or neck).
- * after the expiry date (EXP) printed on the pack
- * if the packaging is torn or shows signs of being tampered with, or if the tablets do not look quite right
(If it has expired or is damaged, return it to your pharmacist for disposal).

If you are not sure whether you should start taking Duphaston, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- * any other medicines
- * any other substances such as foods, dyes or preservatives.

You may need close monitoring if you have certain medical conditions.

Tell your doctor if you have any of the following:

- * epilepsy
- * migraine
- * asthma
- * heart or kidney problems
- * depression.

Tell your doctor if you are pregnant or breast feeding.

Your doctor will advise you whether you should take Duphaston tablets.

If you have not told your doctor about any of the above, tell them before you start taking Duphaston.

Your doctor will give you a thorough examination prior to prescribing this medicine and will give you further examinations regularly during treatment. Your doctor is likely to check your blood pressure, breasts, tummy, and do a Pap smear test.

Special Warning

Although not reported with the use of Duphaston tablets, users of other progestogens (contained in oral contraceptives) may be exposed to an increased risk of a number of serious conditions. These include blood clots, stroke, heart attack, liver tumours, gall bladder disease and high blood pressure. Ask your doctor about the risks involved with taking progestogens for a long time.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a

prescription from a pharmacy, supermarket or health food shop.

How to take Duphaston

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day.

The dose and treatment time with Duphaston tablets depends on the condition being treated and response to therapy.

How much to take

Absence of periods

The usual dose is 1 or 2 tablets one or two times daily, from the 15th to the 25th day of the menstrual cycle. Sometimes the tablets will be given from the 5th to the 25th day. Treatment will usually be for 3 to 6 months.

If the tablets are to be given in combination with an oestrogen, then the usual dose is one tablet daily from the 11th to the 25th day.

In patients with very irregular cycles who are given Duphaston to start bleeding, the usual dose is one tablet daily for 5 days.

Irregular bleeding

- * To stop bleeding, 1 or 2 tablets are given one or two times daily for 5-10 days.
- * To prevent further heavy bleeding, 1 or 2 tablets are given one or two times a day from the 11th to 25th day of the menstrual cycle and repeated when necessary.

Endometriosis

The usual dose is 1 or 2 tablets one or two times a day from the 5th to the 25th day of the menstrual cycle. Sometimes the tablets are taken

continuously.

Painful periods

The usual dose is 1 or 2 tablets given one or two times a day from the 5th to the 25th day of the menstrual cycle.

Supplement to Hormone Replacement Therapy

One tablet daily for 10-12 days per month is the usual dose for most patients. In the event of unacceptable bleeding patterns the dose may be increased to 2 tablets daily for 10-12 days.

How to take it

Swallow the tablets with a glass of water

When to take it

Take Duphaston at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

It does not matter if you take Duphaston before or after food.

How long to take it

Take your medicine for as long as your doctor tells you to.

If you forget to take Duphaston

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the one you missed.

This may increase the chance of you getting an unwanted side effect.

If you forget to take Duphaston, do so as soon as you remember, and then go back to taking it as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much Duphaston.

Do this even if there are no signs of discomfort or poisoning.

Signs of overdose are feeling sick and vaginal bleeding in females.

While you are taking Duphaston

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Duphaston.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Duphaston.

If you become pregnant while taking this medicine, tell your doctor.

Tell your doctor if you have any prolonged or recurrent vaginal bleeding which is unusual while taking Duphaston tablets.

Tell any doctor if you go for any types of tests that you are taking Duphaston tablets. The tablets may change the results of the tests.

If you are taking Duphaston with an oestrogen for hormone replacement therapy include foods that are good sources of calcium and Vitamin D in your daily diet and exercise regularly.

Calcium, Vitamin D and exercise may help prevent thinning of the bones. Your doctor can advise you on which foods and types of exercise are best for you.

Things you must not do

Do not give Duphaston to any one else, even if they have the same condition as you.

Do not take Duphaston to treat any other complaints unless your doctor tells you to.

Do not stop taking Duphaston or change the dose without checking with your doctor.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking Duphaston.

All medicines can have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- * dizziness or headache
- * breast pain or tenderness
- * acne
- * swelling of the ankles and feet
- * weight change
- * feeling sick
- * change in body and facial hair.

These are all mild side effects of Duphaston.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital, if you notice any of the following:

- * menstrual changes, which may include change in the pattern, change in the cycle length, spotting, breakthrough bleeding, or no bleeding at all
- * severe and/or sudden headache
- * if you faint
- * shortness of breath, slurred speech, or vision changes
- * soreness of the veins particularly in the legs or groin
- * heart or lung problems
- * depression

- * severe stomach pains
- * yellowing of the skin or eyes (jaundice)
- * skin rash, or irritation.

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

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Duphaston

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your Duphaston in a cool dry place where the temperature stays below 30 degrees C and protect from light.

Do not store it or any medicines in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

Do not leave your tablets in the car or on a window sill.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use Duphaston beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly.

Medicines cannot be stored indefinitely.

Disposal

If your doctor tells you to stop taking Duphaston, or your tablets have passed their expiry date, ask your pharmacist what to do with

any that are left over.

Product Description

What it looks like

Duphaston tablets are round, biconvex, scored, white film-coated tablets, marked "S" on one side, the other side marked "155" on each side of the score line. They are available in blister strips containing 28 tablets.

Ingredients

The tablets contain dydrogesterone 10 mg as the active ingredient, and lactose, hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate and opadry white Y-1-7000 E171.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Duphaston is manufactured in The Netherlands for:

Solvay Pharmaceuticals

A division of Solvay Biosciences Pty. Ltd.
Level 1, Bldg. 2, 20 Bridge St.
Pymble NSW 2073

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