PACKAGE LEAFLET

Package leaflet: Information for the patient

Dydrogesterone Waymade 10 mg 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 Dydrogesterone Waymade is and what it is used for
2. What you need to know before you take Dydrogesterone Waymade
3. How to take Dydrogesterone Waymade
4. Possible side effects
5. How to store Dydrogesterone Waymade
6. Contents of the pack and other Information

1. What Dydrogesterone Waymade is and what it is used for

What Dydrogesterone Waymade is
Dydrogesterone Waymade contains a medicine called "dydrogesterone". Dydrogesterone is an artificially produced hormone. It is very similar to the hormone "progesterone", which is produced in the body. Medicines like Dydrogesterone Waymade are called "progestogens".

What Dydrogesterone Waymade is used for
Dydrogesterone Waymade can be used alone or in combination with an estrogen. Whether you also take an estrogen depends on the symptoms for which you are taking Dydrogesterone Waymade.

Dydrogesterone Waymade is used:

- **In the context of progesterone deficiencies**
  - to relieve painful periods
  - to relieve the symptoms of endometriosis (a problem caused by growth of the womb lining outside the womb)
  - for the treatment of menstrual irregularities
  - to relieve the symptoms of premenstrual syndrome (PMS)

- **To treat the symptoms of menopause in the context of a hormone replacement therapy (HRT) as an adjunct to estrogen treatment in women with uterus**
  - These symptoms vary from woman to woman
  - They may include hot flashes, night sweats, sleep disturbances, vaginal dryness and urological problems

- **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)**

How Dydrogesterone Waymade works

There is usually a balanced amount of the natural hormone progesterone and estrogen (the other main female hormone) in the body. If your body does not make enough progesterone, Dydrogesterone Waymade compensates for this and restore the balance.

Your doctor may prescribe an estrogen along with Dydrogesterone Waymade. Whether he actually does this depends on the reason you are taking Dydrogesterone Waymade. Some women taking estrogen alone in HRT may experience an unusual thickening of the womb lining. This can also be the case if your uterus has been removed but you have been diagnosed with endometriosis (a build-up of womb lining outside the uterus). 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 Dydrogesterone Waymade

Do not take Dydrogesterone Waymade

- if you are allergic to dydrogesterone or any of the other ingredients of this medicine (listed in section 6)
- if you have a tumour condition that can be aggravated by progestogens, or are suspected of having e.g. a brain tumour called a "meningioma"
- if you have vaginal bleeding of unknown cause
- if you suffer from severe acute and chronic liver diseases as well as disorders in the metabolism of bile pigments (e.g. Dubin-Johnson syndrome, Rotor syndrome)
- if you suffer or have suffered from liver tumours
- if you suffer from phlebitis with formation of a blood clot (thrombophlebitis)
- if you suffer from blood clot formation (thrombosis) or acute blockage of a blood vessel by a blood clot carried with the bloodstream (thromboembolic diseases)

If any of the above applies to you, do not take Dydrogesterone Waymade. If you are not sure, talk to your doctor or pharmacist before taking Dydrogesterone Waymade.

If you are **taking Dydrogesterone Waymade together with an estrogen, for example as part of HRT**, please also read the 'Do not take' section of the package leaflet you will receive with the estrogen-containing medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dydrogesterone Waymade.

Special caution is required when taking Dydrogesterone Waymade,

- if you have high blood pressure or develop high blood pressure while taking Dydrogesterone Waymade.

If you need to take Dydrogesterone Waymade for unusual bleeding, your doctor will find the cause of the bleeding before you start taking this medicine.

If unusual vaginal bleeding or spotting occurs while taking Dydrogesterone Waymade, it is usually nothing to worry about. Such bleeding is especially likely during the first months.

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 rule out the possibility that you have cancer of the womb lining.

Talk to your doctor or pharmacist before taking Dydrogesterone Waymade if one of the following conditions applies to you:
– depression
– liver problems
– a rare blood disorder that runs in the family (is congenital) called “porphyria”.
– jaundice and/or itching caused by bile stasis

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking Dydrogesterone Waymade. It is especially important to inform them if the above symptoms have ever worsened during pregnancy or with previous hormone treatment. Your doctor may monitor you more closely during treatment. If the symptoms worsen or reappear while taking Dydrogesterone Waymade, your doctor will probably stop the treatment.

Higher doses should be used with caution in the case of
– stroke (also in the history)

Dydrogesterone Waymade and HRT
As well as the benefits, HRT also has some risks that you and your doctor need to consider when deciding whether to take these medications. If you are taking Dydrogesterone Waymade along with estrogen as part of HRT, the following information is important to you. Please also read the package leaflet you will receive with your prescribed estrogen medicine.

Early menopause
There is limited experience with the treatment of women with early menopause (due to a failure of the ovaries’ function or their surgical removal). In younger women the level of risk is low. This means that the benefit-risk ratio for younger women taking HRT for early menopause may be better than for older women.

Medical examinations
Before starting (or resuming) a HRT your doctor will take your own medical history and that of your family. Your doctor will decide whether a physical examination is necessary. This may include a breast examination and/or an abdominal examination if necessary.

Before and during treatment, your doctor may use screening methods such as a mammogram (breast X-ray). Your doctor will tell you how often to have these tests. Once you start taking Dydrogesterone Waymade, you should see your doctor for regular check-ups (at least once a year).

Endometrial cancer and endometrial hyperplasia
Women who have a uterus who use an estrogen-only therapy for a long time have an increased risk for:
- endometrial cancer (cancer of the uterine lining)
- endometrial hyperplasia (an unusual enlargement of the lining of the uterus)

Taking Dydrogesterone Waymade with the estrogen (for at least 12 days per month - or 28-day cycle or continuous estrogen-progestogen combination therapy) may prevent this additional risk.

Breast cancer
The available data show that the use of hormone replacement therapy (HRT) with a combination of estrogen and progestogen or the use of estrogens alone for HRT increase the risk of breast cancer.

This additional risk depends on the length of time the HRT is taken and can be seen after about 3 (1-4) years of use. After stopping HRT, the additional risk decreases over time, but the risk may persist for up to 10 years or more if you have been taking HRT for longer than 5 years.
Be sure to:
- you go for regular breast screening - your doctor tells you how often to go
- you check your breasts regularly and monitor these changes:
  - retractions (dimples) in the skin

- nipple changes
- lumps you can see or feel

If you notice any changes, see your doctor right away.

Ovarian cancer
Ovarian cancer is rare - much rarer than breast cancer. Taking HRT containing estrogen alone or a combination of estrogen and progestogen is associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer changes with age. For example, approximately 2 out of 2000 women aged 50 to 54 years who do not take HRT will be diagnosed with ovarian cancer within a 5-year period. For women who have taken HRT for 5 years, there will be approximately 3 cases per 2000 users (i.e. approximately 1 extra case).

Blood clots (thromboses)
For women using HRT, the risk of developing **blood clots in the veins** (thromboses) is up to 1.3 to 3 times higher compared to non-users. There is an increased risk especially in the first year of HRT.

You are more likely to develop a blood clot if:
- you are older
- you have cancer
- you are very overweight
- you are taking estrogens
- you are pregnant or have recently given birth
- you (or a close relative) have had a previous blood clot, including in your leg or lungs
- you have been immobile for a long time because of a major surgery, injury or illness (see also information under “Surgery”)
- you have a condition called systemic lupus erythematosus (SLE) – a specific autoimmune disorder that causes, among others, joint pain, skin rashes and fever.

If any of the above applies to you (or if you are unsure), talk to your doctor about whether HRT is appropriate for you.

If you notice painful swelling in your legs, sudden chest pain or difficulty breathing:
- see a doctor right away
- stop using your HRT medication until your doctor allows it again.

These may be signs of a blood clot.

If you are taking medicines used to prevent blood clots (anticoagulants) - such as warfarin, phenprocoumon, tell your doctor or pharmacist. Your doctor will pay special attention to assessing the benefits and risks of a HRT.

Surgery
If you have planned surgery, tell your doctor before surgery that you are taking HRT. Do this well in advance of surgery. You will probably need to stop taking HRT several weeks before surgery. Under certain circumstances, you may need some other treatment before and after surgery. Your doctor will tell you when you can start taking HRT again.

Heart disease
There is no evidence that HRT provides protection against heart disease. Women who take estrogen-progestogen HRT are slightly more likely to develop heart disease than women who do not take any HRT. The risk of heart disease also increases with age. The number of additional cases of heart disease due to estrogen-progestogen HRT use is very low in healthy women shortly after menopause. The number of additional cases increases with age.
If you feel chest pain that spreads into your arm or neck:
- see a doctor right away

- do not take HRT anymore until your doctor says you can

This pain may be a sign of a heart attack.

Stroke
Combined estrogen-progestogen or estrogen-only HRT increases the risk of stroke. This risk is up to 1.5 times higher than for non-users. The risk for women taking HRT compared to those not taking it does not change with age or time since menopause. However, as the risk of stroke depends on age, the overall risk of stroke for women taking HRT will increase with age.

If you experience a severe, unexplained/unusually strong headache or migraine (which may also be associated with visual disturbance):
– see a doctor right away
– do not take HRT again until your doctor says you can

This may an early warning sign of a stroke.

Other medicines and Dydrogesterone Waymade
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or herbal medicines.

Especially tell your doctor or pharmacist if you are taking any of the medicines listed below.
These medicines may reduce the effect of Dydrogesterone Waymade causing bleeding or spotting:
- herbal preparations containing St. John‘s Wort, sage or ginkgo biloba
- medicines to treat convulsions (epilepsy) - such as phenobarbital, carbamazepine, phenytoin
- medicines to treat infections - such as rifampicin, rifabutin, nevirapine, efavirenz
- medicines to treat HIV infection (AIDS) - such as ritonavir, nelfinavir

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

Dydrogesterone Waymade with food and drink
Dydrogesterone Waymade can be taken regardless of meals.

Children and adolescents
There is no use for Dydrogesterone Waymade in children before their first menstrual period. It is not known how safe or effective Dydrogesterone Waymade is in adolescents aged 12 to 18 years.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Dydrogesterone Waymade is not authorised for use in pregnancy.
Children of mothers who have taken a certain type of progestogen may be at increased risk of hypospadias (a birth defect of the penis affecting the urethra). However, this increased risk has not yet been confirmed. So far, there is no evidence that taking dydrogesterone during pregnancy is harmful.
Dydrogesterone tablets have been used by more than 10 million pregnant women.
- If you are pregnant, consult your doctor before taking Dydrogesterone Waymade.
- See your doctor if you become pregnant or think you may be pregnant. He or she will explain the benefits and risks of taking Dydrogesterone Waymade in pregnancy.

Breast-feeding
If you are breastfeeding, do not take Dydrogesterone Waymade. It is not known whether Dydrogesterone Waymade passes into breast milk and affects the baby. Studies with other progestogens show that small amounts of these drugs pass into breast milk.

Fertility
There is no evidence that dydrogesterone reduces your fertility when taken as recommended by your doctor.

Driving and using machines
You may feel a little sleepy or feel slightly dizzy after taking Dydrogesterone Waymade. It will be more likely within the first few hours after taking it than later. If this happens, do not drive or use any tools or operate machinery. Wait to see how Dydrogesterone Waymade affects you before driving, using tools, or operating machinery.

Dydrogesterone Waymade contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Dydrogesterone Waymade

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will adjust the dose to suit you.

How to take this product
– Take each tablet with water.
– You can take the tablets regardless of meals.
– If you have to take more than one tablet, spread the use evenly throughout 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 ensure a steady amount of medicine in your body. At the same time, this will help you not to forget to take the tablets.

Posology
The number of tablets you take and the days you take them and the total duration of therapy will depend on the reason you are being treated for. If you have natural periods so far, day 1 of your cycle is when you start bleeding. If you no longer have natural periods, your doctor will decide with you when to determine day 1 of your cycle and when to start taking the tablets.

<u>To relieve painful periods</u>
- Cycle days 5 to 25: Take 2 tablets a day.

<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>For the treatment of 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 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.

For the treatment of symptoms of menopause (HRT)

- If you are taking "continuous sequential" HRT (e.g. taking an estrogen tablet or having an estrogen patch or estrogen gel throughout your cycle)
    - take 1 tablet a day and only during the last 14 days of each 28-day cycle.
- If you are taking "cyclic" HRT (e.g. you take an estrogen tablet or use an estrogen patch or estrogen gel for 21 days of the cycle, followed by 7 days without medication)
    - take 1 tablet per day and only during the last 12 to 14 days of estrogen treatment.
- If necessary, your doctor may increase the dose to 2 tablets a day.

For menstrual bleeding that is unusually heavy or happens between periods

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.

To re-start periods that have stopped before the menopause

- Take 2 tablets a day.
- Do this for fourteen days during the second half of your expected cycle.

The starting day of days you take your tablets for will depend on the length of your cycle.

If you take more Dydrogesterone Waymade than you should

If you (or someone else) have taken too many Dydrogesterone Waymade tablets, it is unlikely to harm you seriously. However, if you are worried, contact your doctor for advice.

If you forget to take Dydrogesterone Waymade

- Take the missed tablet as soon as you remember. However, if more than 12 hours have passed after the regular intake time, skip the forgotten tablet and take your next tablet at your next usual intake time.
- Do not take the double dose to make up for a forgotten tablet.
- If you miss an intake, bleeding or spotting may occur.

If you stop taking Dydrogesterone Waymade

Do not stop taking Dydrogesterone Waymade without first consulting your doctor.

4. Possible side effects

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

Side effects of taking Dydrogesterone Waymade alone

Treatment with Dydrogesterone Waymade may cause symptoms similar to those experienced in the early stages of pregnancy, such as loss of appetite, stomach pressure, nausea, oedema and weight gain, nervous restlessness, dizziness, worsening of mood and calf cramps. These symptoms disappear when the treatment is stopped.

If you notice or suspect any of the following side effects, stop taking Dydrogesterone Waymade and see a doctor right away.

- liver problems – symptoms may include yellowing of the skin or whites of the eyes (jaundice), feeling weak, a general discomfort or abdominal pain (may affect up to 1 in 100 people)

- allergic reactions – symptoms may include difficulty breathing or reactions affecting the whole body such as nausea, vomiting, diarrhoea or low blood pressure (may affect up to 1 in 1000 people)
- swelling of the face and throat that may cause difficulty breathing (may affect up to 1 in 1000 people)

Other side effects of taking Dydrogesterone Waymade alone:

Common (may affect up to 1 in 10 people)
- migraine, headache
- nausea
- sensitive or painful breasts
- irregular, extraordinary heavy or painful menstrual periods
- missed menstrual period, prolonged menstrual period or bleeding less frequently than normal

Uncommon (may affect up to 1 in 100 people)
- weight gain
- dizziness
- depressed mood
- vomiting
- allergic skin reactions – such as rash, itching or hives

Rare (may affect up to 1 in 1,000 people)
- drowsiness
- swelling of the breasts
- a certain type of anaemia caused by the destruction of red blood cells
- swelling caused by fluid retention in the tissue, often in the lower legs or ankles
- an increase in the size of progestogen-dependent tumours (such as meningioma)

In younger patients, side effects are expected to be similar to those in adults.

Side effects of taking Dydrogesterone Waymade with an estrogen (estrogen-progestogen HRT)
If you are taking Dydrogesterone Waymade with estrogen, please also read the information in the package leaflet you will receive with your prescribed estrogen- containing medicine. See section 2 "What you need to know before you take Dydrogesterone Waymade" of this package leaflet for more information about the side effects listed above.

If you notice any of the following side effects, stop taking Dydrogesterone Waymade and see your doctor right away
- Painful swelling in your leg, sudden chest pain, or difficulty breathing. These may be signs of a blood clot.
- Chest pain that shoots up into the arm or neck. This may be a sign of a heart attack or a coronary artery disease.
- A severe, unexplained headache or migraine (with or without visual disturbances). These can be signs of a stroke.

See a doctor immediately if you notice changes such as
dimples on the skin of your breasts, changes in the nipple or lumps you can see or feel.

These changes may be signs of breast cancer disease.

Other side effects that may occur when taking Dydrogesterone Waymade together with the use of an estrogen include excessive thickening or cancer of the uterine lining and ovarian cancer.

Reporting of side effects
If you 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 Yellow Card Scheme

website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dydrogesterone Waymade

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 Dydrogesterone Waymade contains

The active substance is dydrogesterone.
Each tablet contains 10 mg dydrogesterone.

The other ingredients are lactose monohydrate, maize starch, hypromellose, colloidal anhydrous silica, magnesium stearate, macrogol (MW 8000) and talc. The colour used is titanium dioxide (E171).

What Dydrogesterone Waymade looks like and contents of the pack

The tablets are white to off white, round, biconvex, bevelled edge, film coated tablets with break line on one side and "AL" debossed on other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Dydrogesterone Waymade is available as a pack containing 10, 14, 20, 28, 42 or 60 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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Miles Gray Road, Basildon,
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This leaflet was last revised in October 2025

To request a copy of this leaflet in Braille, large print or audio format, contact the licence holder at the above address or telephone: 01268 535200 (select option Medical Information) / e-mail: medinfo@waymade.co.uk