

## **Package Leaflet: Information for the user**

### **Dydrogesteron Lotus 10 mg filmomhulde tabletten** dydrogesteron

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Dydrogesterone Lotus is and what it is used for**

This medicine contains dydrogesterone as its active substance.

Dydrogesterone is a female progestogen hormone. Progestogen hormones have roughly the same effect as natural progesterone. Together with oestrogen hormones, it regulates the menstrual cycle.

#### **Dydrogesterone Lotus is used:**

- **In problems you may get if your body doesn't produce enough progesterone:**
  - regulating the menstrual cycle;
  - the presence of uterine lining outside the uterus (endometriosis);
  - painful periods;
  - absent periods
  - abnormally heavy and/or irregular periods
  - infertility due to low progesterone levels;
  - supporting the luteal phase as part of treatment with assisted reproductive technology;
  - reducing the risk of threatened miscarriage;
  - if you have had multiple miscarriages (repeated miscarriage).
- **Hormone replacement therapy (HRT)**
  - Together with oestrogen, Dydrogesterone tablets are also used:
  - to prevent abnormalities of the [uterine] lining during treatment of symptoms after menopause;

The body normally seeks a balance between the amount of natural hormones progesterone and oestrogen (the other female hormone). If your body does not produce enough progesterone, this medicine compensates for this and restores the balance.

Your doctor may also ask you to use oestrogen in addition to this medicine. This depends on the reason why you are using Dydrogesterone tablets.

For some women on hormone replacement therapy (HRT), use of oestrogen alone can cause abnormal thickening of the uterine lining. This may also apply if you do not have a uterus and have had endometriosis (uterine lining outside the uterus). Using this medicine during part of your menstrual

period can help prevent your uterine lining from getting too thick.

## 2. What you need to know before you take Dydrogesterone Lotus.

### Do not take Dydrogesterone Lotus

- if you are allergic to dydrogesterone or any of the other ingredients of this medicine (listed in section 6).
- if you have, or have had, tumours that grow under the influence of sex hormones or if you are suspected of having tumours that grow under the influence of sex hormones,
- if you have vaginal bleeding for which no cause has been established,
- if you are using this medicine for supporting the luteal phase as part of treatment with assisted reproductive technology, and your doctor diagnoses an abortion or miscarriage, treatment with dydrogesterone should be stopped,
- if you have severe liver disease or have previously had severe liver disease where liver functions have not yet recovered.
- if you have meningioma or have ever been diagnosed with a meningioma (a generally benign
- tumour of the tissue layer between the brain and the skull).

Do not take this medicine if any of the above points apply to you. If you are not sure, contact your doctor or pharmacist before taking it.

If dydrogesterone is given in combination with another hormone (oestrogen) (e.g. as hormone replacement therapy in connection with menopausal symptoms), you must carefully take into account the contraindications of the oestrogen product, as stated in the package leaflet for that product.

### Warnings and precautions

If you are taking this medicine for abnormal monthly periods, your doctor will first investigate the cause of such bleeding before you are given this medicine.

If you experience unexpected vaginal bleeding or breakthrough bleeding, this is generally nothing to worry about. This is common especially during the first months of using this medicine. **However, make an appointment with your doctor right away** if the bleeding or breakthrough bleeding:

- persists for more than a few months,
- starts after you have been on treatment for a few months,
- persists even though you have already stopped treatment.

This may be a sign of thickening of the uterine lining. Your doctor will investigate the cause of the bleeding or breakthrough bleeding and may do a test to determine if you have endometrial cancer.

Contact your doctor in the following situations:

- If you get a migraine-like headache while using dydrogesterone, which you have never had before.
- If you suffer from severe headaches or migraines more often than usual.
- If your blood pressure suddenly becomes much higher.
- If you have a stroke.
- If you have thrombosis.
- If you have abnormal vaginal bleeding.
- If you are using dydrogesterone due to the risk of miscarriage, the status of both mother and fetus should be monitored during treatment.
- If you suffer from dark moods.
- If you have rare conditions known to be influenced by sex hormones, such as: severe itching, jaundice due to blockage of the bile ducts, herpes of pregnancy, a certain metabolic disorder (porphyria) and otosclerosis (where hardening of the middle ear occurs, which causes hearing to deteriorate).
- Meningioma

Use of this medicine has been linked to the development of a generally benign tumour of the tissue layer between the brain and the skull (meningioma). If you are diagnosed with meningioma, your doctor will stop your treatment with (see section 'Do not take...'). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

If any of the above points apply to you or if you are not sure, contact your doctor or pharmacist. It is particularly important to tell them if the above problems have ever get worse during pregnancy or previous hormone therapy. Your doctor may wish to monitor you more closely during treatment. If the problems get worse or return while you are using this medicine, your doctor may deem it necessary to stop it.

### **Dydrogesterone Lotus and hormone replacement therapy (HRT)**

In addition to benefits, HRT also has some risks, which you and your doctor have to consider if you decide to use these medicines. If you are taking Dydrogesterone tablets in combination with an oestrogen as part of HRT, the following information is important for you. Please also read the package leaflet for the oestrogen product.

#### Early menopause

There is limited evidence on the risks of HRT when used to treat early menopause. There is a low risk in younger women. This means that the benefit/risk balance may be more favourable for younger women using HRT for early menopause than for older women.

#### Medical examination

Before you start (or restart) HRT, your doctor needs to be fully informed about your personal medical history and that of your immediate family. You will undergo a general medical and gynaecological examination. Regular check-ups, including a breast examination, will take place during treatment. A careful assessment of the benefits and risks of HRT treatment should be made periodically - at least yearly - to determine whether it needs to be continued. You may need to have regular check-ups by your doctor during use.

#### Cancer of the uterine lining (endometrial cancer)

Long-term use of oestrogens without addition of progestogens increases the risk of cancer and abnormal growth of the uterine lining in women with a uterus. To reduce this risk, the oestrogens have to be used together with progestogen tablets for at least 12 days of each month.

#### HRT and breast cancer

Studies have shown that using hormone replacement therapy (HRT) with an oestrogen-progestogen combination or oestrogen alone increases the risk of breast cancer. The extra risk depends on how long you use HRT. The extra risk occurs after 3 years of use. After stopping HRT, the extra risk will decrease again, but if you have used HRT for more than 5 years, the extra risk may persist for a further 10 years or more.

Your doctor will tell you which changes in your breasts you should consult your doctor about.

#### HRT and ovarian cancer

Ovarian cancer is rare, much rarer than breast cancer.

A slight increase in the risk of ovarian cancer has been reported with the use of oestrogen therapy or a combination of oestrogen/progestogen HRT.

The risk of ovarian cancer is dependent on age. In women aged 50 to 54 years not using HRT, about 2 in 2 000 women will be diagnosed with ovarian cancer over a 5-year period. Among women who have been using HRT for 5 years, there are about 3 cases in every 2 000 users (i.e. about 1 extra case).

#### HRT and thrombosis

Studies show that women using HRT are about 1.3 to 3 times more likely to develop venous thrombosis (formation of a blood clot in a vein of the legs, lungs or elsewhere in the body) than

women not using HRT. This extra risk is highest during the first year of HRT use.

A blood clot can be serious and if it gets into the lungs, it can lead to chest pain, shortness of breath, fainting and even death.

The risk of venous thrombosis is greater if:

- you are elderly
- you have cancer
- you are seriously overweight
- you are using oestrogen
- you are pregnant or have recently given birth
- you have ever had venous thrombosis, have a blood clotting disorder or have a history of venous thrombosis in your immediate family
- you have been bedridden for a prolonged period of time due to surgery, injury or illness (see also information under “Surgery”)
- you have systemic lupus erythematosus (a certain immune system disorder)

If any of the above situations apply to you or if you are not sure, contact your doctor to check whether you need to use HRT.

If you get venous thrombosis or a lung embolism while using HRT, you should stop taking HRT immediately. **Report to your doctor immediately any symptoms that may indicate venous thrombosis or lung embolism, such as painful swelling of one of your legs, sudden chest pain or shortness of breath.**

If you are already using a blood-thinning agent, e.g. warfarin, you must tell your doctor. In this case, the benefits and risks of HRT use will be carefully weighed up.

### Surgery

If you need to have an operation, tell your treating doctor before the operation that you are using HRT. Do this in good time before surgery. In such situations, you may need to stop using HRT several weeks before scheduled surgery. In some cases, you may need different treatment before and after surgery. Your doctor will tell you when you can start using HRT again.

### HRT and coronary artery disease

Two main studies with one certain type of HRT (conjugated oestrogens combined with medroxyprogesterone acetate) have shown that the risk of cardiovascular disease may have been increased during the first year of HRT use. It is still unclear whether this also applies to other types of HRT products.

If you get chest pain radiating to your arm or neck, you must:

- consult a doctor at once,
- stop using HRT until your doctor says you can start again.

This pain may be a sign of a heart attack.

### HRT and stroke

The risk of a stroke is about 1.5 times higher in women using HRT than in women not using HRT. The number of extra cases of stroke as a result of HRT use increases with advancing age.

### Comparison

In women in their 50s not using HRT, an average of 8 in 1 000 will have a stroke over a 5-year period. Among women in their 50s using HRT, there are 11 cases of stroke per 1 000 users over a 5-year period (i.e. 3 extra cases per 1 000).

If you get severe, unexplained headache or migraine (with or without vision problems), you must:

- consult a doctor at once,
- stop using HRT until your doctor says you can start again.

This may be a sign of a stroke.

### **Children and adolescents up to 18 years of age**

This medicine must not be used by children before they have their first period. It is not known how safe and effective it is in young people aged 12 to 18 years.

### **Other medicines and Dydrogesterone Lotus**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.**

This also applies to medicines that do not need a prescription.

You should tell your doctor if you are or have been using the following medicines. These medicines can make your treatment less effective. This can also lead to irregular blood loss.

- herbal medicines containing St. John's wort (*Hypericum perforatum*),
- medicines for epilepsy (such as phenobarbital, phenytoin, carbamazepine, primidone),
- medicines for infections (such as rifampicin),
- medicines for HIV infections (AIDS) (such as ritonavir, nevirapine, efavirenz),
- medicines for the hepatitis C virus

If any of the above points apply to you or if you are not sure, contact your doctor or pharmacist before using Dydrogesterone tablets.

### **Dydrogesterone Lotus with food and drink**

This medicine can be taken with or without food.

### **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

There may be an increased risk of a birth defect affecting the urethra in the penis (hypospadias) in children whose mothers have used certain progestogens. However, this increased risk is not yet certain. More than 9 million pregnant women have used Dydrogesterone tablets. So far, there is no evidence that using it during pregnancy is harmful.

#### Breast-feeding

Do not use this medicine if you are breast-feeding. It is unknown whether it is excreted in human milk and affects the infant. Studies with other progestogens show that they pass into human milk in small amounts.

#### Fertility

As far as is known, this medicine does not impair fertility when used as prescribed by a doctor.

### **Driving and using machines**

You may feel slightly drowsy when you are using Dydrogesterone tablets. This is most likely within the first few hours after you have taken it. If this happens, you must not drive a car or use machines. Wait to see how it affects you before you drive or use machines.

### **Dydrogesterone Lotus 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. This also applies to rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

## **3. How to take Dydrogesterone Lotus**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor

or pharmacist if you are not sure.

### **How to take Dydrogesterone Lotus**

- Take each tablet with some water.
- You can take the tablets with or without food.
- If you use more than 1 tablet per day, you must take them spread over the day as much as possible. For example, take one tablet in the morning and one tablet in the evening.
- Try to take the tablets at the same time each day. This will ensure that a constant amount of medicine is present in your body. It will also help you remember to take your tablets.
- The tablets are scored, just to make it easier to break the tablets for easier swallowing. The score line is not intended for breaking the tablet into two equal doses.

### **How much Dydrogesterone Lotus do I take?**

The number of tablets you take and the days you take them depend on what you are being treated for. If you are still having your monthly periods, day 1 of your menstrual cycle is the first day of your period. If you no longer have monthly periods, your doctor will decide with you when day 1 of the menstrual cycle is and when you start taking the tablets.

#### For regulating the menstrual cycle:

- Take 1 tablet per day.
- Do this from day 11 to 25 of the cycle.
- With this dosing scheme, it is possible to achieve a menstrual cycle lasting 28 days.

#### For endometriosis (presence of uterine lining outside the uterus):

- Take 1 to 3 tablets per day.
- You will be asked to take your tablets as follows:
  - throughout your entire menstrual cycle.
  - or only on days 5 to 25 of your menstrual cycle.

#### For painful periods:

- Take 1 or 2 tablets per day.
- Do this only on days 5 to 25 of your menstrual cycle.

#### For abnormally heavy or irregular periods:

- For stopping your period:
  - Take 2 tablets per day.
  - Do this for 5 to 7 days. After this, you will have a heavy withdrawal bleed.
- For continuous treatment:
  - Take 1 tablet per day.
  - Do this during the second half of your menstrual cycle.

The start date and number of days you take your tablets depend on the length of your menstrual cycle. Withdrawal bleeding will usually occur a few days after the last dydrogesterone tablet.

#### For infertility as a result of low progesterone levels:

- Take 1 tablet per day.
- Do this from day 14 to 25 of the cycle
- Continue treatment for at least 3 consecutive cycles.

#### For supporting the luteal phase as part of treatment with assisted reproductive technology:

- Take 3 tablets per day, starting on the day the eggs are collected. Administration of this medicine must be continued for 12 weeks if pregnancy has been confirmed.

#### To reduce the risk of a threatened miscarriage:

- Start with 4 tablets. Thereafter, 1 tablet every 8 hours. If the signs do not disappear or return, 2 tablets every 8 hours.

- Treatment should be continued for a week after the symptoms have disappeared. After this, the amount can be slowly reduced.

If you have had multiple miscarriages:

- 1 tablet twice daily up to week 20 of pregnancy. After this, the amount can be slowly reduced. Treatment should preferably be started before conception.

For absent periods before the menopause:

- Take 1 or 2 tablets per day.
- Do this from days 11 to 25 of the cycle

To prevent abnormalities of the uterine lining during treatment of symptoms after menopause;

- Based on a cycle with 28 days of oestrogen treatment: 1 to 2 tablets per day for 14 days per cycle. Withdrawal bleeding will usually occur a few days after the last tablet.

**If you take more Dydrogesterone Lotus than you should**

If you (or anyone else) has taken too much of this medicine, it will usually do no harm. No treatment is needed. If you are concerned, contact your doctor.

**If you forget to take Dydrogesterone Lotus**

- Take the missed tablet as soon as you remember. However, if it is more than 12 hours since you should have taken the tablet, skip the missed tablet and take the next tablet at the usual time.
- Do not take a double dose to make up for a forgotten dose.
- Slight bleeding may occur if you miss a dose.

**If you forget to take Dydrogesterone Lotus when used to support the luteal phase as part of treatment with assisted reproductive technology**

- Take the missed tablet as soon as you remember and contact your doctor.

**If you stop taking Dydrogesterone Lotus**

Do not stop taking this medicine until you have contacted your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Side effects when Dydrogesterone Lotus is used alone:**

**Stop using Dydrogesterone Lotus and consult a doctor straight away if you notice any of the following side effects:**

- Liver problems – signs may include yellowing of the skin or whites of the eyes (jaundice), feeling weak, generally feeling unwell or stomach pain (occurring in less than 1 in 100 people).
- Allergic reactions – signs may include difficulty breathing or reactions all over the body such as nausea, vomiting, diarrhoea or low blood pressure (occurring in less than 1 in 1 000 people).
- Swelling of the skin around the face and throat, which may cause difficulty in breathing (may affect up to 1 in 1 000 people).

Stop using this medicine immediately if you notice any of the above side effects.

**Other side effects when Dydrogesterone Lotus is used alone:**

**Very common (may affect more than 1 in 10 people):**

- vaginal bleeding

**Common (may affect up to 1 in 10 people):**

- migraine, headache
- feeling sick (nausea), vomiting, abdominal pain
- irregular, heavy or painful periods
- no periods or fewer periods than normal
- sensitive or painful breasts

**Uncommon (may affect up to 1 in 100 people):**

- feeling depressed
- feeling dizzy
- vomiting
- liver problems (yellowing of the skin or whites of the eyes, feeling weak, generally feeling unwell or stomach pain)
- allergic skin reactions, such as skin rash, severe itching or hives
- weight gain

**Rare (may affect up to 1 in 1 000 people):**

- enlargement of tumours growing under the influence of progestogens (for example, a meningioma)
- anaemia due to excessive breakdown of the blood (haemolytic anaemia)
- hypersensitivity
- feeling drowsy
- sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioneurotic oedema)
- swelling of the breasts
- swelling due to fluid retention, often in the lower legs or ankles.

**Side effects when Dydrogesterone Lotus is used with an oestrogen (oestrogen-progestogen HRT)**

Also read the oestrogen package leaflet if you are using this medicine together with an oestrogen. See section 2 “What you need to know before you use Dydrogesterone Lotus” for more information on the above side effects.

**Stop using Dydrogesterone Lotus consult a doctor straight away if you notice any of the following side effects:**

- Painful swelling of your leg, sudden chest pain or breathing difficulties. These may be signs of a blood clot.
- Chest pain radiating to your arm or neck. This may be a sign of a heart attack.
- Severe, unexplained headache or migraine (with or without vision problems). These may be signs of a stroke.

Stop using this medicine immediately if you notice any of the above side effects.

Make an appointment with your doctor if you notice the following:

- Dimpling in the skin of your breast, changes in the nipples or if you see or feel lumps. These may be signs of breast cancer.

Other side effects when dydrogesterone is used with an oestrogen include abnormal thickening or cancer of the uterine lining and ovarian cancer.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Dydrogesterone Lotus**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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.

## **6. Contents of the pack and other information**

### **What Dydrogesterone Lotus contains**

- The active substance is dydrogesterone. Each film-coated tablet contains 10 mg dydrogesterone.
- The other ingredients in the tablet core are: lactose monohydrate, maize pregelatinized starch, Hypromellose 2910 E464, silica colloidal anhydrous and magnesium stearate E572.
- The other ingredients in the tablet coating are: lactose monohydrate, hypromellose E464, titanium dioxide E171, triacetin E1518.

### **What Dydrogesterone Lotus looks like and contents of the pack**

- The tablets are round, biconvex, white to off-white film-coated tablet (approx. 7.1 mm in diameter), debossed with “711” on one side and plain on another. (see also section 3 of this leaflet).
- The tablets are packaged in PVC/PVDC-Al blister.  
Available in boxes containing 10, 14, 20, 30 or 42 tablets per box.  
Not all pack sizes may be marketed.”

## **Houder van de vergunning voor het in de handel brengen en fabrikant**

### Vergunninghouder:

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