

**Package leaflet: Information for the user**  
**Lumivela 0,150 mg /0,03 mg filmomhulde tabletten**

**Desogestrel / Ethinylestradiol**

**Important things to know about combined hormonal contraceptives (CHCs):**

- These methods are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 “Blood clots”)

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

**1. What Lumivela is and what is used for**

**Composition and pill type**

Lumivela is a combined oral contraceptive, also called the pill.

- Each of the 21 white tablets contains a small quantity of two different female hormones: desogestrel (a hormone that works similarly to a progestogen) and ethinylestradiol (a hormone that works similarly to an oestrogen). Because of the small amounts of hormones, Lumivela is considered a low-dose contraceptive. Since the amount of each hormone is the same in all white tablets in the strip, it is called a single-phase combination pill.
- The 7 green tablets contain no active substances and are also called placebo tablets.

**What is it used for**

Lumivela is used to prevent pregnancy.

When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

## 2. What you need to know before you take Lumivela

### General notes

Before you start using Lumivela you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 Blood clots).

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sex, or you should take extra non-hormonal contraceptive precautions (e.g. use a condom or another barrier method). Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the monthly changes of body temperature and of cervical mucus that occur during the menstrual cycle.

**Like other hormonal contraceptives, Lumivela will not protect you against HIV (AIDS) or any other sexually transmitted disease (STDs).**

### Do not take Lumivela

You should not use Lumivela if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate. See also section “When to take special care with Lumivela”.

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section ‘Blood clots’);
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called ‘migraine with aura’;
- if you have (or have ever had) pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood

- if you have (or have ever had) jaundice (yellowing of the skin or eyes) or severe liver disease.
- if you have (or have ever had) cancer affected by sex hormones (breast cancer or cancer of the genitalia).
- if you have (or have ever had) a liver tumour.
- if you have any vaginal bleeding that has not been explained by your doctor.
- If you have an abnormal swelling of the endometrium
- if you are allergic to ethinylestradiol, desogestrel or any of the other ingredients of this medicine (listed in section 6). This can be recognised by itching, rash or swelling
- if you are allergic to peanut or soya.

If you suffer from any of these, or get them for the first time while taking Lumivela, immediately discontinue taking it and contact your doctor as soon as possible. In the meantime, use another, non-hormonal contraceptive method. Also see ‘General notes’ at the start of section 2.

Do not use Lumivela if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section “Other medicines and Lumivela”).

### **When to take special care with Lumivela**

When should you contact your doctor?

#### Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see ‘Blood clot’) section below.

For a description of the symptoms of these serious side effects please go to “How to recognise a blood clot”.

### ***Tell your doctor if any of the following conditions apply to you***

. Also if any of the following applies or if any of the conditions develops or gets worse while you are using Lumivela you should also tell your doctor:

- If you smoke.
- If you have diabetes
- If you are overweight.
- If you have a high blood pressure.
- If you have a problem with your heart valves or a certain disturbance of the rhythm;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- if you have varicose veins.
- If anyone in your immediate family has ever had a thrombosis, a heart attack or a stroke.
- If you have ever had migraines.
- if you suffer from epilepsy
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);

- if you need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clots’).
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Lumivela.
- if anyone in your immediate family has had breast cancer
- if you have liver or gallbladder disease
- if you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE –; a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have a condition that occurred the first time or worsened during pregnancy or previous use of sex hormones (for example, hearing loss, a metabolic disease called porphyria, a skin disease that causes vesicles during pregnancy called gestational herpes, a neurological disease called Sydenham’s Chorea that causes sudden movements of the body
- if you have or have ever had chloasma (a discoloration of the skin especially of the face or neck known as “pregnancy patches”). If so, avoid direct sunlight or ultraviolet light.
- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

#### The Pill and Blood Clots (Thrombosis)

### **BLOOD CLOTS**

Using a combined hormonal contraceptive such as Lumivela increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a ‘venous thrombosis’, ‘venous thromboembolism’ or VTE)
- in the arteries (referred to as an ‘arterial thrombosis’, ‘arterial thromboembolism’ or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

**It is important to remember that the overall risk of a harmful blood clot due to Lumivela is small.**

### **HOW TO RECOGNISE A BLOOD CLOT**

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> <li>• swelling of one leg or along a vein in the leg or foot especially when accompanied by:               <ul style="list-style-type: none"> <li>• pain or tenderness in the leg which may be felt only when standing or walking</li> <li>• increased warmth in the affected leg</li> <li>• change in colour of the skin on the leg e.g. turning pale, red or blue</li> </ul> </li> </ul>	Deep vein thrombosis
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing;</li> <li>• sudden cough without an obvious cause, which may bring up blood;</li> <li>• sharp chest pain which may increase with deep breathing;</li> <li>• severe light headedness or dizziness;</li> <li>• rapid or irregular heartbeat</li> <li>• severe pain in your stomach;</li> </ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, heaviness</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>• fullness, indigestion or choking feeling;</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>• sweating, nausea, vomiting or dizziness;</li> <li>• extreme weakness, anxiety, or shortness of breath;</li> <li>• rapid or irregular heartbeats</li> </ul>	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>• sudden confusion, trouble speaking or understanding;</li> <li>• sudden trouble seeing in one or both eyes;</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>• sudden, severe or prolonged headache with no known cause;</li> <li>• loss of consciousness or fainting with or without seizure.</li> </ul> <p>Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	Stroke
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an extremity;</li> <li>• severe pain in your stomach (acute abdomen)</li> </ul>	Blood clots blocking other blood vessels

## BLOOD CLOTS IN A VEIN

### What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

### When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Lumivela your risk of a blood clot returns to normal within a few weeks.

### What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with Lumivela is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains desogestrel, such as Lumivela, between about 9 and 12 women will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot” below)

	<b>Risk of developing a blood clot in a year</b>
Women who are <b>not using</b> a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using Lumivela	About 9-12 out of 10,000 women

### **Factors that increase your risk of a blood clot in a vein**

The risk of a blood clot with Lumivela is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m<sup>2</sup>);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Lumivela may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Lumivela ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Lumivela needs to be stopped.

If any of the above conditions change while you are using Lumivela, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

## **BLOOD CLOTS IN AN ARTERY**

### **What can happen if a blood clot forms in an artery?**

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

### **Factors that increase your risk of a blood clot in an artery**

It is important to note that the risk of a heart attack or stroke from using Lumivela is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Lumivela you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Lumivela, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

### **The pill and cancer**

The Pill slightly increases breast cancer in comparison to women who do not use the pill. No difference is found 10 years after stopping use of the Pill. It is not known whether this difference is caused by the Pill. It may be that the women who use the Pill were examined more often, so that the breast cancer was noticed earlier.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain. Chronic infection with Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer. In women who use the Pill for a long time the chance of getting cervical cancer may be slightly higher. This finding may not be caused by the Pill itself but may be related to sexual behaviour and other factors (such as better check-ups of the cervix).



### •Psychiatric disorders:

Some women using hormonal contraceptives including Lumivela have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### Other medicines and Lumivela

Tell your doctor, pharmacist or family planning nurse if you are using, have recently used or might use any other medicines or herbal products apart from Lumivela. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Lumivela. They can tell you whether it is necessary to use additional non-hormonal contraceptive such as a condom and, for how long you should use it or whether you should change another medicine you need.

Do not use Lumivela if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir as this may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

Lumivela can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use Lumivela”.

Some medicines:

- may influence the levels of Lumivela in the blood
- may stop Lumivela from working properly to prevent pregnancy
- may cause unexpected bleeding.

These include medicines used for the treatment of:

- epilepsy (e.g. primidone, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate)
- tuberculosis (e.g. rifampicin, rifabutin);
- HIV infection (e.g., ritonavir, nelfinavir, nevirapine, efavirenz)
- Hepatitis C Virus infection (e.g., boceprevir, telaprevir);
- other infectious disease (e.g. griseofulvin)
- high blood pressure in the blood vessels in the lungs (bosentan)
- depressive moods (the herbal remedy St. John’s wort).

If you are taking medicines or herbal products that might make Lumivela less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Lumivela may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

- Lumivela may influence the effect of other medicines, e.g.
  - medicines containing cyclosporin
  - the anti-convulsant lamotrigine (this could lead to an increased frequency of seizures).

### Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the Pill, because hormone contraceptives can affect the results of some tests.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

Do not use Lumivela if you are or you think you might be pregnant. If you think you might be pregnant while using Lumivela contact your doctor as soon as possible.

#### **Breast-feeding**

Lumivela is not recommended for use during breast-feeding. Contact your doctor if you still want to use Lumivela while breast-feeding.

### **Driving and using machines**

Lumivela has no known effect on the ability to drive or use machines.

### **Lumivela contains lactose and soybean oil**

If you have been told by your doctor that you can not tolerate certain sugars, contact your doctor before taking this product.

If you are allergic to peanut or soya, do not use this medicinal product.

### **Children and adolescents**

No clinical data on efficacy and safety are available in adolescents below 18 years

### **When should you contact your doctor?**

#### ***Regular check-ups***

Your doctor may advise you to make appointments regularly for a Pill check-up. Your personal situation will determine how often you should return for a check-up and which tests will be done.

#### ***Contact your doctor as soon as possible if:***

- you notice possible signs that might indicate you are having a blood clot. This might mean that you have a blood clot in a blood vessel of the leg (deep vein thrombosis), a blood clot in a blood vessel of the lung (pulmonary embolism), a heart attack or stroke (see section 'The Pill and Blood clots (Thrombosis)').
- For a description of the symptoms of these serious side effects please go to 'How to recognise a blood clot'.
- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also 'Do not take Lumivela' and 'When to take special care with Lumivela'); do not forget about the items related to your immediate family;
- you feel a lump in your breast
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section 'When to take special care with Lumivela')
- you are going to use other medicines, specially antibiotics (see also 'Other Medicines and Lumivela')
- your ability to move around is limited for a long period of time or you are to have surgery (consult your doctor at least 4 weeks in advance)
- you experience sustained or worsening bleeding irregularities
- you forgot tablets in the first week of the pack and had intercourse in the seven days

- you have severe diarrhoea
- you miss your period twice in a row. Do not start the next pack until told to by your doctor.

### 3. How to take Lumivela

Always take this medicine exactly as your doctor or pharmacist has told you. If you doubt you are using it correctly, ask your doctor or pharmacist.

#### When and how to take the tablets

Lumivela comes in strips of 28 tablets. Each blister contains 21 active white tablets and 7 green placebo tablets.

The two differently coloured tablets of Lumivela are arranged in order.

On the blister each tablet is marked with the day of the week on which it is to be taken. Take your tablet about the same time each day, with some liquid if necessary.

**Do not confuse the tablets:** Follow the direction of the arrows on the pack until all 21 white tablets have been taken, and then one green tablet per day for the last 7 days. Then you should start a new strip (21 white tablets and 7 green tablets). Consequently there is no drug-free interval between strips.

Because of the different composition of the tablets it is necessary to begin with the first tablet on the upper left and that you take the tablets every day. For the correct order, follow the direction of the arrows on the strip.

#### Preparation of the strip

To help you keep track, there are 7 stickers each with 7 days of the week for each strip of Lumivela. Choose the week sticker that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the week sticker that starts with “WED”.

Stick the week sticker along the top of the blister where it reads “Place the label here”, so that the first day is above the tablet marked “1”. There is now a day indicated above every tablet and you can see whether you have taken certain pill. The arrows show the order you are to take the pills.

During the 7 days when you are taking the green placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day after the last white active tablet of Lumivela. Once you have taken the last green tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip *on the same day of the week*, and that the withdrawal bleed should occur on the same days each month.

If you use Lumivela in this manner, you are protected against pregnancy during the 7 days when you are taking a placebo tablet.

#### When can you start with the first strip?

- *When no contraceptive pill has been used in the past month*  
Start taking Lumivela on the first day of the cycle (i.e. the first day of menstrual bleeding). Lumivela will work immediately, it is not necessary to use additional contraceptive method. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method such as a condom for the first 7 days.

- *When changing from another combined hormonal contraceptive, vaginal ring or patch*  
You can start taking Lumivela the day after the last tablet of your present pill pack (so, without a break) If your previous Pill pack contained inactive tablets, you can start Lumivela on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your previous Pill (or the day after the last inactive tablet of your previous Pill).

In case you use a vaginal ring or a patch you should start using Lumivela on the day of removal. You can also start using Lumivela later, but at latest seven days after removal of the ring or the last patch.

If you have used the Pill, patch or ring completely according to the prescriptions and you are certain that you are not pregnant, you can also stop using the Pill or remove the ring or patch on any day of your current cycle and change immediately to using Lumivela.

If you follow these indications, you do not need to use an additional contraceptive method, such as a condom.

- *When changing from a progestogen-only-method (minipill)*  
You can stop taking the minipill any day and start taking Lumivela the next day, at any time. But make sure you also use an additional contraceptive method, such as a condom, for the first 7 days of tablet-taking.
- *When changing from an injectable, implant or a progestogen-releasing intrauterine device (IUD)*  
Start taking Lumivela when your next injection is due or on the day your implant or IUD is removed. Make sure you also use an additional contraceptive method, such as a condom, for the first 7 days that you are taking Lumivela.
- *After having a baby*  
If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Lumivela. Sometimes it is possible to start sooner. Your doctor will advise you. The same applies in case you are breast-feeding and want to take Lumivela.
- *After a miscarriage*  
Follow the advice of your doctor.

### **If you take more Lumivela than you should**

There are no reports of serious harmful results of taking too many Lumivela tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina. If you have taken too many Lumivela tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

### **What to do if you forget to take your tablets**

The tablets in the 4<sup>th</sup> row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Lumivela. Throw away the forgotten placebo tablet.

If you miss a white, active tablet from the **1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> row**, do as follows:

- If the missed pill is taken **within 12 hours** contraceptive protection will not be reduced. Take the tablet as soon as you remember and take the following tablets at the usual time.
- If you are **more than 12 hours** late taking a tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher is the risk that the contraceptive

efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning of the pack or at the end of the strip. Therefore, you should follow the rules given below (see table):.

- **More than one tablet forgotten in this strip**

Contact your doctor.

- **One tablet forgotten in week 1**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet or you have forgotten to start a new strip after the placebo-tablet period, you may be pregnant. In that case, contact your doctor.

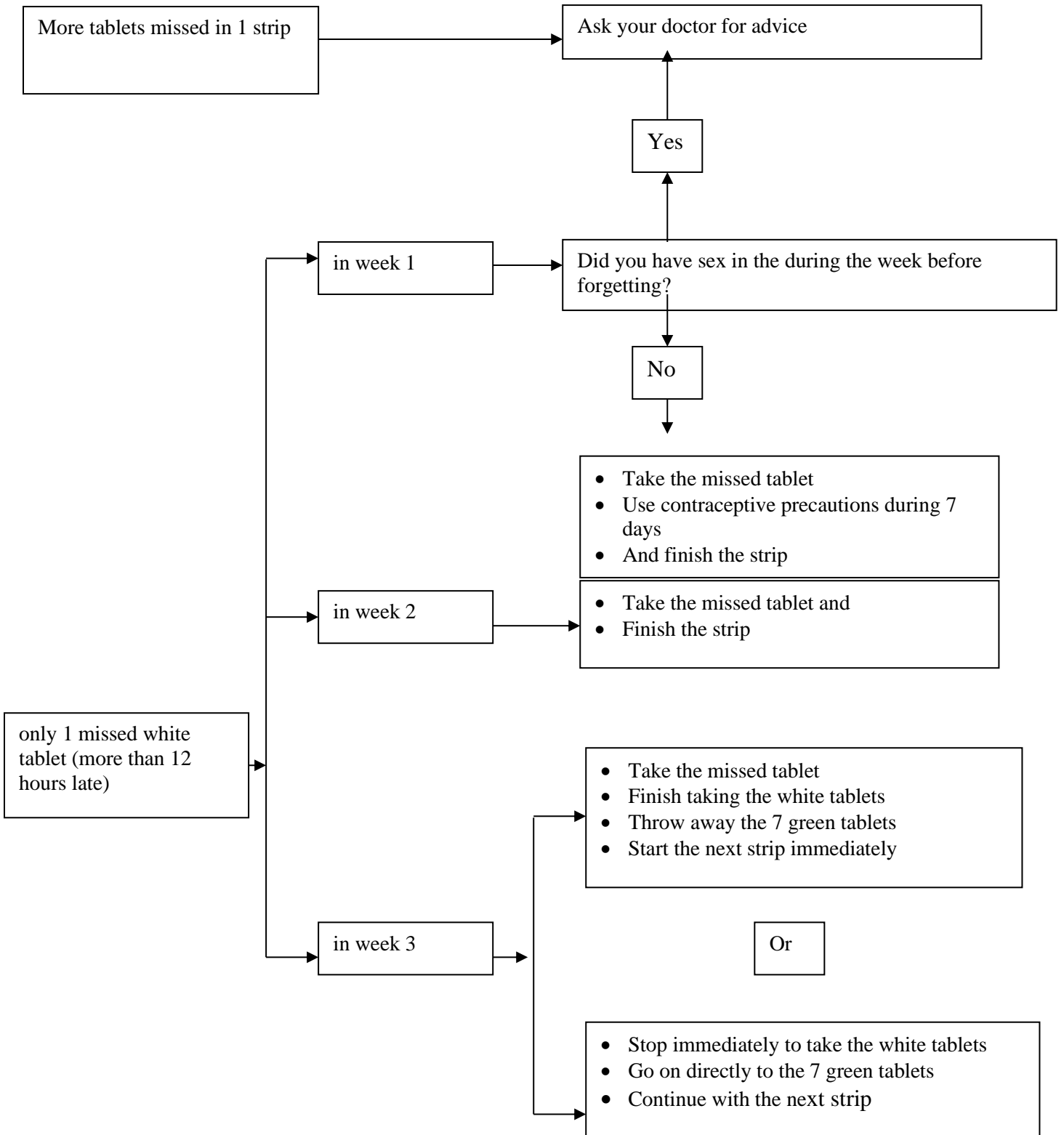
- **One tablet forgotten in week 2**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra

- **One tablet forgotten in week 3**

You may choose between either of the following options, without the need for extra contraceptive precautions:

1. Take the missed tablet as soon as you remember, even if that means taking two tablets at the same time. Take the next tablets at the usual time. When you finish the active white tablets from the current strip, start the next strip the next day without taking the green placebo tablets. You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding during the second pack.
  2. Stop taking the active white tablets from the current strip and go directly to the 7 green placebo tablets (**do always count the day you forgot to take the tablet**). Then continue the with the next pack. When following this method, you can always start your next pack on the same day of the week as you usually do.
- If you have forgotten any of the active tablets (white) in a strip, and you do not bleed during the normal placebo days, you may be pregnant. Contact your doctor before you start the next strip.



**What to do in case you have gastrointestinal disturbances (e.g., vomiting, severe diarrhoea)**

If you are sick (vomit) or have very bad diarrhoea your body may not get its usual dose of hormone from the tablet. If you vomit within 3-4 hours after taking an active white tablet, this is like missing a tablet. You must follow the advice given for missed tablets. Talk to your doctor if you suffer from severe diarrhoea.

**You want to delay your period**

You can postpone your period although it is not recommended. You can delay your period in exceptional cases by starting a new strip of Lumivela instead of the placebo-tablet period, and finishing it. You can continue with this pack for as long as you wish until the pack is empty. While using the second pack you may have some breakthrough bleeding or spotting. Start your next pack after the usual placebo-tablet period of 7 days.

**You want to change the starting of your period: what you must know**

If you take your tablets as directed, you will have your period on about the same day during the placebo-tablet week. If you want to change this just shorten (never lengthen) the placebo-tablet period. For example, if your placebo-tablet period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the placebo-tablet period very short (for example, 3 days or less) then it may be that you do not have any bleeding during this placebo-tablet period. You may have some breakthrough bleeding or spotting during the use of the next pack.

**You have unexpected bleeding**

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body clock has adjusted to the Pill (usually after about 3 strips). Tell your doctor if it continues, becomes heavy or starts again.

**You have missed a period**

If you have taken all of your tablets at the right time, and you have not vomited, or had severe diarrhoea or used other medicines then you are very unlikely to be pregnant. Start your next strip at the normal time.

If you miss your period twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next pack of Lumivela until your doctor has checked you are not pregnant.

**If you want to stop taking Lumivela**

You can stop taking Lumivela any time you want to. If you do not want to get pregnant, contact your doctor for advice about the use of another reliable birth control. If you stop because you want to get pregnant, it is generally recommended that you wait until you had natural period before trying to conceive. This helps you to work out when the baby will be due.

**4. Possible side effects**

Like all medicines, Lumivela can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Lumivela, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you use Lumivela”.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

As with all Pills, for the first few months, the pattern of your periods can change. This difference can show itself in frequency of the bleeding (failing to appear, less often, more often, or continuously), the amount of the bleeding, or the duration of the bleeding.

*Common (may affect 1 up to 10 women):*

- Depression,
- Headache,
- Nausea, abdominal pain
- Tender or painful breast
- Weight gain

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

- Fluid retention
- Decreased sexual desire;
- Migraine
- Vomiting, diarrhoea;
- Rash or hives;
- Breast enlargement

*Rare (may affect up to 1 in 1000 women):*

- harmful blood clots in a vein or artery for example:
  - in a leg or foot (i.e. DVT),
  - in a lung (i.e. PE),
  - heart attack,
  - stroke,
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA),
  - blood clots in the liver, stomach/intestine, kidneys or eye. The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot)
- Hypersensitivity reactions;
- Increased sexual desire;
- Discomfort of the eyes if you wear contact lenses;
- Erythema nodosum (bruise-like swelling to the shins), Erythema multiforme (a rash with red, irregular stains or ulcers);
- Breasts producing a milky fluid from the nipples, changes in vaginal secretions
- Decreased weight;



### **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 internet at {to be completed nationally}; or you can report via {to be completed nationally}. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Lumivela**

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

Do not store this medicine above 30°C. Store in the original package in order to protect from light.

### **Expiry Date**

*Do not use this medicine after the expiry date which is stated on the package, after 'EXP.'. The expiry date refers to the last day of that month.*

Do not use Lumivela if you notice a change of colour, broken tablets or any other visible signs of deterioration.

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 Lumivela contains**

A strip of Lumivela contains 21 white active tablets in the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> rows of the strip and 7 green placebo tablets in row 4.

#### **Active tablets**

- The active substances are desogestrel and ethinylestradiol. Each white tablet contains 150 micrograms desogestrel and 30 micrograms ethinylestradiol.
- The other ingredients are: Lactose monohydrate, maize starch, povidone K-30 (E1201), rrr-alpha-tocopherol (E307), soybean oil, silica colloidal hydrated (E551), silica colloidal anhydrous (E551), stearic acid (E570), hypromellose 2910 (E464), triacetin (E1518), polysorbate, titanium dioxide (E171).

#### **Green inactive tablets**

Lactose monohydrate, maize starch, povidone K-30 (E1201), silica colloidal anhydrous (E551), magnesium stearate (E572), hypromellose 2910 (E464), triacetin (E1518), polysorbate, titanium dioxide (E171), FD & C blue 2 aluminium lake (E132) and yellow iron oxide (E172).

#### **What Lumivela looks like and contents of the pack**

- Each active film-coated tablet is white and rounded. Each tablet is coded on one side “C” and on the reverse side “7”.
- Each inactive placebo film-coated tablet is green and rounded.
- Lumivela is available in blisters of 28 tablets: 21 active tablets and 7 green placebo tablets.

Pack sizes are 1, 3, 6 or 13 strips, each strip with 28 tablets. Not all package sizes may be marketed.

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

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

Exeltis Healthcare S.L.  
Av.Miralcampo 7-Poligono Ind.Miralcampo  
19200, Azuqueca de Henares, Guadalajara  
Spanje

### *Fabrikant*

Laboratorios León Farma, S.A.  
C/ La Vallina s/n, Pol. Ind. Navatejera.  
24193 - Villaquilambre, León.  
Spanje

## **In het register ingeschreven onder:**

RVG 121096

## **Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

België:	Lumivela Continu 30 0,150 mg/0,030 mg filmtabletten Lumivela Continu 30 0,150 mg/0,030 mg comprimés pelliculés Lumivela Continu 30 0,150 mg/0,030 mg Filmtabletten
Finland:	Lumivela 150 mikrog/30 mikrog tabletti
Luxemburg:	Lumivela Continu 30 0,150 mg/0,030 mg comprimés pelliculés
Nederland:	Lumivela 0,150/0,03 mg filmomhulde tabletten

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2025.**