Package leaflet: Information for the user
Lumivela 0,150/0,02 mg filmomhulde tabletten

Desogestrel / Ethinylestradiol

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

- They 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Lumivela is and what is used for

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

- Each of the 21 white tablets contains a small amount of two types of female hormones, namely, a progestogen, desogestrel and an oestrogen, ethinylestradiol.
- The 7 green tablets contain no active substances and are also called placebo tablets.

These help to stop you from getting pregnant, just as your natural hormones would stop you conceiving again when you are already pregnant.

The combined contraceptive pill protects you against getting pregnant in three ways. These hormones

1. stop the ovary from releasing an egg each month (ovulation).
2. also thicken the fluid (at the neck of the womb making it more difficult for the sperm to reach the egg.
3. alter the lining of the womb to make it less likely to accept a fertilised egg.

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").

Before you can begin taking Lumivela, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests.

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

Lumivela, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

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.

- 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 (severe hypertriglyceridemia)
  - 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) an inflammation of the pancreas (pancreatitis) associated with high levels of fatty substances in your blood
- if you have (or have ever had) a liver disease and your liver function is still not normal.
- if you have (or have ever had) a tumour in the liver.
- if you have (or have ever had) or if you are suspected to having breast cancer or cancer of the genital organs.
- if you have any unexplained bleeding from the vagina.
- If you have endometrial hyperplasia (abnormal growth of the lining of the womb)
- 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.
- 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?

<u>Seek urgent medical attention</u>

- 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' (thrombosis) section below.

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

In some situations you need to take special care while using Lumivela or any other combination pill, and your doctor may need to examine you regularly.

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 a close relative has or has ever had breast cancer

- If you have a disease of the liver or the gallbladder
- If you have diabetes
- if you have depression
- 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 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 you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- if you have varicose veins.
- if you have epilepsy (see "Other medicines and Lumivela")
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's Chorea)
- 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.

Talk to your doctor or pharmacist before taking Lumivela.

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?

• swelling of one leg or along a vein in the leg or foot especially when accompanied by:
  • pain or tenderness in the leg which may be felt only when standing or walking
  • increased warmth in the affected leg
  • change in colour of the skin on the leg e.g. turning pale, red or blue
	Deep vein thrombosis

• sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat • severe pain in your stomach; 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').	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone; • fullness, indigestion or choking feeling; • upper body discomfort radiating to the back, jaw, throat, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety, or shortness of breath; • rapid or irregular heartbeats	Heart attack

Are you experiencing any of these signs?	What are you possibly suffering from?
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. 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.	Stroke
• swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen)	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)

	Risk of developing a blood clot in a year
Women who are **not using** 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 **levonorgestrel, norethisterone or norgestimate**	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^2);
- 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 then 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

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump**.**

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.

The most important risk factor for cervical cancer is an existing infection with certain virus (human papillomavirus). In infected women taking the pill over a long period of time (>5 years), there are more frequent cases of cervical cancer. However, the increased risk could also be due to sexual behavior (e.g. frequent change in partners) and less frequent use of a condom.

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.

Bleeding between periods

During the first few months that you are taking Lumivela, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What to do if no bleeding occurs during the gap week

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is high unlikely that you are pregnant. If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

Children and adolescents

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

Other medicines and Lumivela

Always tell your doctor which medicines or herbal products you are already using, have recently used or might use. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Lumivela. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

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 can have an influence on blood levels of Lumivela and make it less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

  - medicines used for the treatment of
    - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
    - tuberculosis (e.g. rifampicin)
    - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
    - other infections (e.g griseofulvin)

    - high blood pressure in the blood vessels in the lungs (bosentan)

  - the herbal remedy St. John's wort.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Lumivela with food and drink

Lumivela may be taken with or without food, if necessary with a small amount of water.

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

If you are pregnant, do not take Lumivela. If you become pregnant while taking Lumivela stop immediately and contact your doctor. If you want to become pregnant, you can stop taking the pill at any time (see also "If you want to stop taking Lumivela").

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Use of Lumivela is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast feeding you should contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There is no information suggesting that use of Lumivela affects driving or use of machines.

Lumivela contains lactose and soybean oil

If have been told by your doctor that 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.

3. How to take Lumivela

Each blister contains 21 active white tablets and 7 green placebo tablets.

The two differently coloured tablets of Lumivela are arranged in order. A strip contains 28 tablets.

Take one tablet of Lumivela every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

Do not confuse the tablets: take a white tablet once per day for the first 21 days, 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 2nd or 3rd 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?

- *If you have not used a contraceptive with hormones in the previous month*
  Begin Lumivela on the first day of the cycle (that is the first day of your period). If you start Lumivela on the first day of your period you are immediately protected against pregnancy. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

- *Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch*
  You can start Lumivela preferably on the day after the last active tablet (the last tablet containing active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.

- *Changing from a progestogen-only-method (progestogen-only-pill, injection, implant or a progestogen-releasing IUD)*
  You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

- *After a miscarriage*
  Follow the advice of your doctor.

- *After having a baby*
  You can start Lumivela between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Lumivela use. If after having a baby, you have had sex before starting Lumivela (again), be sure that you are not pregnant or wait until your next period.

- *If you are breastfeeding and want to start Lumivela (again) after having a baby.*
  Read the section on "Breast-feeding".

Ask your doctor what to do if you are not sure when to start

If you take more Lumivelathan 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 Lumivela

The tablets in the **4th** 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 **1st, 2nd or 3rd row**, do as follows:

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a white tablet at the beginning or the end of the strip. Therefore, you should adhere to the following rules (see also the diagram below):

- **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 precautions.

- **One tablet forgotten in week 3**

You can choose between two possibilities:

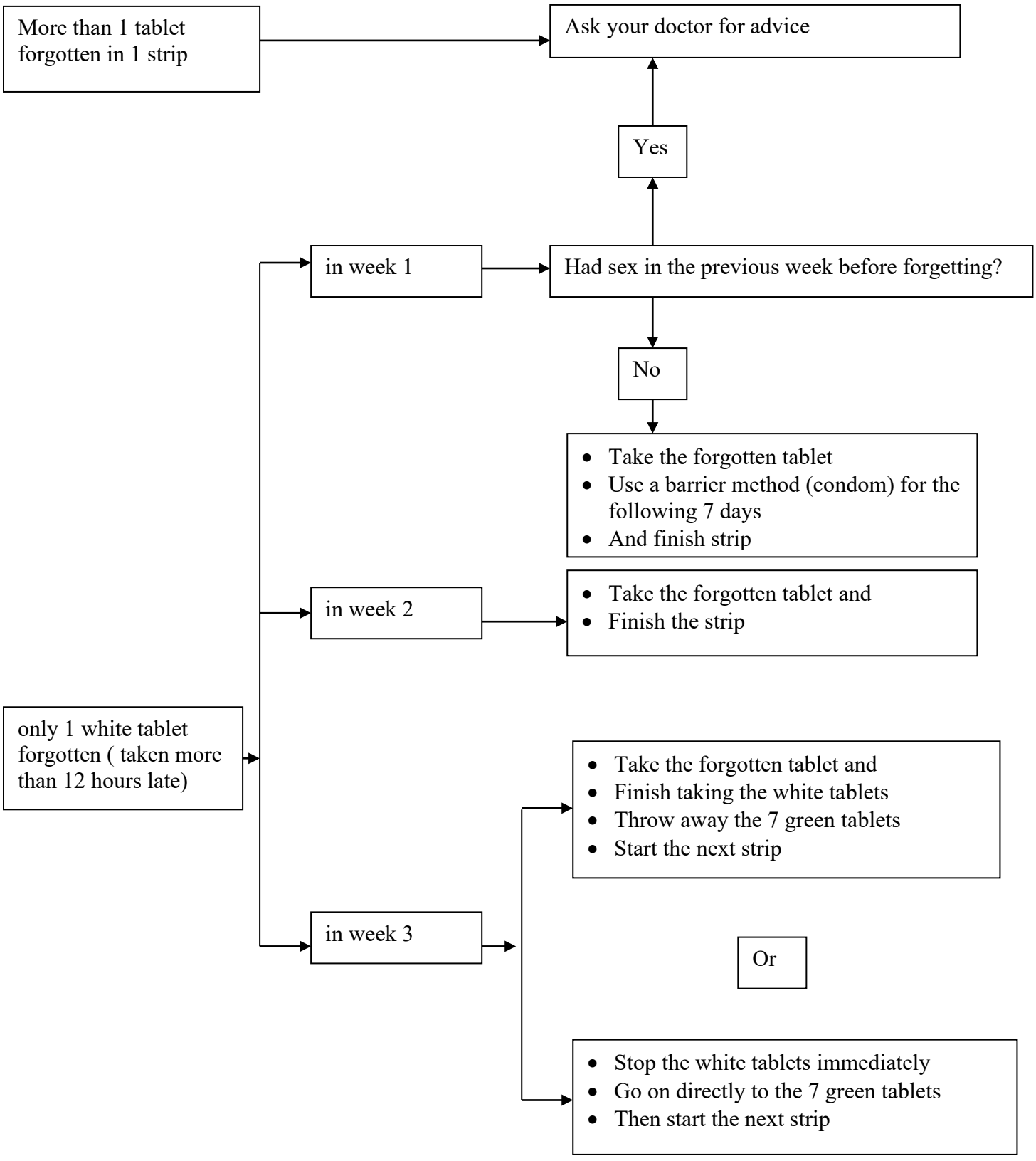
1. Take the forgotten tablet you forgot as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip.

   Most likely, you will have a period at the end of the second strip but you may also have light or menstruation –like bleeding during the second strip.

2. You can also stop taking the active white tablets from the current strip and go directly to the 7 green placebo tablets **(record the day on which you forgot your tablet)**. If you want to start a new strip on the day you always start, take the placebo tablets for less than 7 days.

If you follow one of these two recommendations, you will remain protected against pregnancy.

- If you have forgotten any of the active tablets (white) in a strip, and you do not have bleeding during the normal placebo days, you may be pregnant. Contact your doctor before you start the next strip.


More than 1 tablet forgotten in 1 strip
Ask your doctor for advice
Yes
in week 1
Had sex in the previous week before forgetting?
No
Take the forgotten tablet
Use a barrier method (condom) for the following 7 days
And finish strip
in week 2
Take the forgotten tablet and
Finish the strip
only 1 white tablet forgotten (taken more than 12 hours late)
Take the forgotten tablet and
Finish taking the white tablets
Throw away the 7 green tablets
Start the next strip
in week 3
Or
Stop the white tablets immediately
Go on directly to the 7 green tablets
Then start the next strip

What to do in case of vomiting or severe diarrhoea
If you vomit within 3-4 hours of taking an active white tablet or you have severe diarrhoea, there is a risk that the active substances in the tablet are not fully absorbed into your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Lumivela".

Delay of menstrual period: what you need to know
Even though it is not recommended, you can delay your menstrual period by going straight to a new strip of Lumivela instead of the placebo-tablet period, and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual placebo-tablet period of 7 days, start the next strip.

You might ask your doctor for advice before deciding to delay your menstrual period.

Change of the first day of your menstrual period: what you must know
If you take the tablets according to the instructions, then your period will begin during the placebo-tablet week. If you have to change this day, you do this by making the placebo-tablet period shorter (but never longer!). 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 then experience light or menstruation-like bleeding.

If you are not sure what to do, consult your doctor.

If you want to stop taking Lumivela
You can stop taking Lumivela whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Lumivela and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

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

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”.

Serious reactions
More serious reactions associated with combined hormonal contraceptive pills are detailed above in section 2 under “The pill and venous and arterial blood clots (thrombosis)”· and “The pill and cancer”. Please read these subsections carefully, and if you have any questions, ask your doctor.

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”).

The following serious side effects have been reported in women using the pill:

Crohn’s disease or ulcerative colitis (chronic inflammatory bowel diseases), systemic lupus erythematosus (SLE, a disease of the connective tissue), epilepsy, the rash known as herpes gestationis, chorea (a movement disease), a blood disorder called haemolytic uraemic syndrome – HUS (a disorder where blood blots cause the kidneys to fail), brown patches on the face and body (chloasma), movement disorder called Sydenham’s chorea, yellowing of the skin, gynaecological disorders (endometriosis, uterine myoma)

Other possible side effects
The following side effects have been reported in women using the pill, which can occur in the first few months after starting Lumivela, but they usually stop once your body has adjusted to the pill. The most commonly reported side effects (more than 1 in every 10 users may be affected) are irregular bleeding and weight gain.

Common or uncommon (between 1 and 100 in every 1,000 users may be affected): none or reduced bleeding, tender breast, breast enlargement, breast pain, decreased sexual desire, depression, headache, nervousness, dizziness, migraine, nausea, vomiting, acne, rash, nettle-rash (urticaria), fluid retention, high blood pressure.

Rare (between 1 and 10 in every 10,000 users may be affected): vaginal candidiasis (fungal infection), impaired hearing (otosclerosis), hypersensitivity, increased sexual desire, eye irritation due to contact lens, loss of hair (alopecia), itching, skin disorders (erythema nodosum – a skin disease associated with joint pain, fever, hypersensitivity, or infection, and characterised by small, painful, pink to blue nodules under the skin and on the shins that tend to recur, erythema multiforme - a skin disease characterised by solid raised spots on the skin or fluid-filled blisters lesions and reddening or discoloration of the skin often in concentric zones about the lesions), vaginal discharge, breast discharge, 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 eyeThe 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)

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 30ºC.
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 1st, 2nd and 3rd 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 20 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), macrogol 400, 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 (1518), 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 “5”.

- Each inactive film-coated tablet is green and rounded.

- Lumivela is available in blisters of 28 tablets: 21 white 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.
24008 - Navatejera, León.
Spain

In het register ingeschreven onder:
RVG 121094

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

België:	Lumivela Continu 20 0,150 mg/0,020 mg filmtabletten
	Lumivela Continu 20 0,150 mg/0,020 mg comprimés pelliculés
	Lumivela Continu 20 0,150 mg/0,020 mg Filmtabletten
Denmarken	Lumivela, filmovertrukne tabletter
Finland:	Lumivela 150 mikrog/20 mikrog tabletti
Ijsland	Lumivela 150 míkróg / 30 míkróg filmuhúðaðar töflur
Luxemburg:	Lumivela Continu 20 0,150 mg/0,020 mg comprimés pelliculés
Nederland:	Lumivela 0,150/0,02 mg filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in november 2022