Package leaflet: Information for the user

Vonodiol 100 mcg/20 mcg film-coated tablet

Levonorgestrel / Ethinylestradiol

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

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")

What is in this leaflet

1. What Vonodiol is and what it is used for

- Vonodiol is a contraceptive pill used to prevent pregnancy.

- Each tablet contains a small amount of two different female hormones, namely levonorgestrel and ethinylestradiol.

- Contraceptive pills that contain two hormones are called 'combination pills.'

Vonodiol is called a 'low-dose' contraceptive pill because it contains only a small amount of hormones.

2. What you need to know before you use Vonodiol

General notes

Before you start using Vonodiol 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 Vonodiol, 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 Vonodiol, or where the reliability of the Vonodiol may be decreased. In such situations you should either not have intercourse 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 Vonodiol alters the monthly changes of the body temperature and of the cervical mucus.

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

When not to take Vonodiol
You should not use **Vonodiol** 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.

Do not use Vonodiol:

- If you have (or have had in the past) a blood clot (deep vein thrombosis, DVT) in a blood vessel of the leg, lungs (pulmonary embolus, PE) or other organs
- If you have (or have had in the past) a heart attack or 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 a disease that may increase the risk of a thrombosis in the arteries:
  - severe diabetes with damaged blood vessels
  - 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 ever had) a type of migraine called "migraine with aura"
- If you have or have had in the past a liver disease and your liver function is still not normal
- If you have or have had a tumour in the liver
- If you have (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 unexplained absence of your period for several months
- If you are allergic to levonorgestrel or ethinylestradiol, or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.

- If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section Other medicines and Vonodiol).

<u>Additional information about special populations</u>

Use in children

Vonodiol is not intended for use in females whose periods have not yet started

Use in older women

Vonodiol is not intended for use after the menopause.

Women with hepatic impairment

Do not use Vonodiol if you suffer from liver disease. See also 'Do not use Vonodio and "Warnings and precautions"

Women with kidney impairment

Ask your doctor. Available data do not suggest a need to change the use of Vonodiol.

Warnings and precautions

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' (thrombosis) 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.

In some situations, you need to take special care while using Vonodiol or any other combination pill, and your doctor may need to examine you regularly. If the condition develops, or gets worse while you are using Vonodiol, you should also tell your doctor.

- If a close relative has or has had breast cancer
- If you have a disease of the liver or the gallbladder
- If you have diabetes
- If you have depression. Some women using hormonal contraceptives including <product name> 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.
- If you have Crohn's disease or ulcerative colitis (inflammatory bowel disease)
- If you have SLE (systemic lupus erythematosus; a disorder of the immune system)
- If you have HUS (haemolytic uremic syndrome); a blood disorder that causes kidney damage
- If you have sickle cell anaemia (an inherited disease of the red blood cells)
- o 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)
- o if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots')
- o 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 <invented name>
- o 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 Vonodiol)
- If you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, porphyria (a disease of the blood), gestational herpes (skin rash with vesicles during pregnancy), Sydenham's chorea (a disease of the nerves in which sudden movements of the body occur)

- If you have or have ever had chloasma (golden brown pigment patches, so called “pregnancy patches”, especially on the face). If this is the case, avoid direct exposure to 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.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Vonodiol 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 Vonodiol 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
• 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 Vonodiol 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 Vonodiol 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.

- 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 Vonodiol	About 5-7 out of 10,000 women

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

The risk of a blood clot with Vonodiol 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 Vonodiol may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Vonodiol 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 Vonodiol needs to be stopped.

If any of the above conditions change while you are using Vonodiol, 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 Vonodiol is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Vonodiol 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 Vonodiol, 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.

Vonodiol and cancer
Cervical cancer in long-term users has been reported, but the effect of sexual behaviour or other factors such as human papilloma virus (HPV) is not clear.

Breast cancer has been observed slightly more often in women using combined 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 combined pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combined 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.

Bleeding between periods

During the first few months that you are taking Vonodiol, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding occurs for more than three months, or if it begins after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in 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 highly 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.

Other medicines and Vonodiol

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

Do not use Vonodiol if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir dasabuvir, glecaprevir/pibrentasvir oe sofosbuvir/velpatasvir/voxilaprevir, as there products 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.

Vonodiol can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Vonodiol".

Some medicines can have an influence on the blood levels of Vonodiol and can make it less effective in preventing pregnancy or can cause unexpected bleeding. These include:
- medicines used for the treatment of:
  - the mobility of the stomach and intestines (e.g. metoclopramide)
  - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine topiramate or felbamate)
  - 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)
  - fungal infections (griseofulvin)
  - Arthritis, arthrosis (etoricoxib)
  - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

Vonodiol may influence the effect of other medicines, e.g.
- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

Vonodiol with food and drink

Vonodiol 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 oral contraceptives can affect the results of some tests.

Pregnancy and breast-feeding

Pregnancy

Do not take Vonodiol if you are pregnant. If you become pregnant while taking Vonodiol, stop taking Vonodiol immediately and contact your doctor. If you want to become pregnant, you can stop taking Vonodiol at any time (see also "If you stop taking Vonodiol").
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Use of Vonodiol 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.

Driving and using machines

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

Vonodiol contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Vonodiol

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Each blister strip contains 21 tablets. Each tablet is marked with the weekday when the tablet should be taken. For example, if you start to take the tablets on a Tuesday, press the tablet through the aluminium foil, at a blister marked "TUE". Take the tablets every day in the order shown by the arrows.
Take one tablet of Vonodiol every day for 21 days, with water if necessary. You may take the tablets with or without food, but you should take the tablets every day around the same time.

Once you have finished all 21 tablets, you will not take any tablets during the next 7 days. Your period (withdrawal bleed) will start during these 7 days, usually 2–3 days after taking the last Vonodiol tablet.
Start the next blister pack on the 8th day even if your period continues. This way you will always start a new pack on the same day of the week, and the withdrawal bleed will occur roughly at the same time each month.

When can you start with the first strip

- *If you have not used a contraceptive with hormones in the previous month.*
  Begin with Vonodiol on the first day of the cycle (that is the first day of your menstruation). If you start Vonodiol on the first day of your menstruation you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

- *Changing from another combined hormonal contraceptive, or vaginal ring or patch*
  Start taking <invented name> on the day after the last active tablet of your previous pill or, at the latest, on the day following the usual tablet-free break or the last placebo tablet of the previous hormonal contraceptive. In the case of a vaginal ring or patch, start taking <invented name> on the day of removal of the last ring or patch of a cycle pack, or, at the latest, when the next application would have been due.

- *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 the 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 first trimester miscarriage or termination*
  Follow your doctor's advice.

- *After having a baby or second trimester miscarriage or termination*
  Start Vonodiol between 21 and 28 days after delivery or second trimester miscarriage or termination. If you start later than day 28, you must use an additional barrier method (for example, a condom) during the first 7 days of Vonodiol use.
  If, after having a baby, you have had intercourse before starting Vonodiol (again), you must first be sure that you are not pregnant, or you must wait until the next menstrual bleed.

  Let your doctor advise you in case you are not sure when to start

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

If you take more Vonodiol than you should

There are no reports of serious harmful results of taking too many Vonodiol 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 Vonodiol tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Vonodiol

- If you are **less than 12 hours late** taking a tablet, the protection from pregnancy is not reduced. Then still 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 from pregnancy may be reduced. The greater the number of the tablets that you have forgotten, the greater is the risk of becoming pregnant.
- Therefore, you should keep to the following rules:

- tablet-taking must never be discontinued for longer than 7 days.
- the effectiveness of <invented name> depends on 7 days of uninterrupted tablet-taking.

- **If you are more than 12 hours late during days 1-7 (see also the diagram)**

  Take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take the next tablets at the usual time. In addition, a barrier method such as a condom should be used for the next 7 days. If you have had sex in the 7 days before missing the tablet, the possibility of a pregnancy must be considered. The more tablets have been missed and the closer they are to the regular tablet-free break, the higher the risk of pregnancy. See your doctor if this has happened to you.

- **If you are more than 12 hours late during days 8-14 (see also the diagram)**

  Take the last missed tablet as soon as you remember, even if this means taking two tablets at the same time. Then continue to take the next tablets at the usual time. Provided you have taken the tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive precautions. If you have not taken the tablets correctly or have missed more than one tablet, you should use extra contraceptive precautions for the next 7 days.

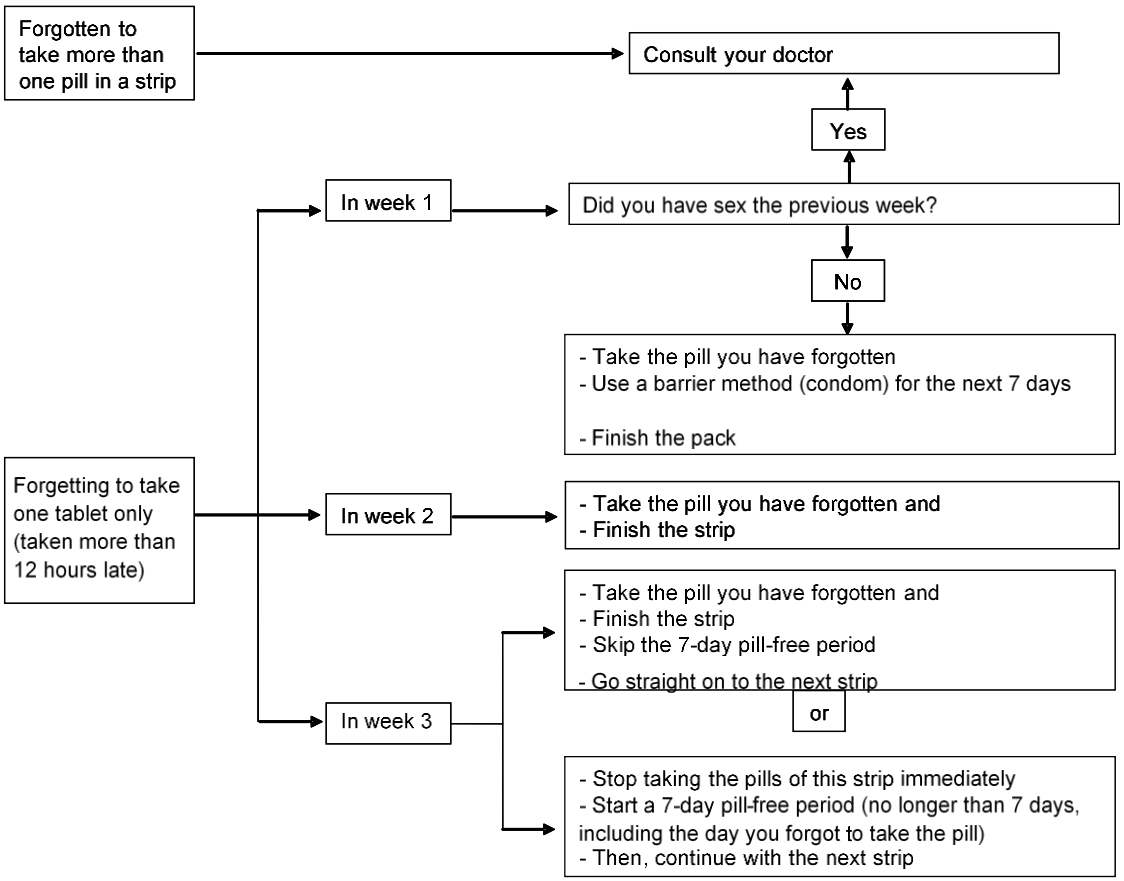
- **If you are more than 12 hours late during days 15-21 (see also the diagram)**

  The risk of pregnancy increases the nearer you are to the tablet-free break of 7 days. However, pregnancy can still be prevented by adjusting the dosage.
  If you use the following advice, there is no need to use extra contraceptive precautions, provided that all the tablets have been taken correctly in the 7 days before the first missed tablet. If this is not the case, you should follow the first of these two options and use extra contraceptive precautions for the next 7 days as well.

  1. Take the forgotten tablet as soon as you remember, even if that means taking two tablets at the same time. Then take the rest of the tablets at the usual time. Instead of having a 7 day tablet –free break, continue immediately with the next pack of 21 tablets. There will probably be no withdrawal bleed until the end of the second pack, but you may experience spotting or breakthrough bleeding on tablet-taking days

  2. You can stop taking the tablets form the current pack and have a ttablet-free beak of of 7 daysincluding the days you missed tablets, and then continue with the next pack.

- If you have forgotten any of the tablets in a strip and you do not have bleeding in the first tablet-free period, this may mean that you are pregnant.



What you must do in case of vomiting or severe diarrhoea
If you vomit within 3-4 hours of taking a 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 similar to if you forget a tablet. After vomiting or diarrhoea, you must take another tablet from a reserve strip as soon as possible. If possible take it *within 12 hours* of when you normally take your tablet. If this is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Vonodiol".

If you do not want to change your normal tablet-taking routine, you can take the extra tablet from another pack.

If the vomiting or diarrhoea continues, talk to your doctor. You will need to use extra contraceptive measures.

Delaying of menstrual period: what you must know

Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible by going straight on to a new strip of Vonodiol instead of the tablet-free period, to the end of the second strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this second strip. After the usual tablet-free period of 7 days, *continue with* the following 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 want to change the starting day or have your period on another day of the week, you can shorten your next tablet-free break by as many days as you like. The shorter the break, the higher the risk that there will be no withdrawal bleed and that you will experience breakthrough bleeding and spotting during the second pack. Never lengthen your tablet-free break.

If you are not sure how to proceed, contact your doctor for advice.

If you stop taking Vonodiol

You can stop taking Vonodiol 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 Vonodiol and wait for a menstrual 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, this medicine 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 Vonodiol, please talk to your doctor.

Serious side effects

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").

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 take Vonodiol".

The following is a list of the side effects that have been linked with the use of Vonodiol:

Common: may affect up to 1 in 10 people
- headache
- mood changes (including depression)
- nausea, abdominal ache
- painful breasts
- breast pain or tenderness
- weight increase

Uncommon: may affect up to 1 in 100 people
- decreased interest in sex
- skin rash
- migraine
- vomiting, diarrhoea
- itching or raised bumps on the skin
- swollen breasts
- fluid retention

Rare: may affect up to 1 in 1,000 people
- contact lens intolerance
- allergic reactions
- increased interest in sex
- breast or vaginal discharge
- red skin lesions or nodules
- skin redness or blotchiness
- weight decrease

- 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).
The following serious adverse events have been reported slightly more often in women using contraceptive pills, but it is not known whether this is caused by the treatment (see section 2: "Warnings and precautions")

- raised blood pressure
- liver tumours or breast cancer

The following conditions have also been associated with combination oral contraception:

Crohn's disease, ulcerative colitis, epilepsy, migraine, cervical cancer, porphyria (metabolism disorder which causes abdominal pains and mental disorders), systemic lupus erythematosus (where the body attacks and injures its own organs and tissues), herpes in late pregnancy, Sydenham's chorea (rapid involuntary jerking or twitching movements), haemolytic uraemic syndrome (a condition which occurs after diarrhoea caused by E.coli), liver problems shown by jaundice, gall bladder disorders or gallstone formation.

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 HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vonodiol

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

Do not store above 30ºC.

Expiry date

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vonodiol contains

The active substances are levonorgestrel and ethinylestradiol.

Each tablet contains 0.10 mg of levonorgestrel and 0.02 mg of ethinylestradiol. The other ingredients (excipients) are lactose, povidone K-30 (E1201), magnesium stearate (E572) and opadry II pink [polyvinyl alcohol, talc (E553b), titanium dioxide (E171), polyethylene glycol 3350, red aluminium lake (E129), lecithin (E322), iron oxide red (E172) and blue aluminium lake (E132)].

What Vonodiol looks like and contents of the pack

- Each film-coated tablet is pink and rounded.
- Vonodiol is available in strips (blisters) of 21 tablets.
- Pack sizes are of 1, 3, 6 or 13 strips, each strip with 21 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Theramex Ireland Limited
3rd Floor, Kilmore House,
Park Lane,
Spencer Dock,
Dublin 1,
D01 YE64,
Ireland

Manufacturer

Laboratorios León Farma, S.A.
Polígono Industrial Navatejera, La Vallina S/N
24008 Navatejera (Leon) - Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Lavinia
Germany:	Asumate 20 0,10 mg/0,02 mg Filmtabletten
Ireland:	Vonodiol 100 mcg / 20 mcg Film-coated tablets
Netherland:	Ethinylestradiol/ levonorgestrel 0,02 mg /0,10 mg Focus filmomhulde tabletten
Spain:	Linelle 0,10 mg/0,02 mg, comprimidos recubiertos con película EFG

This leaflet was last revised in October 2022.