

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

### **Violite 100/20 micrograms film-coated tablets** levonorgestrel/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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

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

#### **1. What Violite is and what it is used for**

Violite is a combined oral contraceptive pill for the prevention of pregnancy. It contains two different female hormones, levonorgestrel and ethinylestradiol.

Each of the 21 round pink tablets contains 100 micrograms of levonorgestrel and 20 micrograms of ethinylestradiol.

#### **2. What you need to know before you take Violite**

##### **General notes**

Before you start using Violite 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 start taking Violite your doctor will ask you some questions around your personal health history and that of your close relatives. Your doctor will also measure your blood pressure and may also carry out some other tests for example a breast exam or cervical screen as appropriate.

In this leaflet some situations are described where you should stop using Violite or where the reliability of Violite may be decreased and there is a higher risk of pregnancy. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions (e.g. use a condom or other barrier method). Do not use the rhythm or temperature methods. These methods can become unreliable because Violite alters the monthly changes in body temperature and cervical mucus.

When taken correctly combined oral contraceptives, have a failure rate of approximately 1% per year. The failure rate may increase when pills are missed or taken incorrectly, if you have a stomach upset or when you take certain other medicines or herbal remedies.

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

### **Do not take Violite**

You should not use Violite 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 take Violite:

- 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 breast cancer or cancer of the genital organs;
- if you have any unexplained bleeding from the vagina;
- if you have ever had a severe liver disease, e.g active viral hepatitis and severe cirrhosis and you have been told by your doctor that your liver function test results are not yet back to normal;
- if you have ever had liver tumours;
- if you are pregnant or suspect you may be pregnant;
- if you are allergic to any of the ingredients in Violite.

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

### **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.**

If the condition develops, or gets worse while you are using Violite, you should also tell your doctor.

- 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 have inflammation of the pancreas (pancreatitis)
- 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 Violite;
- if a close relative has had breast cancer
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins;
- if you have constantly elevated blood pressure or a significant increase in blood pressure which does not respond adequately to your blood pressure medication;
- if you or your close family have ever had problems with your heart, or circulation such as high blood pressure
- if you have diabetes;
- if you are overweight (obese);
- if you have a disease of the heart valves or heart rhythm disorder (atrial fibrillation);
- if you or your close family have ever had problems with blood clotting;
- if you have the inherited disease called porphyria;
- if you have migraines;
- if you have epilepsy
- if you suffer from depression;
- if you have a loss of hearing due to a disorder known as otosclerosis;
- if you suffer from a disease known as Sydenham’s Chorea. The symptoms include irregular, sudden involuntary movements;
- if you have had during a pregnancy or when using another contraceptive pill a skin condition which caused itching, red patches and blisters (herpes gestationis);
- if you have had during a pregnancy temporary brown patches on your skin (chloasma). The pill can make this recur so you should avoid strong sunlight or sunbeds while taking Violite;
- if you experience any sudden unexplained changes in your vision;
- if you have gallstones, gallbladder disease, liver disease or have problems caused by a blockage of the bile ducts (cholestasis) - this may cause intense itching;
- 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.

**Psychiatric disorders**

Some women using hormonal contraceptives including Violite 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.

## BLOOD CLOTS

Using a combined hormonal contraceptive such as Violite 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 Violite 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
<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> </ul>	Stroke

<ul style="list-style-type: none"> <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>	
<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 Violite 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 Violite 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 such as Violite, 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).

<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 Violite	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 Violite is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m2);

- 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 Violite may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Violite 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 (more than 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 Violite needs to be stopped.

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

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

### **Violite and cancer**

- Cervical cancer in long-term users has been reported, but the effect of sexual behavior 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. As breast cancer is rare in women under 40 years of age, the excess number is small in relation to the overall risk of breast cancer. 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.

- Benign liver tumours (non-cancerous) are rare, and malignant liver tumours (cancerous) are even more rarely reported in combined pill users. Contact your doctor if you have unusually severe stomach pain.

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on the Pill, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users is small. For example:

- Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

**Your risk of breast cancer is higher:**

- If you have a close relative (mother, sister or grandmother) who has had breast cancer
- If you are seriously overweight

**See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

**Bleeding between periods**

During the first few months that you are taking Violite, you may have unexpected bleeding (bleeding or spotting outside the tablet free week). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

**What to do if no bleeding occurs in the tablet free 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 this is not the case or if the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately as pregnancy must be ruled out before the pill is continued. Do not start the next blister pack until you are sure that you are not pregnant.

**Other medicines and Violite**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. There are some medicines that may interact with Violite.

Medicines can sometimes interfere with each other. If you receive treatment from any other doctor, nurse or qualified healthcare professional make sure they are aware that you are using Violite as a contraceptive.

They can advise if it will be necessary to take any additional precautions (e.g. using a condom or other barrier contraceptive) while you are taking other medicines while you are taking Violite.

Some medicines can make Violite less effective in preventing pregnancy, or can cause unexpected bleeding, or have an influence on the blood levels of Violite.

These include:

- medicines used for treatment of:
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors) (e.g. ritonavir, raltegravir, nevirapine);
  - epilepsy (e.g. barbiturates, phenytoin, primidone, felbamate, carbamazepine, oxcarbazepine or topiramate);

- fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole);
- certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
- arthritis, arthrosis (etoricoxib);
- infections (e.g. rifabutin, rifampicin, griseofulvin);
- sleep disorders (modafinil);
- gout (phenylbutazone);
- the herbal remedy St. John's Wort (*Hypericum perforatum*), which is used to treat certain types of depression;
- grapefruit juice

Do not use Violite if you have Hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasbuvir, glecaprevier/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these 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. Violite can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Violite".

If you have been told to take additional contraceptive precautions while taking any of the above medicines follow your doctor's instructions carefully. If you need to take the medicine beyond the end of your current tablet pack, miss your tablet-free week and start the next pack straight away. In some cases you may need to continue to use additional barrier contraception for several weeks after you have stopped taking the medicine.

Violite may interfere with the following medicines:

- Cyclosporine (to reduce the body's immune response)
- Lamotrigine (for epilepsy).
- Melatonin (for insomnia)
- Midazolam (for sedation and epilepsy)
- Theophylline (for asthma and other breathing difficulties)
- Tizanidine (muscle relaxant)

Taking an antibiotic medicine called troleandomycin may increase the risk for intrahepatic cholestasis (retention of bile in the liver) while taking the combined pill.

*Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.*

### **Violite with food and drink**

Violite 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 hormonal contraceptives can affect the results of some tests.

### **Pregnancy**

Do not take Violite if you are pregnant. If you think you may have become pregnant while using Violite tell your doctor immediately.

### **Breastfeeding**

It is not recommended that you take the combined pill while you are breastfeeding as the hormones can affect your milk. If you wish to breastfeed, your doctor will be able to advise you on suitable alternative methods of contraception.

Always ask your doctor, nurse, or healthcare professional for advice before taking any medicine.



### **Driving and using machines**

The effect of Violite on the ability to drive or operate machinery has not been studied. Dizziness has been reported as a side effect. If you experience dizziness do not drive or operate machinery until it has resolved.

### **Violite 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 Violite**

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

Each blister strip of Violite 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 Violite 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 Violite 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 taking Violite on the first day of the cycle (that is, the first day of your period). If you start Violite on this day you are immediately protected against pregnancy. You may also begin on day 2-5 of your cycle, but 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 Violite 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 Violite 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 (oral pill, injection, implant or an intrauterine system IUS).*  
You may change to Violite tablets on any day from a progestogen-only pill (from an implant or an IUS 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 the advice of your doctor.
- *After having a baby or second trimester miscarriage or termination*  
Start Violite 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 Violite use.

If, after having a baby, you have had sex before starting Violite (again), you must first be sure that you are not pregnant, or you must wait until your next period before taking Violite.

- *If you are breast-feeding and want to start Violite (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.*

### **Use in children and adolescents**

You should not take Violite before you have started to have a monthly period.

### **Use in older patients**

You should not take Violite after the menopause.

### **Use in patients with liver problems**

You should not take Violite if you have severe liver problems.

### **Use in patients with kidney problems**

You should talk to your doctor before taking Violite if you have kidney problems.

### **If you forget to take Violite**

- 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 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 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 Violite 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.

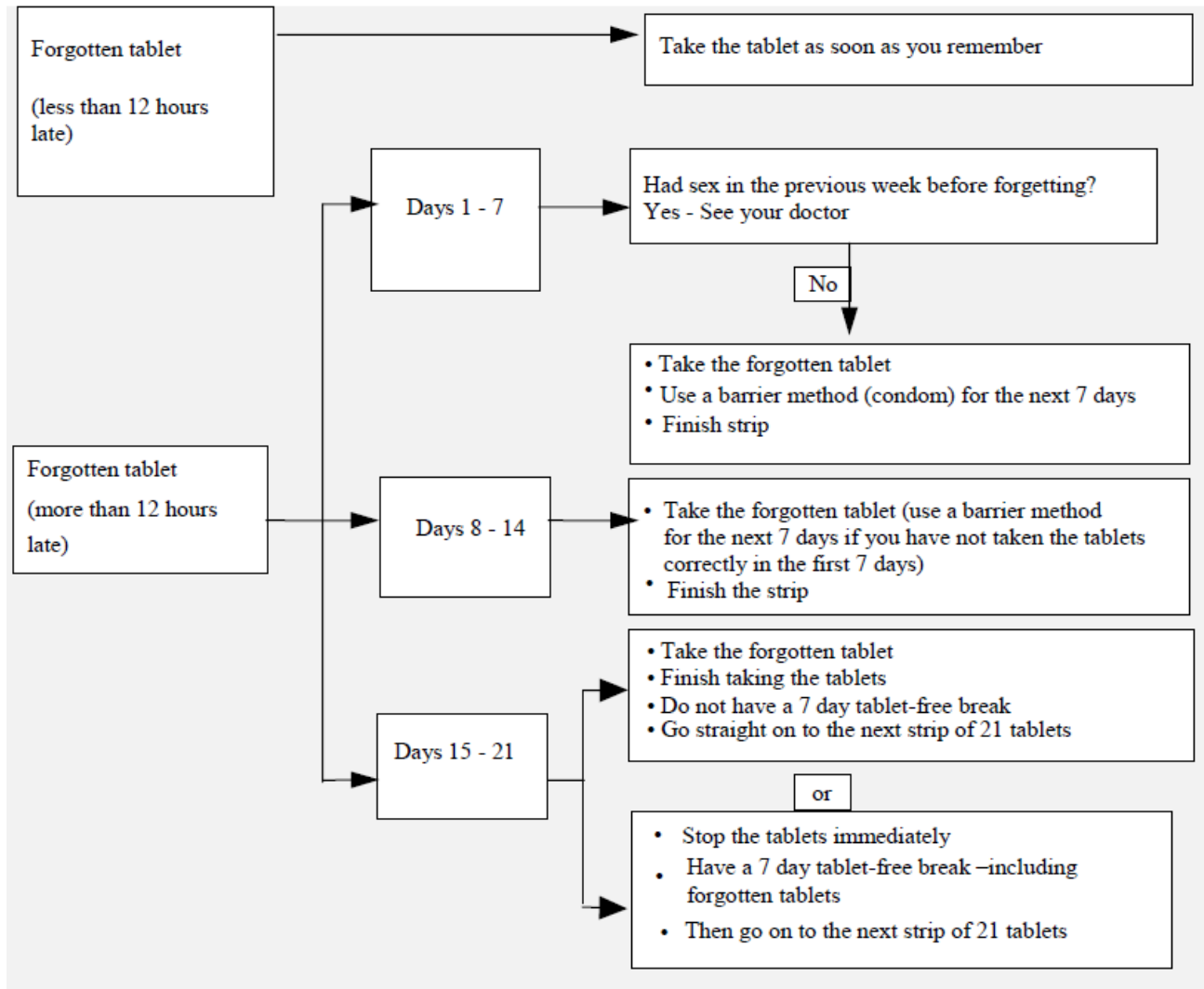
1. Take the forgotten tablet as soon as you remember, even if that means taking two tablets at the same time. Then take the rest of the tablets at the usual time. Instead of having a 7 day tablet-free break, continue immediately with the next pack of 21 tablets. There will probably be no withdrawal bleed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

the end of the second pack, but you may experience spotting or breakthrough bleeding on tablet-taking days.

- You can stop taking the tablets from the current pack and have a tablet-free break of 7 days, including the days you missed tablets, and then continue with the next pack.

If you miss several tablets and have no withdrawal bleed during the first normal tablet-free break, the possibility of a pregnancy must be considered.

### Missed pill chart



### If you have vomiting or diarrhoea

Vomiting or diarrhoea may make Violite less effective in preventing pregnancy.

If you vomit within 3-4 hours of taking a tablet or have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet 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, follow the advice given under “If you forget to take Violite”.

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.

### How to delay a period

You can delay your period by starting another pack of Violite without any tablet-free week. You may have some spotting or bleeding while taking the second pack, this is nothing to worry about. You should have a normal bleed after finishing the second course of tablets.

*It is advisable to consult your doctor before deciding to delay your menstrual period.*

#### **Changing of the first day of your menstrual period: what you need to 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 what to do, talk to your doctor.*

#### **If you stop taking Violite**

You can stop taking Violite 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 Violite 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 take more Violite than you should**

There are no reports of serious harmful results from taking too many Violite 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. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

If you have taken too many Violite tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

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 Violite, 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 use Violite”.

**If you experience any of the following serious side effects, seek medical advice immediately:**

#### **Rare side effects** (may affect up to 1 in 1,000 people)

- 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).

- A serious allergic reaction – **Rare side effect (may affect up to 1 in 1,000 people)**  
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat, skin rash, hives.
- A blood clot in the eye - **it is not known how frequently this occurs**  
Symptoms include loss of vision, pain and swelling of the eye especially if sudden.
- Haemolytic uremic syndrome (a condition which affects your blood and kidneys) – **it is not known how frequently this occurs**  
Symptoms include vomiting, diarrhoea (which may be bloody), fever, feeling weak, passing less urine than usual.
- Pancreatitis - **it is not known how frequently this occurs**  
Symptoms include severe upper abdominal pain which may spread to your back.
- Erythema multiforme - **Rare side effect (may affect up to 1 in 1,000 people)**  
Symptoms include a skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister. You may also have ulcers in the mouth, eyes or genitals and have a fever.

Other side effects include:

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

- mood swings, depression
- headache,
- breast pain or tenderness
- weight increase
- nausea, abdominal pain

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

- decreased interest in sex
- skin rash
- vomiting, diarrhoea
- migraine
- swollen breasts
- fluid retention
- itching or raised bumps on the skin

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

- contact lens intolerance
- allergic reactions
- increased interest in sex
- weight decrease
- breast or vaginal discharge
- red skin lesions or nodules

- skin redness or blotchiness
- 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).

### Description of selected adverse reactions

Adverse reactions with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined oral contraceptives are listed below (see also sections ‘Do not take Violite’, ‘Take special care with Violite’):

#### *Tumors*

- Breast cancer has been seen 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. As breast cancer is rare in women under 40 years of age the excess number is small in relation to overall risk of breast cancer.
- Liver tumors (benign and malignant)

#### *Other conditions (frequency unknown):*

- Women with increased blood fats (hypertriglyceridemia) resulting in an increased risk of inflammation of the pancreas (pancreatitis) when using combined oral contraceptives;
- High blood pressure;
- Occurrence or worsening of conditions for which a link to combined oral contraceptives is not definite: jaundice and/or itching related to blocked bile flow (cholestasis); gallstone formation; a blood disease called porphyria; systemic lupus erythematosus (a disease affecting your natural defense system); hemolytic uremic syndrome (a blood clotting disease); a nerve disease called Sydenham’s chorea, a type of skin condition that occurs during pregnancy (herpes gestationis); hearing loss (otosclerosis-related);
- In women with hereditary angioedema (symptoms include sudden swelling of e.g. the eyes, mouth, throat etc.) products containing estrogens may induce or worsen symptoms of angioedema;
- Disturbed liver function;
- If you are a diabetic, your blood glucose control may be affected. There is generally no need to change your diabetic treatment while using Violite;
- Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- Chloasma (a discolouration of the skin especially of the face/neck known as ‘pregnancy patches’);
- **Bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Violite.

A few women have a little unexpected bleeding or spotting while they are taking Violite, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Violite as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day.

#### *Interactions*

Unexpected bleeding and/or contraceptive failure may result from interactions of other drugs with oral contraceptives (e.g. the herbal remedy St. John's Wort, or drugs for epilepsy, tuberculosis, HIV infections and other infections). See section 'Other medicines and Violite'.

**Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- Carries on for more than the first few months
- Starts after you've been taking Violite for a while
- Carries on even after you've stopped taking Violite.

**The following conditions may occur or get worse with combined oral contraceptives:**

Crohn's disease, ulcerative colitis, 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, loss of hearing.

If you are at all worried about any new symptoms or other aspects of your health while taking Violite, please tell your doctor.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Violite**

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

Do not store above 25°C

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

If you stop taking Violite: 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 Violite contains**

The **active substances** are ethinylestradiol and levonorgestrel.

- Each coated tablet contains 20 microgram ethinylestradiol and 100 microgram levonorgestrel.

The **other ingredients** are:

Tablet core: Lactose monohydrate, Polacrillin potassium, Microcrystalline cellulose, Magnesium stearate.

Tablet coating: Opadry II pink, consisting of: Macrogol 3350, Titanium dioxide (E171), Polyvinyl alcohol, Talc (E553b), Iron oxide red (E172), Iron oxide yellow (E172).

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

Pink, cylindrical, biconvex, film coated tablet of 6 mm approximately.

Violite is packed in PVC/PVDC/Aluminium blister packs of 21 tablets.

Each pack may contain either:

1 × 21 film-coated tablets or

3 × 21 film-coated tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Gedeon Richter Plc.

Gyömrői út 19-21,

H-1103 Budapest

Hungary

**Manufacturer**

Cyndeia Pharma, S.L.

Polígono Industrial Emiliano Revilla Sanz

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