

Are you experiencing any of these signs?	What are you possibly suffering from?
Symptoms most commonly occur in one eye: <ul style="list-style-type: none"> • immediate loss of vision or • painless blurring of vision which can progress to loss of vision. 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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. <p>Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	Stroke
<ul style="list-style-type: none"> • 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 Marvelon 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 Marvelon 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 Marvelon 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 Marvelon	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 Marvelon 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/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 Marvelon may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Marvelon 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 Marvelon needs to be stopped.

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

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

2.2.2 The Pill and cancer

The Pill reduces your risk of cancer of the ovary and womb if used in the long term. However, it also seems to slightly increase your risk of **cancer of the cervix** – although this may be due to having sex without a condom rather than the Pill itself. All women should have regular **smear tests**.

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 number of cases of breast cancer in current and recent users of the Pill 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.
- 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.
- 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.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

→See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice). You may need to stop taking Marvelon.

2.2.3 Psychiatric disorders

Some women using hormonal contraceptives including Marvelon 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.

2.3 Other medicines and Marvelon

Tell your doctor, pharmacist or family planning nurse if you are using, have recently used or might use any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use Marvelon. This is because Marvelon can also affect how well other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g., lamotrigine). Remind your doctor if you are taking these in case your treatment needs to be adjusted.

Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines may stop Marvelon from working properly. These include medicines used for the treatment of:

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

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

Do not use Marvelon if you have Hepatitis C and are taking medicinal products containing ombitasvir/ paritaprevir/ ritonavir and dasabuvir or glecaprevir/ pibentavir 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. Marvelon can be restarted approximately 2 weeks after completion of this treatment. See section 2.1 "Do not use Marvelon".

2.4 Marvelon with food and drink

There are no special instructions about food and drink while on Marvelon.

2.5 Pregnancy and breast-feeding

Do not use Marvelon if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Marvelon.

Marvelon is not recommended for use during breast-feeding. Ask your doctor or family planning nurse about alternative contraception. Breast-feeding may not stop you getting pregnant.

2.6 Driving and using machines

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

2.7 Marvelon contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using Marvelon.

2.8 Use in adolescents

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

3. How to take Marvelon

3.1 How to take it

To prevent pregnancy, always take this medicine exactly as described in this leaflet or as your doctor, family planning nurse or pharmacist has told you. Check with your doctor, family planning nurse or pharmacist if you are not sure.

Take Marvelon every day for 21 days

Marvelon comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills. You don't need to use extra contraception during these seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

Then start your next strip

Start taking your next strip of Marvelon after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

As long as you take Marvelon correctly, you will always start each new strip on the same day of the week.

3.2 Starting Marvelon

As a new user or starting the Pill again after a break

Either take your first Marvelon pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Or if your period has already begun start taking Marvelon on day 5 (counting the first day of your period as day 1) whether or not your bleeding has stopped. You must also use extra contraception, such as condoms, until you have taken the first seven pills correctly.

Changing to Marvelon from another contraceptive Pill

- **If you are currently on a 21-day Pill:** start taking Marvelon the next day after the end of the previous strip. You will have contraceptive protection with your first pill but you will not have a bleed until after you finish your first strip of Marvelon.
- **If you are currently on a 28-day Pill:** start taking Marvelon the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after you finish your first strip of Marvelon.
- **Or if you are taking a progestogen-only Pill** (mini-Pill or POP): start Marvelon on the first day of bleeding, even if you have already taken the POP for that day. You will have contraceptive cover straight away. If you don't usually have any bleeding while you are taking a progestogen-only Pill, you can stop taking it any day and start Marvelon the next day. You will need to use extra contraception, such as a condom, for seven days.

Changing to Marvelon from a progestogen-only injection, implant or progestogen releasing intrauterine device (IUD)

Start taking Marvelon when your next injection is due or on the day that your implant or IUD is removed. Make sure you also use an additional contraceptive method, such as a condom, for the first 7 days that you are taking Marvelon.

Starting Marvelon after a miscarriage or abortion

If you have had a miscarriage or an abortion, your doctor may tell you to start taking Marvelon straight away. This means that you will have contraceptive protection with your first pill.

Contraception after having a baby

If you have just had a baby, ask your doctor for advice about contraception.

If you are not breast-feeding:

- you can start taking Marvelon three weeks after the birth or,
- you can start taking Marvelon more than three weeks after the birth but you need to use extra contraception, such as a condom until you have taken the first seven pills correctly.
- If you have had sex since the birth there is a chance that you could be pregnant, you should therefore use another form of contraception, such as a condom. In this case, take your first Marvelon pill on the first day of your next period.

3.3 A missed pill

If you miss a pill, follow these instructions:

