

PACKAGE LEAFLET: INFORMATION FOR THE USER

RIGEVIDON®
150 micrograms/30 micrograms coated tablets
levonorgestrel and 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Rigevidon is and what it is used for
- What you need to know before you take Rigevidon
- How to take Rigevidon
- Possible side effects
- How to store Rigevidon
- Contents of the pack and other information

1. WHAT RIGEVIDON IS AND WHAT IT IS USED FOR

Rigevidon is a combined oral contraceptive, also called the pill. It contains two types of female hormones: an oestrogen, ethinylestradiol, and a progestogen, levonorgestrel in a low dose.

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

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

General information

If taken correctly, the pill is an effective reversible form of contraception. However, in certain circumstances the effectiveness of the pill may reduce or you should stop taking the pill (see later). In these cases either do not have sex, or use extra non-hormonal contraceptive precautions (such as condoms or another barrier method) during intercourse to ensure effective contraception.

Remember, combined oral contraceptive pills like Rigevidon will not protect you against sexually-transmitted diseases (such as AIDS). Only condoms can help to do this.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RIGEVIDON

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

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

When not to take Rigevidon

You should not use Rigevidon 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 Rigevidon

- if you are allergic to ethinylestradiol or levonorgestrel or any of the other ingredients of this medicine (listed in section 6.),
- if you have (or have ever had) a blood clot (thrombosis) 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 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 (or have ever had) a type of migraine called 'migraine with aura'.
- if you have any of the following disease that may increase the 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) or if you are suspected of having breast cancer or cancer of the genital organs.
- if you have (or have ever had) a liver disease and your liver function is still not normal.
- if you have (or have ever had) a tumour in the liver.
- if you have unexplained bleeding from your vagina.

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

St. John's wort should not be used concomitantly with Rigevidon because the contraceptive effect can be reduced.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rigevidon.

When should you contact your doctor?

Seek urgent medical attention

- 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.
 - 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 clots' section below).
- For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

If you get any of the following diseases/conditions, you can only take Rigevidon under strict medical supervision, since these conditions may get worse while you are taking the pill.

If the condition develops, or gets worse while you use Rigevidon, you should also tell your doctor.

- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).
- if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots').
- if you or your close family have ever had problems with your heart, or circulation such as high blood pressure.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- if you have varicose veins.
- if you or your close family have ever had problems with blood clotting.
- if you have migraine.
- if you have diabetes.
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases).
- if you have the inherited form of deafness known as otosclerosis.
- if you have depressed mood (depression or mood changes).
- if you have the movement disorder called Sydenham's chorea.
- if you have liver and/or gall bladder disease (yellowing of the skin, gallstones).
- if you have the inherited disease called porphyria.
- if you have sickle cell anaemia (an inherited disease of the red blood cells).
- if you have a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail).
- if you have systemic lupus erythematosus SLE -; a disease affecting your natural defence system.
- if you have the rash known as herpes gestationis (eruption of vesicles on the skin during pregnancy).
- if you have brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Rigevidon 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 '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 Rigevidon 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 Rigevidon 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 Rigevidon 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 Rigevidon 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	About 5-7 out of 10,000 women
Women using Rigevidon	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 Rigevidon 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 Rigevidon may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Rigevidon 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 Rigevidon needs to be stopped.

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

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

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