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

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

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 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 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/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 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

product name	labelling number	country code	design code	plant code	item code	version
Rigevidon	K-15255-2.7	UK	-	-	-	v_01

colour: P Black, P 214, P 191
printing technology:
font (size [leading]): Cronos Pro (9 pt) [10.08 pt]
Studio: -
date: 2023.06.05.
made by: -

packaging material	size	technical drawing	supervised technical drawing by	date
UTAS-3	345 x 635 (±0,5]/40 x 86 (±1) mm	PIL_RTU_86x40_345x635_temp /Page01	-	2019.04.11.

increased even more.

If any of the above conditions change while you are using Rigevidon, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

The pill and cancer
An increased risk of cervical cancer in long-term users of the pill has been reported in some studies. It is uncertain whether this increased risk is caused by the pill as it could be due to the effects of sexual behaviour and other factors.

Breast cancer has been found slightly more often in women who take the pill than in women of the same age who do not take the pill. If women stop taking the pill this reduces the risk so that 10 years after stopping the pill, the risk of finding breast cancer is the same as for women who have never taken the pill. It is not certain whether the pill causes the increased risk of breast cancer. It may be that women taking the pill are examined more often, so that breast cancer is noticed earlier.

In women using the pill malignant and benign liver tumours have been reported. Liver tumours may lead to life-threatening intra-abdominal haemorrhage (bleeding in the stomach). So, if you have pain in your upper stomach that does not soon clear up, tell your doctor.

Psychiatric disorders
Some women using hormonal contraceptives including Rigevidon 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.

Regular check-ups
Once you have started taking Rigevidon, your doctor will see you again for regular check-ups yearly, or if you have any problem you can see your doctor at any time.

Children and adolescents
Rigevidon is not indicated for use before the first menstrual bleeding (menarche).

Other medicines and Rigevidon
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Rigevidon. They can tell you if you need to use additional contraceptive precautions (for example, condoms) and if so, for how long.

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

Some medicines
- can have an influence on the blood levels of Rigevidon,
- can make it **less effective in preventing pregnancy,**
- can cause unexpected bleeding.

These include
- medicines used for the treatment of
  - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate, rufinamide, perampanel);
  - tuberculosis (e.g. rifampicin);
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapin, efavirenz);
  - fungal infections (e.g. griseofulvin);
  - increase of blood pressure in the lung vasculature (bosentan);
  - sleeping disorders (modafinil);
  - a certain type of skin cancer (vemurafenib);
  - the symptomatic treatment of arthrosis (etoricoxib);
  - uterine fibroids (ulipristal).

If you already take or if you want to take St John's wort preparation ask your doctor for advice as Rigevidon may not be suitable for you.

Rigevidon may **influence the effect** of other medicines, e.g.
- ciclosporin (medicine used for the treatment of suppression of tissue rejection following transplant surgery)
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

Effect on 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

<u>Pregnancy</u>
You must not use Rigevidon when you are pregnant. If you become pregnant or you think you might be pregnant, stop taking Rigevidon and talk to your doctor immediately.

<u>Breastfeeding</u>
Rigevidon should not be taken during breast-feeding. If you are breast-feeding and want to take the pill, you should discuss this with your doctor.

Driving and using machines
There are no data suggesting that Rigevidon, coated tablet affects driving or using machines.

Rigevidon contains lactose, sucrose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

The daily dosage is one coated tablet.
You should try to take your pill at about the same time each day. You may find it easiest to take it either last thing at night or first thing in the morning.

Swallow each pill whole, with water if necessary.
Each pack of Rigevidon contains 1 memo strip of 21 coated tablets or 3 memo strips of 21 coated tablets. The memo strip has been designed to help you remember to take your pills.

The pack is marked with the day of the week on which each pill should be taken. Following the direction of the arrow printed on the pack you should take one pill each day for 21 days until the strip is empty.

Then you have 7 days when you do not take a pill. During the 7 pill-free days, on day 2 or 3, you will have menstruation-like withdrawal bleeding, i.e. your monthly period.

Start your next strip on the 8th day (following the 7 pill-free days) – even if the bleeding has not yet ended. As long as you take Rigevidon correctly, you will always start each new strip on the same day of the week, and you will always have your monthly period on the same day of the month.

Starting the first pack

If no oral contraception has been used during the preceding cycle
Take the first pill on the first day of your period. This is the first day of your cycle - the day when bleeding starts. Take a pill marked for that day of the week (for example, if it is Tuesday when your period starts, take the pill marked Tuesday on the pack). Follow the direction of the arrow and continue taking one pill each day until the strip is empty.
If you start on day 2-5 of your period, you should use another method of contraception as well, such as the condom, for the first seven pill-taking days, but this is only for the first pack.
You do not need to use any other form of contraception during the seven-day break provided you have taken the 21 pills properly and you start the next pack on time.

Changing to Rigevidon from another combined hormonal contraceptive
Start taking Rigevidon on the day after you take the last pill from the strip of your previous contraceptive. Do not leave a gap between packs. If your previous pill strip also contains dummy pills, you should start with Rigevidon on the day after the last active hormonal intake, but no later than on the day after the usual hormone-free interval with your previous combined hormonal contraceptive (or after taking the last dummy pill of your previous pack). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.
If you are unclear or have further questions, ask your doctor or pharmacist.

Changing to Rigevidon from a progestogen-only pill (POP, or minipill)
You can stop taking pills only containing progestogen any time, and start taking Rigevidon the next day at the usual time. But be sure to use additional prevention (such as condoms) during intercourse in the first 7 days, during which you take the pills.

Changing to Rigevidon from a contraceptive injection or implant
If you have had an injection or implant of the hormone progestogen, you can start to take Rigevidon on the day that your next injection is due, or on the day that your implant is removed. However, you should use another method of contraception (such as condoms) during intercourse in the first 7 days, during which you take the pills.

Starting after childbirth or miscarriage or abortion
After a birth, abortion or miscarriage, your doctor should advise you about taking the pill.

You can start using Rigevidon immediately after a miscarriage or abortion which occurs during the first three months of pregnancy. In this case you do not need extra contraceptive precautions.

If you have had a delivery or abortion during the second three months of pregnancy, your doctor will advise you about taking the pill.

The duration of treatment is not limited but regular check-up is recommended.

If you take more Rigevidon than you should
If you take more Rigevidon than you should, it is not likely that it will do you any harm, but you may have nausea, vomiting abdominal pain, breast pain, numbness, drowsiness/fatigue and in young girls, small amount of vaginal bleeding. If you have any of these symptoms, you should talk to your doctor who can tell you what, if anything, you need to do.

If you forget to take Rigevidon
If you forget to take a pill please follow these instructions. Be aware, that contraceptive efficacy can be reduced in case you forget a dose especially if this increases the time between the last tablet in the current blister pack and the first tablet of the next pack.

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If one pill is 12 hours late or less
You are still protected against pregnancy if you take the late pill as soon as you remember, and keep taking your next pills at the usual time. This may mean taking two pills in one day.

If you are more than 12 hours late in taking a pill
If you are more than 12 hours late in taking a pill, your protection against pregnancy might be reduced so you must use extra contraceptive precautions. The more pills you have missed, the more risk there is that your contraceptive protection is reduced.

If you have missed more than one pill, ask your doctor for advice.

What to do if you miss the pill at the first week
You must take the last missed tablet as soon as you remember, even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You must also use a barrier method of contraception, e.g. a condom, for the next 7 days. If intercourse has taken place during the preceding 7 days the possibility of pregnancy must be considered. The more missed tablets and the closer to the tablet-free interval this happens, the greater the risk of pregnancy.

What to do if you miss the pill at the second week
You must take the last missed tablet as soon as you remember even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. Provided that the tablets have been taken in a correct manner during the 7 days preceding the missed tablet, it is not necessary to take further contraceptive measures. However, if this is not the case, or if more than 1 tablet has been missed, you should take extra contraceptive precautions for 7 days.

What to do if you miss the pill at the third week
The risk of reduced reliability is imminent because of the forthcoming tablet-free interval. The reduced contraceptive protection may, however, be prevented by adjusting the tablet intake. Therefore, by following one of the following two alternatives, it is not necessary to take further contraceptive precautions, provided that all tablets have been taken correctly during the 7 days preceding the first missed tablet. **If you have not taken Rigevidon correctly during the 7 days preceding the first missed tablet, you should follow the first of the two alternatives. Additionally a barrier method (such as a condom) should be used concomitantly for the next 7 days.**

1. You should take the last missed tablet as soon as you remember, even if it means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You should then start the next pack immediately after taking the last tablet in the current pack, i.e. without a tablet-free interval between the packs. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or breakthrough bleeding, on the days you are taking tablets.
2. You may also stop taking tablets from the current pack. In that case, you should keep a period without tablets of up to 7 days, including those days when you forgot to take your tablets, and thereafter continue with the next pack.

If you have missed tablets and then do not get a withdrawal bleeding in the first normal tablet-free interval, the possibility of pregnancy must be considered.

If you stop taking Rigevidon
You can stop taking Rigevidon at any time. If you stop taking Rigevidon to have a baby, use another method of contraception until you have had a true period. In this case it will be easier for your doctor to tell you when your baby will be born.

What to do if you have a stomach upset
If you have been sick or had diarrhoea within 3-4 hours after taking the pill, the active substances in the pill may not be fully absorbed into your body.
The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from another pack 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 Rigevidon".

What to do if you want to delay or to shift your period
If you want to delay or to shift your period, you should contact your doctor for advice.

If you want to delay your period, you should continue the next pack of Rigevidon, after taking the last tablet in the current pack, without a pill-free interval. You can take as many pills from this next pack as you want, until the end of the second blister pack. When you use the second pack, you may have breakthrough bleeding or spotting. Regular intake of Rigevidon is resumed after the usual 7 day tablet-free interval.

If you want to shift your period to another day of the week
If you take Rigevidon correctly, you will always have your monthly period on the same day of the month. If you want to shift your period to another day of the week, rather than the one you are used to with the present pill intake, you may shorten (but never lengthen) the forthcoming pill-free interval by as many days as you like. For example, if your monthly period usually starts on Friday and you want it to start on Tuesday (i.e. three days earlier), you should start the next pack of Rigevidon three days earlier. The shorter the pill-free interval, the greater the possibility that you will not have a withdrawal bleeding, and that you may have breakthrough bleeding or spotting during the second pack.

If you have bleeding between periods
A small number of women may have a little breakthrough bleeding or spotting while taking Rigevidon, especially during the first few months. Normally, this bleeding is nothing to worry about, and will stop in a day or two. Keep taking the pills as usual, and the problem should disappear after the first few packs.
If the bleeding keeps on returning, is annoying or long-lasting, talk to your doctor.

If you miss a period
If you have taken all your pills correctly, and you have not had a stomach upset, or used other medicines, then you are very unlikely to be pregnant. Continue to take Rigevidon as usual.

If you have missed your period twice in a row, then you might be pregnant and you should see your doctor immediately. You are only allowed to continue taking the pill after doing a pregnancy test and on your doctor's advice.

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

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 the veins (venous thromboembolism (VTE)) or blood clots in the arteries (arterial thromboembolism (ATE)) is present for all women using 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 Rigevidon".

The following side effects have been reported in women using the pill, which can occur in the first few months after starting Rigevidon, but they usually stop once your body has adjusted to the pill.

Common (may affect up to 1 in 10 people): Vaginitis, including vaginal candidiasis, mood swings including depression, changes in interest in sex, nervousness, dizziness, feeling sick, being sick, abdominal pain, acne, tender breast, breast pain, breast enlargement and discharge, painful menstruation, abnormality of cervix (change in cervical ectropion) and vaginal secretion, no or reduced bleeding, fluid retention/edema, changes in weight.

Uncommon (may affect up to 1 in 100 people): Changes in appetite, elevated blood pressure, abdominal cramps, bloating, rash, chloasma (yellow brown patches on the skin), which may persist, excessive hair growth, hair loss, changes in serum lipid levels including hypertriglyceridemia.

Rare (may affect up to 1 in 1,000 people): Severe allergic reaction (anaphylactic reaction with very rare cases of hives, swelling of face, tongue, severe circulatory and respiratory disorders), glucose intolerance, eye irritation when wearing contact lenses, yellowing of the skin (jaundice), the skin condition erythema nodosum (characterized by painful reddish skin nodules), 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).

Very rare side effects (may affect up to 1 in 10,000 people): Benign or malignant tumour of liver, aggravation of immune system disease (lupus), aggravation of porphyria, exacerbation of chorea (an involuntary movement disorder), inflammation of the optic nerve, blood clots in the blood vessels of the eye, aggravation of varicose veins, inflammation of the large intestine (ischaemic colitis), inflammation of the pancreas, gallbladder disease (including gallstones), erythema multiforme (characterized by rash with target-shaped reddening or sores), a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail), decrease in serum folate levels.

Not known (frequency cannot be estimated from the available data): Inflammatory bowel disease (Crohn's Disease, ulcerative colitis), hepatocellular injury (e.g. hepatitis, hepatic function abnormal).

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RIGEVIDON
Keep this medicine out of the sight and reach of children

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

Store below 25 °C.

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 Rigevidon contains
The active substances are levonorgestrel and ethinylestradiol.
One coated tablet contains 150 micrograms levonorgestrel and 30 micrograms ethinylestradiol. The other ingredients are: Colloidal anhydrous silica, magnesium stearate, talc, maize starch, lactose monohydrate (33 mg), sucrose, calcium carbonate, titanium dioxide (E171), copovidone, macrogol 6000, povidone carmellose sodium.

What Rigevidon looks like and contents of the pack
White, biconvex, circular coated tablets.

Each box contains 1, 3, 6 or 13 calendar pack(s) of 21 coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Gedeon Richter Plc., Gyömrői út 19-21, 1103 Budapest, Hungary

Manufacturer
Gedeon Richter Plc., Gyömrői út 19-21, 1103 Budapest, Hungary

This leaflet was last revised in September 2023.

RIGEVIDON®

RIGEVIDON®

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GEDEON RICHTER

K-15255-2.7

product name		labelling number	country code	design code	plant code	item code	version	
Rigevidon		K-15255-2.7	UK	-	-	-	v_01	
colour		printing technology	font (size [leading]):			Studio		
P Black			Cronos Pro (9 pt) [10.08 pt]			-		
P 214						date		
P 191						2023.06.05.		
						made by		
-						-		

packaging material	size	technical drawing	supervised technical drawing by	date
UTAS-3	345 x 635 (±0,5]/40 x 86 (±1) mm	PIL_RTU_86x40_345x635_temp /Page02	-	2019.04.11.