

RIGEVIDON COATED TABLETS

Ethinylestradiol/Levonorgestrel (0.03 mg/0.15 mg)

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What Rigevidon is used for

Oral contraception.

How Rigevidon works

Rigevidon works by inhibition of ovulation and changes in the cervical secretion to prevent pregnancy.

Before you use Rigevidon

- When you must not use it
- If you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis), your lungs (pulmonary embolism) or other organs.
- If 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 and you are off your feet for a long time
- If you have ever had a heart attack or stroke.
- If you have (or have ever had) angina (a condition that causes severe chest pain and may be a first sign of a heart attack) or 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 blood vessel:
 - 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.
- If you are allergic to ethinylestradiol or levonorgestrel or any of the other ingredients of this medicine.
- If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir. Rigevidon can be restarted 2 weeks after you stop this medication.

Pregnancy and lactation

Do not take Rigevidon if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Rigevidon, stop taking it immediately and contact your doctor.

Do not take Rigevidon if you are breast-feeding.

Before you start use it

Before the use of the tablet, your doctor will ask you some questions about your personal health history and that of your close relatives, will carry out comprehensive medical and gynecological examination, and will exclude pregnancy.

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

Warnings and precautions

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, a blood clot in the lung, a heart attack or a stroke (see section ‘Blood clots’).

Tell your doctor if any of the following conditions apply to you or gets worse while you are using Rigevidon:

- 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 inflammation of the pancreas.

- If you have ever had problems with the 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 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 chronic inflammatory bowel diseases
- If you have the inherited form of deafness known as otosclerosis
- If you have depressed mood (depression)
- If you have the movement disorder called Sydenham's chorea
- If you have gall bladder disease (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 blister 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.

If you are suffering from hereditary angioedema, estrogen-containing medicinal products may induce or exacerbate the swelling under the skin.

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. **It is important to remember that the overall risk of a harmful blood clot due to Rigevidon is small.**

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Symptoms of blood clots can include:

Deep vein thrombosis:

- unusual unilateral leg pain and/or swelling

Pulmonary embolism:

- sudden breathlessness or rapid breathing
- sudden onset of coughing
- sharp chest pain which may increase with deep breathing

Blood clot in the eye:

- sudden, partial or total loss of vision

Heart attack:

- chest discomfort, pressure, squeezing pain below the breastbone, sometimes radiating to the back, jaw, throat, arm and stomach
- rapid or irregular heartbeats
- anxiety, shortness of breath
- fullness, indigestion or choking feeling

Stroke:

- sudden weakness or numbness of the face, arm or leg, especially on one side of the body;
- sudden confusion, trouble speaking or understanding
- loss of consciousness

Blood clots blocking other blood vessels:

- swelling and slight blue discolouration of an extremity;
- severe pain in your stomach

The pill and cancer

An increased risk of cervical cancer in long-term users of the pill has been reported in some studies.

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, liver tumours have been reported. In isolated cases, liver tumours may lead to life-threatening bleeding in the stomach. So, if you have pain in your upper stomach that does not soon clear up, tell your doctor.

Regular check-ups

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

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.

Rigevidon contains lactose and sucrose

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

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Some medicines can have an influence on the blood levels of Rigevidon can make it **less effective in preventing pregnancy**, can cause unexpected bleeding, such as medicines used for the treatment of:

- epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidone, felbamate, oxacarbazepine, topimarat),
- tuberculosis (e.g. rifampicin),
- HIV and Hepatitis C Virus infections or other infections (e.g. ritonavir, nevirapine, efavirenz),
- inflammation and pain of the joints (etoricoxib) and St. John's wort (*Hypericum perforatum*) preparation.

Rigevidon may **influence the effect** of other medicines, e.g.

- ciclosporin (to prevent transplant rejection);
- lamotrigine (used for the treatment of epilepsy)

How to use Rigevidon

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. 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.

Swallow each pill whole, with water.

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.

Changing to Rigevidon from another combined hormonal contraceptive pill

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 (placebo), 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).

Changing from a combined contraceptive vaginal ring or patch

Start taking Rigevidon preferably on the day of removal, or at the latest when the next application would have been due.

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

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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, implant or from a progestogen-releasing intrauterine system (IUS)

If you have had an injection, implant or IUS 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 or IUS 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

Following first-trimester abortion you may start taking the tablets immediately.

Following delivery or second-trimester abortion tablet taking should be started on day 21-28 following delivery or abortion.

If you start later than this, be sure to use additional prevention (such as condoms) during intercourse in the first 7 days.

What to do if you have a stomach upset

If you vomited 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. 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 use it'.

What to do if you want to delay or to shift your period

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.

If you want to shift your period to another day of the week, other than the one in which period usually occurs in the currently used regimen week, you may shorten (but never lengthen) the

forthcoming pill-free interval by as many days as you like. 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 tablet use from 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

Contact your doctor.

- *When to use it*

Use as directed by your doctor or pharmacist. You should try to take your pill at about the same time each day.

- *How long to use it*

Continue taking Rigevidon for as long as your doctor recommends.

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 Rigevidon 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 forget to use it*

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,

your protection against pregnancy might be reduced so you must use extra contraceptive precautions.

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

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

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 contraceptive failure is imminent because of the ensuing 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

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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.

- 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 use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms that may occur in this case are: nausea, vomiting, abdominal pain, breast pain, dizziness, drowsiness/fatigue and in young girls, small amount of vaginal bleeding.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists that are treating you that you are taking Rigevidon.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not take any new medicines without consulting your doctor.
Do not give Rigevidon to anyone else.

- *Things to be careful of*

Driving and using machines

There are no data suggesting that Rigevidon affects driving or using machines.

Side effects

Like all medicines, Rigevidon can cause side effects, although not everybody gets them.

Common side effects

- vaginal inflammation, including vaginal thrush,
- nervousness, mood swings including depression, altered sexual desire,
- dizziness,
- headache,
- feeling sick, being sick, abdominal pain,
- acne,
- breast pain, breast tenderness, breast enlargement and discharge, painful menstruation, irregular bleeding, abnormality of cervix lining and vaginal secretion, no or reduced menstruation bleeding,
- fluid retention/swelling,
- changes in weight.

Other serious side effects

- severe allergic reaction (with very rare cases of hives, swelling of face, tongue, severe circulatory and respiratory disorders),

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects of Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Rigevidon

- *Storage Conditions*

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

Store below 30°C, protected from light

and moisture. Shelf-life: 2 years

Do not store any medicine in the

bathroom, or near a sink, or on a

window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Each pack of Rigevidon contains 1 strip of 21 coated tablets or 3 strips of 21 coated tablets.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Film-coated tablet.

White, biconvex, circular sugar-coated tablets of 6 mm diameter.

- *Ingredients*

- Active ingredient(s):

Ethinylestradiol

Levonorgestrel

- Inactive ingredients:

Calcium Carbonate

Carmellose Sodium

Colloidal Anhydrous

Copovidone K90

Lactose Monohydrate

Macrogol 6000

Magnesium Stearate

Maize Starch

Povidone K30

Sucrose

Silica

Talc

Titanium Dioxide (E171)

- *MAL number:*

MAL20001225AZ

Manufacturer

Gedeon Richter Plc.

H – 1103, Budapest

Gyömrői út 19-21

Hungary

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.

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Selangor, Malaysia

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