

RIGEVIDON®

150 micrograms/30 micrograms coated tablets
levonorgestrel and ethinylestradiol

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Rigevidon is and what it is used for
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1. WHAT RIGEVIDON IS AND WHAT IT IS USED FOR

Rigevidon is a combined oral contraceptive, also called 'the Pill'. You take it to stop you getting pregnant. 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 pregnancy in three ways. These hormones:

1. stop the ovary from releasing an egg each month (ovulation)
2. thicken the fluid in your cervix (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 may have to 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. BEFORE YOU TAKE RIGEVIDON

Take SPECIAL CARE with Rigevidon

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.

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.

Do NOT take Rigevidon if you

- are allergic (hypersensitive) to ethinylestradiol, levonorgestrel or any of the other ingredients of Rigevidon, which are listed in Section 6 of this leaflet
- have or have ever had a **blood clot (thrombosis)** in a blood vessel of the leg, lung (embolus) or other organs
- have had a **heart attack or stroke**
- have any medical condition which increases your **risk of suffering a heart attack** (for example, angina pectoris, which causes severe pain in the chest) or a stroke (for example, a momentary slight stroke with no lasting effects)
- have **heart disease or fluctuations in heart rhythm**
- if you have or have ever had **migraine with visual disturbances, abnormal touch sensation, or movement**
- have **very high blood pressure**
- have **diabetes affecting your blood vessels**
- have or have ever had **eye disorders** (e.g. a disease of the retina called retinopathy)
- have or have ever had **liver tumours or liver disease**
- have **breast cancer or another cancer**, for example ovarian cancer, cervical cancer, or cancer of the uterus (womb)
- have unexplained **bleeding from your vagina**
- are **pregnant** or think you might be.

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

Tell your doctor before starting to take Rigevidon if you

- have a **disorder of blood-fat (lipid) metabolism**, or other very rare blood disorders
- have **high blood pressure**
- have **varicose veins or inflammation of a vein** (usually in the legs) (thrombophlebitis)
- have **migraines**
- have **diabetes**
- have **Crohn's disease or ulcerative colitis** (chronic inflammatory bowel diseases)
- have the inherited form of **deafness known as otosclerosis**
- have **depression**
- have the **movement disorder called Sydenham's chorea**
- have **liver and/or gall bladder disease** (yellowing of the skin, gallstones)
- have the inherited disease called **porphyria**
- have **sickle cell anaemia**
- have a **blood disorder called haemolytic uraemic syndrome** - HUS (a disorder where blood clots cause the kidneys to fail)
- have **systemic lupus erythematosus** - SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs)
- have **itching (pruritus)**
- have the rash known as **herpes gestationis**
- 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.

The above conditions may get worse while you are taking the pill; therefore regular medical check-ups are necessary while you are on the pill.

Also tell your doctor before starting to take Rigevidon if you

- are **smoking**
- are **severely overweight (obese)**

The pill and thrombosis

Your chances of having a blood clot are only increased slightly by taking the Pill.

- Of 100,000 women who are **not on the Pill** and not pregnant, about **5** will have a blood clot in a year.
- Of 100,000 women **taking a Pill** such as Rigevidon, about **15** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year.

Venous thrombosis

The use of any combined pill, including Rigevidon, increases a woman's risk of developing a venous thrombosis (formation of a blood clot in vessels) compared with a woman who does not take any contraceptive pill.

The risk of developing a blood clot in users of a combined pill increases:

- as you **get older**
- if you are **overweight**
- if **one of your close relatives has had a blood clot** (thrombosis) in the leg, lung, or another organ at a young age
- if you must have an **operation (surgery)**, any prolonged period

of immobilization, or if you have had a serious accident. It is important to tell your doctor in advance that you are using Rigevidon as the treatment may have to be stopped. Your doctor will tell you when to start Rigevidon again. This is usually about two weeks after you are back on your feet.

Arterial thrombosis

The use of combined pills has been connected with an increase in the risk of arterial thrombosis (blocking of an artery), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of arterial thrombosis in users of combined pills increases:

- **if you smoke. You are strongly advised to stop smoking when you use Rigevidon, especially if you are older than 35 years**
- if you have an **increased amount of fat in your blood (cholesterol or triglycerides)**
- if you have **high blood pressure**
- if you have **migraines**
- if you have a **problem with your heart** (valve disorder or a disturbance of the heart rhythm).

The pill and cancer

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. The risk goes up the longer you are on the pill, but returns to normal within about 10 years of stopping it. 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.

Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users is small. For example:

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

Your risk of breast cancer is higher:

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

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

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 clear up soon, tell your doctor.

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.

Taking other medicines

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

Some medicines may stop Rigevidon from working properly. These medicines are for example:

- primidone, carbamazepine, oxcarbazepine, topiramate, phenytoin, hydantoin, barbiturates (**to treat epilepsy and other illnesses**)
- rifampicin (**to treat tuberculosis**)
- ritonavir (**to treat HIV infections**)
- griseofulvin (**to treat fungal infections**).

If you are taking these medicines for a short term (up to one week) you should use an additional method of contraception (such as a condom, diaphragm or foam) whilst you are taking the other medicinal product and for 28 days afterwards.

- **antibiotics** (such as ampicillin, tetracycline).

If you are taking any of these antibiotics for a short term (up to one week), you will also need to use an extra method of contraception (condoms, diaphragm or foam) while you are taking the other medicine and for 7 days after you stop taking it.

If these extra precautions overrun the end of the pack, start the next pack the next day without a break. This means taking a pill every day during your normal seven pill-free days. If you run two packs together you may not have a period until the end of two packs. If you don't have a period after the second pack, you must talk to your doctor before you start the next pack.

- herbal remedy commonly known as **St John's wort** (hypericum perforatum).

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 affect the following medicines:

- medicines used for suppression of tissue rejection following transplant surgery (e.g. **ciclosporin**)
- **lamotrigine** (to treat epilepsy).

Before you have any blood or urine tests, 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

Ask your doctor or pharmacist for advice before taking any medicine.

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.

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

You can drive or operate machinery while taking Rigevidon.

Important information about some of the ingredients of Rigevidon

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

If you have been told by your doctor that you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you should not take this medicinal product.

3. HOW TO TAKE RIGEVIDON

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 pack 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 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 7 pill-taking days, but this is only for the first pack.
- You do not need to use any other form of contraception during the 7 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 next day after the end of the previous contraceptive strip. 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 pill, but no later than on the day after the usual 7 day gap with your previous pill (or after taking the last dummy pill of your previous pack). When changing from a combined contraceptive vaginal ring or patch to the pill, 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, miscarriage or abortion

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

If you have had a miscarriage or an abortion during the first three months of pregnancy, you can start taking Rigevidon straight away. In this case you do not need extra contraceptive precautions.

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

If you take more Rigevidon than you should

It is unlikely that taking more Rigevidon than you should will do you any harm, but you may have nausea, vomiting or vaginal bleeding. If you have any of these symptoms, you should talk to your doctor.

If you forget to take Rigevidon

If you forget to take a pill please follow these instructions.

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 greater the risk 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 on the first week

Take the most recently missed pill as soon as you remember, even if this means that you have to take 2 tablets at the same time (or in one day). Thereafter, you should continue taking the next pill 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 previous 7 days the possibility of pregnancy must be considered. The more missed tablets and the closer to the tablet-free interval that this happens, the greater the risk of pregnancy.

What to do if you miss the pill on the second week

Take the most recently missed pill as soon as you remember, even if this means that you have to take 2 tablets at the same time (or in one day). Thereafter, you should continue taking the next pill at the usual time of the day. Provided that the tablets have been taken in a correct manner during the 7 days before 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 on the third week

The risk of pregnancy is high 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 before the first missed tablet. **If you have not taken Rigevidon correctly during the 7 days before the first missed tablet, you should follow the first of the two alternatives. Additionally a barrier method (such as a condom) should be used with the pill for the next 7 days.**

1. Take the most recently missed pill as soon as you remember, even if it means that you have to take 2 tablets at the same time (or in one day). Thereafter, you should continue taking the next pill at the usual time of the day. You should then start the next pack immediately, 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 the pill.
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 withdrawal bleeding in the first normal tablet-free interval, the possibility of pregnancy must be considered.

If you want to 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 proper 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, your body may not get its usual dose of hormones from that pill. In this case the advice concerning missed pills, described above should be followed. In case of vomiting or diarrhoea, use extra contraceptive precautions, such as a condom, for any intercourse during the stomach upset and for the next seven days.

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 pill 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 product ask your doctor.

4. POSSIBLE SIDE EFFECTS

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

These 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.

The following serious adverse events have been reported in women using combined oral contraceptives, see Section 2 under "The pill and thrombosis" and "The pill and cancer".

- Venous thromboembolism (a blood clot in vessels)
- Arterial thromboembolic disorders (the blocking of an artery)
- Cervical cancer (cancer in the neck of the womb)

STOP taking Rigevidon immediately and tell your doctor if any of the following symptoms of a blood-clot formation occurs:

- any **unusual, severe or long-lasting headache or migraine**
- any **sudden changes to your eyesight** (such as loss of vision, blurred vision or double vision)
- **slurred speech** or any other **difficulties affecting your speech**
- **dizziness, fainting or fits**
- sudden **shortness of breath or difficulty in breathing, sudden coughing** for no apparent reason, **bloody spittle**
- sudden **sharp pains in your chest** which may reach your left arm
- **unusual pain or swelling in your legs**
- sudden **weakness or numbness in one side or part of your body**
- **difficulties in moving around** (known as motor disturbances)
- **severe pain in your abdomen** (known as acute abdomen)

Tell your doctor if

- you can **feel a lump in your breast**.

The most commonly reported undesirable effects (affects more than 1 in 10 women) are irregular bleeding, nausea, weight gain, tender breasts and headache.

Common (affects up to 1 in 10 women): Depression, excitability, acne, no or reduced bleeding, weight gain, fluid retention, changes in the sexual desire (increased or decreased), nervousness, eye irritation when wearing contact lenses, sight disturbances and migraine.

Uncommon (affects up to 1 in 100 women) and rare (affects up to 1 in 1000 women): Vomiting, brown patches on your face and body (chloasma), high blood pressure, breast cancer, cervical cancer, blood clot, enhanced levels of blood fat, impaired hearing (otosclerosis), gallstones, inflammation of the pancreas, skin disorders, liver tumours, changes in vaginal secretions or vaginal thrush, chorea (a movement disease), systemic lupus erythematosus (SLE, a disease of the connective tissue).

Before you have any blood tests

Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

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.

5. HOW TO STORE RIGEVIDON

Do not use Rigevidon after the expiry date which is stated on the package. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

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

6. FURTHER INFORMATION

What Rigevidon contains

The active substances are ethinylestradiol and levonorgestrel. One coated tablet contains 30 micrograms ethinylestradiol and 150 micrograms levonorgestrel. 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 and 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

Medimpex France SA, 1-3 rue Caumartin, 75009 Paris, France

Distributed by

Consilient Health (UK) Ltd., 500 Chiswick High Road, London, W4 5RG

Manufacturer

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Rigevidon coated tablet: Austria, Denmark, Greece, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden and United Kingdom

Nora 30 coated tablet: Belgium

Femigyne-ratiopharm erzogene Tablette: Germany

Ethinylestradiol/levonorgestrel 0.03/0.15 A, omhulde tabletten 0,03 mg / 0,15 mg: The Netherlands

This leaflet was last revised in April 2010.



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