

Brevinor (Brev-in-nor) is a medicine which is used in contraception. Brevinor contains ethinylestradiol/norethisterone. It is made by Pharmacia Ltd.

Your medicine

Medicines are used to treat, control or prevent a condition. Do not share your medicine with other people as it may not be suitable for them and could cause them harm. In the same way, you should not use medicines that belong to other people.

The pharmacy label on your medicine tells you how much medicine you should take. It also tells you how often to take your medicine. This is the dose that you and your prescriber have agreed you should take. Depending on your response to the medicine, how the medicine works and the goals of your treatment, your prescriber may vary your dose. You should not change the dose of your medicine unless you are told to do so by your prescriber.

Brevinor contains two hormones that are similar to the hormones oestrogen and progesterone that are produced by the body. Brevinor is used to prevent women from becoming pregnant. It works by preventing the release of eggs from the ovary and changes the lining of the uterus which makes it difficult for an egg to develop. It also increases the thickness of vaginal fluid which can stop a sperm from reaching an egg.

Brevinor may increase the chances of developing blood clots, breast cancer or cervical cancer. However, it may provide some protection against ovarian and endometrial cancer. You and your prescriber will need to weigh up the benefits and risks of taking Brevinor before you start to take it.

Hormonal contraceptives will only prevent a pregnancy if they are taken regularly. It is important you take this medicine at the same time each day. If you want immediate contraceptive cover then start to take Brevinor on the first day of your menstrual period. If you do not start taking Brevinor on the first day of your menstrual period you will need to take extra contraceptive precautions for at least seven days until Brevinor starts to work. For more information about starting Brevinor and if you need to take extra contraceptive precautions ask your prescriber, family planning nurse or read the patient information leaflet that comes with your medicine.

Once you have started to take Brevinor, you should take it once a day for 21 days. After this you should not take any more tablets for the next seven days. Start a new strip of Brevinor immediately after the seven day tablet-free break. During this break you will usually have a withdrawal bleed. If you do not have a withdrawal bleed during the tablet-free break

and you have taken all your pills properly, you are very unlikely to be pregnant. However, if you miss a withdrawal bleed and you have not taken your tablets properly or if you miss two withdrawal bleeds in a row you should immediately contact your prescriber or family planning nurse. This is because there is a possibility that you could be pregnant and Brevinor may harm a baby if taken during pregnancy.

In certain situations the effectiveness of Brevinor may be reduced and you will need to take extra contraceptive precautions. These situations include: missing a dose by more than 12 hours; taking other medicines that interact with Brevinor; having diarrhoea or an upset stomach or any medical condition which interferes with the absorption of your medicine. If any of these situations occur during the last seven days of your strip you should not have a tablet-free break between strips of tablets. Start taking the next strip of tablets without a break.

As there is no gap between strips you will not have a withdrawal bleed at the end of the first strip. But you may have some menstrual bleeding while you are taking the second strip and you should have a withdrawal bleed once you finish the second strip. For more information about situations when the effectiveness of Brevinor may be reduced and when to take additional contraceptive precautions ask your prescriber, family planning nurse or read the patient information leaflet that comes with your medicine.

Other information about Brevinor:

- if you have a history of irregular menstrual cycles or amenorrhoea you may not have any periods when you stop taking Brevinor. For more information speak to your prescriber or family planning nurse

If you feel that the medicine is making you unwell or you do not think it is working, then talk to your prescriber or someone involved in your medical care.

When to take your medicine

Some medicines work best if they are taken at a specific time of day. Getting the most from your medicine can also be affected by what you eat, when you eat and the times at which you take other medicines. Make sure you follow any specific instructions given to you by your prescriber or that are in the Patient Information Leaflet that comes with this medicine.

In the case of Brevinor:

- this medicine should be taken at the same time each day

How to take your medicine

Some medicines have specific instructions about how to take them. This is because they work better when taken correctly. These instructions can include getting the right dose and special instructions for preparing the medicine.

In the case of Brevinor:

- detailed advice on how to take Brevinor can be found in the Patient Information Leaflet that comes with this medicine

If you are having problems taking this medicine, you should talk to your prescriber or pharmacist. They may be able to give you advice on other ways to take your medicine or other medicines that are easier for you to take.

Taking too much of your medicine

Taking extra doses of some medicines can be harmful. In some cases even one extra dose can cause you problems. If you take extra doses of your medicine, you must get medical advice immediately. You may need a test to assess the effect of taking extra doses. This is because the effects of taking too much medicine are very complex and it is therefore essential that you seek medical advice.

Contact your prescriber, pharmacist, specialist clinic or NHS Direct on 0845 46 47 for advice.

Make sure you take all of your medicine containers with you if you are advised to go to hospital.

Stopping your medicine

If you are not having any problems with this medicine, do not stop taking it unless you no longer need this form of contraception or you are advised to stop taking it by your prescriber.

If you are in any doubt, contact your prescriber, pharmacist, specialist clinic or NHS Direct on 0845 46 47.

Looking after your medicine

The instructions on how you should keep your medicine are on the pharmacy label. It is a good idea to keep your medicine in the original container. This will help to keep your medicine in the best condition and also allow you to check the instructions. Do not take the medicine if the packaging appears to have been tampered with or if the medicine shows any signs of damage. Make sure that the medicine is out of the sight and reach of children.

In the case of Brevinor:

- store in a dry place
- do not store in temperatures above 25°C
- protect your medicine from direct sunlight

You must not take the medicine after the expiry date shown on the packaging. If you have any unused medicine, return it to your pharmacist who will dispose of it safely.

Whether this medicine is suitable for you

Brevinor is not suitable for everyone and some people should never use it. Other people should only use it with special care. It is important that the person prescribing this medicine knows your full medical history.

Your prescriber may only prescribe this medicine with special care or may not prescribe it at all if you:

- are allergic or sensitive to or have had a reaction to any of the ingredients in the medicine
- have had a heart attack
- have or have had thrombophlebitis
- have or have had cerebrovascular problems
- have or have had angina
- have or have had metabolic problems
- have had certain problems during pregnancy such as jaundice, rashes or itching
- have vaginal bleeding and the cause of the bleeding is not known
- have or have had migraine or severe headaches
- are pregnant
- have or have had uterine problems such as fibroids
- have or have had depression
- have sickle cell anaemia
- have or have had diabetes
- have or have had high blood pressure
- have or have had epilepsy
- have or have had asthma
- have or have had otosclerosis
- have multiple sclerosis
- have or have had porphyria
- have or have had tetany
- have or have had gallstones
- have or have had kidney problems
- have or have had chloasma
- have a condition that became worse during pregnancy
- wear contact lenses
- have recently had or are about to have surgery
- are immobile for a long period of time
- have or have had heart and circulation problems

- are obese
- have risk factors for developing thromboembolic problems such as having a personal or family history of thromboembolic problems
- are currently having investigations for breast cancer, cancer of the genitals or any cancer that is sensitive to oestrogen
- have or have had breast cancer, cancer of the genitals or any cancer that is sensitive to oestrogen
- have or have had breast problems
- have or have had varicose veins or are currently having injections to treat varicose veins
- have or have had liver problems such as liver tumours or jaundice
- have risk factors for heart disease such as if you have high levels of cholesterol in the blood, have had toxæmia of pregnancy, are over 35 years of age or if you smoke

As part of the process of assessing suitability to take this medicine a prescriber may also arrange tests:

- to determine whether or not the medicine is suitable and whether it must be prescribed with extra caution
- to check that this medicine is not having any undesired effects

Over time it is possible that Brevinor can become unsuitable for some people, or they may become unsuitable for it. If at any time it appears that Brevinor has become unsuitable, it is important that the prescriber is contacted immediately.

Side-effects

A medicine is only made available to the public if the clinical trials have shown that the benefits of taking the medicine outweigh the risks.

Once a medicine has been licensed, information on the medicine's effects, both intended and unintended, is continuously recorded and updated.

Some side-effects may be serious while others may only be a mild inconvenience. Very occasionally, certain side-effects can be beneficial.

Everyone's reaction to a medicine is different. It is difficult to predict which side-effects you will have from taking a particular medicine, or whether you will have any side-effects at all. The important thing is to tell your prescriber or pharmacist if you are having problems with your medicine.

The frequency of these side-effects is unknown

- may affect the results for certain tests

- nausea
- weight gain
- changes in libido
- changes to appetite
- metabolic problems
- raised blood pressure
- eye or eyesight problems - seek medical advice if you suddenly develop an eye or eyesight problem
- thromboembolic problems
- reduced glucose tolerance - people with diabetes may be advised to adjust their anti-diabetic therapy
- menstrual problems including bleeding or spotting in between menstrual periods, lighter menstrual periods or not having a menstrual period. Seek immediate medical advice if you have do not have two withdrawal bleeds in a row
- gallbladder problems
- gastrointestinal problems
- diarrhoea or vomiting - if you have diarrhoea or vomiting after taking Brevinor you may need to take extra contraceptive precautions. For more information speak to your prescriber, family planning nurse or read the patient information leaflet that comes with this medicine
- fluid retention
- cancers such as breast or cervical cancers
- liver tumours - seek medical advice if you have pain in the upper part of your stomach
- migraine – seek medical advice if you get a migraine-type headache for the first time or if your migraine headaches worsen
- headaches – seek immediate medical advice if you have a persistent or an unusually bad headache
- breast pain
- some conditions may occur for the first time or get worse during treatment with Brevinor. If any of these happen to you, seek medical advice. Examples include: breast problems, fibroids in the uterus, depression, varicose veins, sickle-cell anaemia, diabetes, raised blood pressure, heart and circulation problems, epilepsy, asthma, otosclerosis, multiple sclerosis, porphyria, tetany, gallstones, kidney problems or chloasma
- abnormal laboratory test results

If you feel unwell or if you have concerns about a side-effect, you will need to seek advice. If you feel very ill, get medical help straight away. Contact your prescriber, pharmacist, nurse or call NHS Direct on 0845 46 47.

Taking other medicines

If you are taking more than one medicine they may interact with each other. At times your prescriber may decide to use medicines that interact, in other cases this may not be appropriate.

The decision to use medicines that interact depends on your specific circumstances. Your prescriber may decide to use medicines that interact, if it is believed that the benefits of taking the medicines together outweigh the risks. In such cases, it may be necessary to alter your dose or monitor you more closely.

Tell your prescriber the names of all the medicines that you are taking so that they can consider all possible interactions. This includes all the medicines which have been prescribed by your GP, hospital doctor, dentist, nurse, health visitor, midwife or pharmacist. You must also tell your prescriber about medicines which you have bought over the counter without prescriptions.

The following types of medicine may interact with Brevinor:

- sedatives
- antibiotics
- antiepileptics
- antiarthritics

If you are taking Brevinor and one of the above types of medicines, make sure your prescriber knows about it.

Complementary preparations and vitamins

Medicines can interact with complementary preparations and vitamins.

Make sure you tell your prescriber the names of all the complementary preparations and vitamins that you are taking or are planning to take.

Your prescriber can then decide whether it is appropriate for you to take combinations that are known to interact.

In the case of Brevinor:

- this medicine may interact with St. John's Wort

If you have been prescribed Brevinor you should only take something on the above list on the specific advice of your prescriber or pharmacist.

Driving and operating machinery

When taking any medicine you should be aware that it might interfere with your ability to drive or operate machinery safely.

Like all medicines Brevinor can cause side effects. You should see how this medicine affects you and then judge if you are safe to drive or operate machinery. If you are in any doubt, talk to your prescriber.

Diet

Medicines can interact with certain foods. In some cases, this may be harmful and your prescriber may advise you to avoid certain foods.

In the case of Brevinor:

- there are no specific foods that you must exclude from your diet when taking Brevinor

Alcohol

Alcohol can interact with certain medicines.

In the case of Brevinor:

- there are no known interactions between alcohol and Brevinor

Family planning and pregnancy

Most medicines, in some way, can affect the development of a baby in the womb. The effect on the baby differs between medicines and also depends on the stage of pregnancy that you have reached when you take the medicine.

In the case of Brevinor:

- do not take this medicine during pregnancy
- this medicine may harm your baby if taken during pregnancy
- if you become pregnant, or think you have become pregnant while taking Brevinor, you must contact your prescriber
- if you are taking Brevinor and are planning to have a baby you must contact your prescriber or family planning nurse. It is recommended that you stop taking Brevinor at least three months before trying to become pregnant

This medicine is not suitable during pregnancy. Your prescriber will only start your treatment with this medicine once they are certain that you are not pregnant. If you are planning to become pregnant you should discuss with your prescriber or family planning nurse when it is best to stop Brevinor.

Breast-feeding

Certain medicines can pass into breast milk and may reach your baby through breast-feeding.

In the case of Brevinor:

- women who are breast-feeding must not take this medicine

Brevinor

Brevinor 500microgram/35microgram tablets

When used in contraception

Before you have your baby you should discuss breast-feeding with your doctor or midwife. If you wish to breast-feed you should discuss with your prescriber whether there are any other medicines you could take which would also allow you to breast-feed.

Ingredients of your medicine

Medicines contain active ingredients. They may also contain other, additional ingredients that help ensure the stability, safety and effectiveness of the medicine. They are also added to improve the medicine's taste and appearance and to make it easier to take. Some may be used to prolong the life of the medicine.

You should check that you are able to take the ingredients in your medicine, especially if you have any allergies.

Brevinor contains:

- maize starch
- polyvidone
- magnesium stearate
- lactose
- colour (E132)
- ethinylestradiol
- norethisterone

If you are not able to take any of the ingredients in your medicine, talk to your prescriber or pharmacist to see if they can suggest an alternative medicine. If you have reacted badly to Brevinor before, do not take Brevinor. Talk to your prescriber, pharmacist or nurse as soon as possible.