

Package leaflet: Information for the user

Norgeston®

levonorgestrel

▲ Four important things to know about the Pill.

- The Pill will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots and breast cancer.
- Some women should not take the Pill because of current medical problems or illnesses. Please read this leaflet to make sure Norgeston is right for you.
- To prevent pregnancy it is important to take Norgeston as instructed and start each pack on time. Please make sure that you understand what to do if you miss a pill or if you think you are pregnant.

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, family planning nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.

If you get any side effects, talk to your doctor, family planning nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1 What Norgeston does

Norgeston is an oral contraceptive pill (the 'mini Pill'). **You take it to stop you getting pregnant.**

Norgeston contains a type of female sex hormone, called a progestogen. This hormone stops you getting pregnant by working in three ways: by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; by preventing the lining of your womb thickening enough for an egg to grow in it; and in some women it also stops the ovary releasing an egg each month (ovulation).

Norgeston is taken every day without a break. You take a pill every day for 35 days.

Norgeston needs to be taken as directed to prevent pregnancy.

The likelihood of getting pregnant is slightly higher if you take a progestogen-only pill (POP) such as Norgeston than with some other medicines for hormonal contraception such as combined hormonal contraceptives containing an oestrogen and a progestogen. Your doctor can provide further information on this. The effect of Norgeston is similar to that of other POPs. The failure rate may increase if pills are missed or taken incorrectly (see section 3).

The benefits of taking the Pill include:

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn't interrupt sex

Norgeston will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Children and adolescents

Norgeston is not indicated for use before the first menstrual bleeding (menarche).

Use in older women

Norgeston is not intended for use after the menopause.

Women with liver impairment

Do not take Norgeston if you suffer from severe liver disease. See also sections 2.2 and 2.3.

2 What you need to know before you take Norgeston

It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking the Pill

- Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.

While you're on the Pill

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

2.1 The Pill and blood clots

The Pill may slightly increase your risk of having a blood clot (called a *thrombosis*), especially in the first year of taking it.

A clot in a leg vein – a *deep vein thrombosis* (or DVT) – is not always serious. However, if it moves up the veins and blocks an artery in the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a *pulmonary embolism* and is very rare.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

You are more at risk of having a blood clot:

- as you get **older**
- if you **smoke**
- if you are seriously **overweight**
- if you have some **diseases of the heart and blood vessels**
- if you have **diabetes**
- if you suffer from **migraines**
- if you're **off your feet for a long** time because of major surgery, injury or illness
- if you or any of your close family have had **blood clots**
- if you have **varicose veins**

→ **Tell your doctor** if any of these apply to you. Taking the Pill may add to this risk so Norgeston may not be suitable for you.

Signs of a blood clot include:

- a **migraine** for the first time, a migraine that is worse than normal or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting**

→ **See a doctor as soon as possible. Do not take any more Norgeston** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

2.2 The Pill and cancer

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on the Pill, but returns to normal within about 10 years of stopping it. 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:

- In 10,000 women who **take progestogen-only pills like Norgeston for up to 5 years but stop taking it by the time they are aged 20**, it is estimated that less than **1 additional case** of breast cancer would be found up to 10 years afterwards, compared with the number found in 10,000 women who had never taken the Pill.
- For 10,000 women who **take the Pill like Norgeston for 5 years and stop it by the age of 30**, there would be **2 or 3 extra cases** of breast cancer found up to 10 years afterwards (in addition to the 44 cases of breast cancer found in 10,000 women in this age group who had never taken the Pill).
- For 10,000 women who **take Norgeston for 5 years and stop it by the age of 40**, there would be about **10 extra cases** found up to 10 years afterwards (in addition to 160 cases of breast cancer found in 10,000 women in this age group who had never taken the Pill).

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.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice)**. You may need to stop taking Norgeston.

2.3 Norgeston should not be taken by some women

→ **Tell your doctor or family planning nurse** if you have any medical problems or illnesses.

Do not take Norgeston if any of the following apply to you. Taking Norgeston would put your health at risk.

- If you are **pregnant** or might be pregnant
- If you have ever had a **severe liver disease** and have been told by your doctor that your liver function test results are not yet back to normal
- If you have ever had **liver tumours**
- If you have cancer affected by sex hormones –such as current or history of **breast cancer**
- If you have **vaginal bleeding** that has not been explained by your doctor
- If you have ever had a problem with your blood circulation. This includes a **blood clot (thrombosis)** in the legs (*deep vein thrombosis*), lungs (*pulmonary embolism*), heart (**heart attack**), brain (**stroke**) or any other parts of the body
- If you have **severe diabetes with changes to the blood vessels**
- If you are **allergic (hypersensitive)** to any of the ingredients in Norgeston.

→ **If you suffer from any of these**, or get them for the first time while taking Norgeston, contact your doctor as soon as possible. Do not take Norgeston and use another method of contraception.

2.4 Norgeston can make some illnesses worse

Some of the conditions listed below can be made worse by taking Norgeston, or they may mean it is less suitable for you. Remind your doctor:

- If you have **diabetes**
- If you have ever had a **pregnancy develop outside the womb** (an *ectopic pregnancy*) or one of your Fallopian tubes is missing
- If you have **ovarian cysts**
- If you have ever suffered from **yellowing of the skin (jaundice)**
- If you have ever suffered from **persistent itching (pruritus)**
- If you have **brown patches on your face or body (chloasma)**. If so avoid too much exposure to the sun or ultraviolet radiation.

→ **Tell your doctor or family planning nurse if any of these apply to you.** Also tell them if you get any of these for the first time while taking Norgeston, or if any of these or any problems which you had previously during pregnancy or whilst taking an oral contraceptive get worse or come back, because you may need to stop taking Norgeston.

2.5 Psychiatric disorders

Some women using hormonal contraceptives including Norgeston 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.

2.6 Taking other medicines

If you ever need to take another medicine, including medicines obtained without a prescription, at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Norgeston. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Norgeston from working properly and cause unexpected bleeding – for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV and Hepatitis C virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- **some medicines used to treat serious vomiting** (e.g. aprepitant)
- **medicines used to treat high blood pressure in the blood vessels in the lungs** (e.g. bosentan)
- **some medicines used to treat certain heart diseases, high blood pressure** (e.g. verapamil, diltiazem)
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics**
- **certain sedatives** (called *barbiturates*)
- **St. John's Wort** (a herbal remedy)
- **grapefruit juice.**

If you do need to take one of these medicines, Norgeston may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Norgeston can also affect how well other medicines work. For example, taking Norgeston can mean that the levels of some drugs in your blood may either go up (e.g. ciclosporin) or go down (e.g. lamotrigine).

Norgeston may also increase or reduce the effects of some anticoagulant drugs (e.g. coumarins) or inhibit the anticoagulant effect (e.g. phenindione).

Laboratory tests

Norgeston can interfere with the results of some blood tests, so always tell your doctor that you are taking Norgeston if you have a blood test.

2.7 Taking Norgeston with food and drink

There are no special instructions about food while on Norgeston.

2.8 Pregnancy and breast-feeding

Do not use Norgeston if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Norgeston.

Progestogen-only pills like Norgeston have not been shown to have any detrimental effect on breast milk or the growth or development of a healthy baby.

2.9 Driving and using machines

Norgeston has no known effect on the ability to drive or use machines.

2.10 Norgeston contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Norgeston.

3 Taking Norgeston

3.1 How to take it

To prevent pregnancy, always take Norgeston as described below. Check with your doctor or family planning nurse if you are not sure.

Take Norgeston every day for 35 days

Norgeston comes in strips of 35 pills, each marked with a day of the week.

- Take your pill at the same time every day. **Make sure that you are never more than three hours late with a pill otherwise the contraceptive protection may be lost.**
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 35 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then start your next strip

Start your next strip of Norgeston the very next day after finishing the previous pack, again taking a pill marked with the day of the week. Always start the new strip on time.

You will be taking pills through your periods and there must be no break between packs

As long as you take Norgeston correctly, you will always start each new strip on the same day of the week.

3.2 Starting Norgeston

As a new user or starting the Pill again after a break

It is best to take your first Norgeston pill on the first day of your next period. Another method of contraception will not be required.

Changing to Norgeston from another contraceptive Pill

- **If you are currently on a combined oral contraceptive, vaginal ring or patch:** If you have correctly and consistently used the previous combined Pill, start taking Norgeston the day after your last active pill (discarding the placebo pills or disregarding the pill-free interval). If a vaginal ring or transdermal patch has been used correctly and consistently before the switch, start using Norgeston on the day of removal of the last vaginal ring or transdermal patch of a cycle pack and thereby omit the hormone-free interval of this product. Another method of contraception will not be required.
- **Changing from another progestogen-only pill (POP or 'mini Pill'):** you can start taking Norgeston at any time without the loss of contraceptive protection.
- **Changing from a progestogen-only parenteral method (implant, injection):** additional non-hormonal contraceptive protection (e.g. a condom) are not required if you start exactly when the next implant or injection is due.

Starting Norgeston after a miscarriage or abortion

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor may tell you to start taking Norgeston straight away, in which case another method of contraception will not be required.

Contraception after having a baby

If you have just had a baby your doctor will advise you to start taking Norgeston immediately after delivery. If you start taking Norgeston later than this you should use another method of contraception, such as a condom for the first 7 days of pill taking. If you have already had intercourse, then you should exclude the possibility of pregnancy before starting Norgeston or wait until you have your first period.

If you have just had a baby and you are breast feeding please refer to section 2.8 *Pregnancy and Breast-feeding*.

3.3 A missed pill

If you are less than 3 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

If you are more than 3 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- Continue to take your next pills at your usual time.
- **Use extra contraception for the next 7 days**, such as condoms.

If you have missed any of the pills in a strip and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.

3.4 A lost pill

If you lose a pill,

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. When you start your next pack you will have a new starting day, one day earlier than before.

Or if you have another pack and do not want to change the starting day of your next strip, take a pill from that pack. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

3.5 If you are sick or have diarrhoea

If you are sick (*vomit*) within 2 hours of taking a tablet your body may not get its usual dose of hormones from that pill and you should take another pill as soon as possible. Follow the instructions in section 3.4 *A lost pill*. If you are not able to take another pill within 3 hours **use extra contraception for the next 7 days**, such as condoms

If you are persistently sick or have very bad diarrhoea, **use extra contraception during the illness and for the 7 days after recovery**, such as condoms

3.6 Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

3.7 When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping Norgeston until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4 Possible side effects

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

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Norgeston.

4.1 Serious side effects – see a doctor straight away

Signs of a blood clot:

- a **migraine** for the first time, a migraine that is worse than normal, or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting**.

Signs of a severe allergic reaction to Norgeston:

- **swelling** of the **face, lips, mouth, tongue or throat**.

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of severe liver problems include:

- severe **pain in your upper abdomen**
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching**.

→ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Norgeston.

4.2 Less serious side effects

- **bleeding and spotting between your periods**
- **no periods**
- **allergic reactions**, including wheezing, rash or reddened skin.
- **depressive moods, loss of interest in sex**
- **headaches** or **migraine**
- **dizziness**
- **feeling sick** or **being sick**

- **putting on weight or losing weight.**

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Norgeston. Also tell them if any existing conditions get worse while you are taking Norgeston.

4.3 If your periods seem different

A few women have irregular periods, a little unexpected bleeding or spotting or no periods at all while they are taking Norgeston, especially during the first few months. Normally, these changes are nothing to worry about and require no treatment. Keep taking Norgeston as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

- **Make an appointment to see your doctor** if
- you get breakthrough bleeding or spotting that:
 - carries on for more than the first few months
 - starts after you've been taking Norgeston for a while
 - carries on even after you've stopped taking Norgeston.
 - you have had no period for 6 weeks.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Norgeston

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 packaging after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6 What is in Norgeston and who makes it

What is in Norgeston

Each box of Norgeston contains one memo strip of 35 white, round, coated tablets.

Each tablet contains: 30 micrograms of the progestogen levonorgestrel.

Norgeston also contains the inactive ingredients:

lactose, maize starch, povidone, macrogol 6000, calcium carbonate (E170), talc, magnesium stearate (E 572), sucrose, glycol montanate.

The company that holds the product licence for Norgeston is:

Bayer plc, 400 South Oak Way, Reading, RG2 6AD

Norgeston is made by:

Bayer AG, Mullerstrasse 178, 13353 Berlin, Germany or Bayer Weimar GmbH & Co KG, Weimar, Germany.

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