



Gynera® (ethinylestradiol/gestodene)

PACKAGE LEAFLET: INFORMATION FOR THE USER Gynera® 0.03 mg/0.075 mg coated tablets ethinylestradiol/gestodene

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly.
They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2.3 'Blood clots').
The Pill may reduce your risk of cancer of the ovary and womb if used in the long term.
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 Gynera is right for you.
To prevent pregnancy it is important to take Gynera 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 questions or need more advice, 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 any of the side effects gets severe, or if you notice any not listed in this leaflet, please tell your doctor, family planning nurse or pharmacist.

What is in this leaflet:

- What Gynera is and what it is used for
What you need to know before you use Gynera
How to take Gynera
Possible side effects
How to store Gynera
Contents of the pack and other information

1. WHAT GYNERA IS AND WHAT IT IS USED FOR

Gynera is a combined oral contraceptive pill (the 'Pill'). You take it to stop you getting pregnant.

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones stop you getting pregnant by working in three ways: by preventing an egg being released from your ovaries; by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

Gynera is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

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

Gynera needs to be taken as directed to prevent pregnancy.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE GYNERA

General notes

Before you start using Gynera 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 2.3 'Blood clots'. 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, 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 at least 4 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.3). Your doctor will tell you when you can start taking the Pill again.

2-1 When you should not use Gynera

You should not use Gynera 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 use Gynera:

- If you have (or have ever had) a blood clot 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 2.3 '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 any of the following diseases that may increase your 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) a type of migraine called 'migraine with aura'
If you have or have ever had breast cancer
If you have ever had a severe liver disease, and you 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 are allergic (hypersensitive) to any of the ingredients in Gynera.

Do not use Gynera if you have hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir / pibrentasvir or sofosbuvir / velpatasvir / voxilaprevir (see also in section 'Other medicines and Gynera')

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

2-2 When to take special care with Gynera

When should you contact your doctor?

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 (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'.

Some of the conditions listed below can be made worse by taking the Pill. Or they may mean it is less suitable for you. You may still be able to take Gynera but you need to take special care and have check-ups more often.

Tell your doctor if any of the following conditions apply to you.

If the condition develops, or gets worse while you are using Gynera, you should also tell your doctor.

- 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 oestrogens may cause or worsen the symptoms of hereditary and acquired angioedema
If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
If you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system)
If you have haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys)
If you have sickle cell anaemia (an inherited disease of the red blood cells)
If you have inflammation of the pancreas (pancreatitis)
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 2.3 'Blood clots')
If you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Gynera
If you have an inflammation in the veins under the skin (superficial thrombophlebitis)
If you have varicose veins
If you have diabetes
If you or your close family have ever had problems with your heart, or circulation such as high blood pressure
If you or your close family have ever had problems with blood clotting
If you have the inherited disease called porphyria
If you are overweight (obese)
If you have migraines
If you have any illness that worsened during pregnancy or previous use of the Pill (see section 4.2)

2-3 Blood clots

Using a combined hormonal contraceptive such as Gynera increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block 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 having a harmful blood clot due to Gynera is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Table with 2 columns: Are you experiencing any of these signs? and What are you possibly suffering from? Rows include swelling of one leg, sudden unexplained breathlessness, sharp chest pain, sudden cough, sharp chest pain, severe light headedness, severe pain in your stomach, sudden weakness or numbness of the face, arm or leg, sudden confusion, sudden trouble seeing, sudden trouble walking, sudden, severe or prolonged headache, sudden loss of consciousness, swelling and slight blue discoloration of an extremity, severe pain in your stomach.

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

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 Gynera 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 Gynera 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, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
Out of 10,000 women who are using a combined hormonal contraceptive that contains gestodene such as Gynera, between about 9 and 12 women 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 in a vein' below).

Table with 2 columns: Women who are not using a combined hormonal pill and are not pregnant, Women using a combined hormonal contraceptive pill containing levonorgestrel, norethisterone or norgestimate, Women using Gynera. Risk of developing a blood clot in a year.

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with Gynera is small but some conditions will increase the risk. Your risk is higher:

- If you are very overweight (body mass index or BMI over 30kg/m²)
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 Gynera may need to be stopped at least 4 weeks before surgery or while you are less mobile. If you need to stop Gynera 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 Gynera needs to be stopped.

If any of the above conditions change while you are using Gynera, 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 Gynera is very small but can increase:

- with increasing age (beyond about 35 years)
if you smoke. When using a combined hormonal contraceptive like Gynera, 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 increased even more.

If any of the above conditions change while you are using Gynera, 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.

2.4 The Pill and cancer

While high dose Pills reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose Pills like Gynera also provide the same protective effects. However, it also seems that taking the Pill slightly increases your risk of cancer of the cervix – although this may be due to having sex without a condom, rather than the Pill. All women should have regular smear tests.

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:

- 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.

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 Gynera.

2-5 Psychiatric disorders

Some women using hormonal contraceptives including Gynera 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 Other medicines and Gynera

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Gynera. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can have an influence on the blood levels of Gynera and can stop it from working properly – 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)
griseofulvin (an anti-fungal medicine)
certain antibiotics
certain sedatives (called 'barbiturates')
St. John's Wort (a herbal remedy)

If you do need to take one of these medicines, Gynera 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.

Gynera can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine.

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

Do not use Gynera if you have hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir / pibrentasvir or 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. Gynera can be restarted approximately 2 weeks after completion of treatment. See section 'Do not use Gynera'.

2-7 Taking Gynera with food and drink

There are no special instructions about food and drink while on Gynera.

2-8 Pregnancy and breast-feeding

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

If you are breast-feeding, your doctor or family planning nurse may advise you not to take Gynera. They will be able to suggest alternative contraception. Breast-feeding may not stop you getting pregnant.

2-9 Driving and using machines

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

2-10 Gynera contains lactose and sucrose

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

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

3. HOW TO TAKE GYNERA

3-1 How to take it

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

Take Gynera every day for 21 days

Gynera comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
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 21 pills.
Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So, if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills. You don't need to use extra contraception during these seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

Then start your next strip

Start taking your next strip of Gynera after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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

3-2 Starting Gynera

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

It is best to take your first Gynera pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Gynera from another contraceptive Pill

- If you are currently on a 21-day Pill: start Gynera the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Gynera.
If you are currently on a 28-day Pill: start taking Gynera the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Gynera.
Or, if you are taking a progestogen-only Pill (POP or 'mini Pill'): start Gynera on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Gynera 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 Gynera straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion after the third month of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Gynera should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Gynera and for the first 7 days of pill taking.

3-3 A missed pill

If you are less than 12 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 12 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

Take the most recently missed pill as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.

Continue to take a pill every day for the next seven days at your usual time.

If you come to the end of a strip of pills during these seven days, start the next strip without taking the usual seven day break. You probably won't have a bleed until after you finish the second strip of pills, but don't worry. If you finish the second strip of pills and don't have a bleed, do a pregnancy test before starting another strip.

Use extra contraception for seven days after missing a pill, such as condoms.

If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor, family planning nurse or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant. Contact your doctor or family planning clinic, or do a pregnancy test yourself.

If you start a new strip of pills late, or make your 'week off' longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

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. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. 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) or have very bad diarrhoea within 4 hours of taking the Pill, your body may not get its usual dose of hormones from that pill. If you are better within 12 hours of taking Gynera, follow the instructions in section 3.4 A lost pill, which describes how to take another pill.

If you are still sick or have diarrhoea more than 12 hours after taking Gynera, see section 3.3, A missed pill.

→ Talk to your doctor if your stomach upset carries on or gets worse. He or she may recommend another form of contraception.

3-6 Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you've taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or doctors surgery. If you are pregnant, stop taking Gynera and see your doctor.

3-7 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 bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding. Talk to your doctor if you have any of these symptoms.

3-8 When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping Gynera 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, Gynera can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Gynera, please talk to your doctor.

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 use Gynera'.

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

4-1 Serious side effects – see a doctor straight away

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

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 of blood clots and the symptoms of a blood clot).

Signs of a blood clot (see section 2.3 'Blood clots')

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 'What you need to know before you use Gynera').

