

BiNovum® oral contraceptive tablets

Norethisterone/ethinylestradiol
Binovum is a registered trademark

Five important things to know about the Pill.

- The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used for a long time.
- 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 the leaflet to make sure Binovum is right for you.
- To prevent pregnancy it is important to take Binovum as instructed and start each strip on time. Please make sure that you understand what to do if you miss a pill or think you are pregnant.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. 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.

What is in this leaflet:

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1 What Binovum is and what it is used for

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

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones prevent an egg being released from your ovaries so you can't get pregnant. Also, Binovum makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

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

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
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms.

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

Binovum needs to be taken as directed to prevent pregnancy.

2 What you need to know before you take Binovum

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. You may also need other checks, such as a breast examination but only if these are necessary for you or 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), the risk of developing a blood clot in a vein is highest during the first year of taking the Pill for the first time. The risk may also be higher if you restart taking the Pill (the same product or a different product) after a break of 4 weeks or more.

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

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 Binovum, 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.

You are more at risk of having a blood clot in your veins:

- as you get **older**
 - if you are **seriously overweight**
 - if you **smoke**
 - if you or any of your close family have had **blood clots**
 - if you have any **blood clotting problem** that needs treatment with a medicine such as warfarin
 - if you're **off your feet for a long time** because of major surgery, injury or illness
 - if you have had one or more **miscarriages**
 - if you have **recently had a baby**
- **Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Binovum may not be suitable for you.

Signs of a blood clot include:

- **painful swelling in your leg**
 - **sudden chest pain, difficulty breathing**
 - **sudden changes in eyesight** (such as loss of vision or blurred vision)
- **See a doctor as soon as possible. Do not take any more Binovum** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

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 heart attack or stroke:

- as you get **older**
 - if you have **high blood pressure**
 - if you **smoke** or **drink too much alcohol**
 - if you have **high levels of fat** in your blood or are **seriously overweight**
 - if you have an **irregular heartbeat** (atrial fibrillation), problems with **heart valves** or **heart failure**
 - if you or someone in your close family has had a **heart attack** or **stroke** at a young age
 - if you have **migraines**
 - if you have **diabetes**
 - if you have a blood problem called **sickle cell anaemia**
- **Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Binovum may not be suitable for you.

Signs of a heart attack or stroke include:

- sudden **crushing pains in your chest** which may reach your left arm
 - sudden **weakness or numbness** in one side or part of your body
 - **severe headache or migraine** for the first time or worse than normal
 - **slurred speech** or any other difficulties affecting your speech
 - any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- **See a doctor as soon as possible. Do not take any more Binovum** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

2.2 The Pill and cancer

The Pill reduces your risk of cancer of the ovary and womb if used for a long time. However, it also seems to slightly increase 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 are 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 111 will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- as you get **older**
 - 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.

3 How to take Binovum

3.1 How to take it

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

Take Binovum every day for 21 days

- Binovum comes in a strip of 21 pills, each marked with a day of the week.
- Take your pill at the same time every day.
- Start by taking a white pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one white pill each day, until you have finished all of them.
- Then take a peach-coloured pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one peach-coloured pill each day, until you have finished all of them.
- 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 Binovum after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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



3 How to take Binovum (continued)

3.2 Starting Binovum

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

Either take your first Binovum pill up to and including day 5 of your next period (counting the first day of your period as day 1). This way, you will have contraceptive protection with your first pill.

Or start taking Binovum at any time, if you are sure you are not already pregnant. But then you must use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

Changing to Binovum from another contraceptive

If you are currently taking another Pill and you are taking it correctly, you can start Binovum at any time, if you are sure you are not already pregnant. There is no need to wait for your next period to start and you don't need extra contraception. If you are currently using a non-hormonal method and your period started more than 5 days ago, you must use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

Starting Binovum after a miscarriage or abortion

If you have had a miscarriage or an abortion, your doctor may tell you to start taking Binovum straight away. This means that you will have contraceptive protection with your first pill.

Contraception after having a baby

If you have just had a baby, your doctor may tell you to start taking Binovum 21 days after the birth. This means that you will have contraceptive protection with your first pill.

If you start Binovum after this, you must use extra contraception, such as condoms, until you have taken the first 7 pills correctly.

3.3 A missed pill

Missing pills or starting a strip late may make your pill less effective. The chance of pregnancy after missing pills depends on **when** pills are missed and **how many** pills are missed. Missing one pill anywhere in your strip or starting a new strip one day late is **not** a problem.

Missing **more than one** or starting a strip **more than one day late** may affect your contraceptive cover. It is more risky to start a strip late and miss more than one pill.

