

Bayer plc

Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA

Telephone: +44 (0)1635 563 000

Fax: +44 (0)1635 563 393

WWW: <http://www.bayer.co.uk>



Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

Package booklet: Information for the user

Femodene[®]

Gestodene

Ethinylestradiol

About Your Pill

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 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 Femodene is right for you.
- To prevent pregnancy it is important to take Femodene 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.

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1. What Femodene does

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

This low-dose 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.

Femodene 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.

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

Femodene needs to be taken as directed to prevent pregnancy.

2. Make sure Femodene is OK for you

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 booklet.

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.

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.

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 Femodene, about **25** 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.

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 or any of your close family have had **blood clots**
- if you are seriously **overweight**
- if you have a **disorder of blood fat (lipid) metabolism**, or other **very rare blood disorders** that may increase your risk of thrombosis
- if you have **high blood pressure**
- if you have a **heart valve disorder** or an **irregular heartbeat (atrial fibrillation)**
- if you have **recently had a baby**
- if you have **diabetes mellitus**
- if you have certain rare medical conditions such as **systemic lupus erythematosus, Crohn's disease** or **ulcerative colitis**
- if you have **haemolytic uraemic syndrome (HUS** – a disorder where blood clots cause the kidneys to fail)
- if you have **sickle cell disease**
- if you have had a **subarachnoid haemorrhage** (bleeding from the blood vessels of the brain)
- if you're **off your feet for a long time** because of major surgery, injury or illness.

→ **Tell your doctor if any of these apply to you.** Taking the pill may add to this risk so Femodene 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 Femodene** 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 in the long term. 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 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 Femodene.

2.3 Femodene 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 Femodene if any of the following apply to you. Taking Femodene would put your health at risk.

- If you are **pregnant** or might be pregnant

- If you have cancer affected by sex hormones – such as some **cancers of the breast or womb lining** or have ever had either of these conditions
- If you have **vaginal bleeding** that has not been explained by your doctor
- If you or anyone in your close family has ever had a problem with their 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 any condition which makes you **more at risk of a blood clot** (*thrombosis* – see section 2.1, *The Pill and blood clots*)
- If you have **abnormal red blood cells** (*sickle-cell anaemia*)
- If you have disorders of **blood fat** (*lipid*) **metabolism**
- If you have ever had a **severe liver disease**
- If you have certain types of **jaundice** (*Dubin-Johnson* or *Rotor syndromes*)
- If you have ever had **liver tumours**
- If you have **severe diabetes affecting your blood vessels**
- If you have ever had a **blister-like rash** called *herpes gestationis*
- If you have had any of the following **problems while pregnant**:
 - **worsening of a hearing problem** called *otosclerosis*
 - **persistent itching**
- If you are **allergic** (*hypersensitive*) to any of the ingredients in Femodene.

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

2.4 Femodene can make some illnesses worse

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 Femodene but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart, circulation or blood clotting, such as **high blood pressure** or **sickle cell disease**
- If you have **varicose veins**
- If you have had **epilepsy** or **migraines**
- If you have **asthma**
- If you have had **severe depression**
- If you are **overweight** (*obese*)
- If you have any **gynaecological problems**, such as **fibroids**
- If you have ever had **inflamed veins** (*phlebitis*)
- If you have an inherited form of deafness known as **otosclerosis**
- If you have the disease of the nervous system called **multiple sclerosis**
- If you have the inherited disease called **porphyria**
- If you have **calcium deficiency with cramps** (*tetany*)
- If you have the movement disorder called **Sydenham's chorea**
- If you have ever had **breast problems**
- If you have **diabetes**
- If you have **an intolerance to contact lenses**
- If you have **systemic lupus erythematosus**
- If you have ever had **kidney** or **liver problems**, or have had **gall stones** in the past
- If you have **brown patches on your face or body** (*chloasma*)

- If you have **any disease that is prone to worsen during pregnancy**
- If anyone in your family has had **breast cancer**.

→ **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 the Pill, or if any get worse or come back, because you may need to stop taking Femodene.

2.5 Taking other medicines

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 Femodene. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Femodene from working properly – for example:

- **some medicines used to treat epilepsy**
- **griseofulvin** (an anti-fungal medicine)
- **phenylbutazone** (an anti-inflammatory medicine)
- **certain antibiotics**
- **certain sedatives** (called 'barbiturates')
- **St. John's Wort** (a herbal remedy).

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

Femodene can also affect how well other medicines work. For example, if you have diabetes, you may need to take more insulin or other anti-diabetic drugs while you take Femodene. Your doctor will tell you if this is necessary.

2.6 Taking Femodene with food and drink

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

2.7 Pregnancy and breast-feeding

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

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

2.8 Driving and using machines

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

2.9 Femodene contains lactose

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

3. Taking Femodene

3.1 How to take it

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

Take Femodene every day for 21 days

Femodene 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 Femodene after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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

3.2 Starting Femodene

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

It is best to take your first Femodene 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 Femodene from another contraceptive Pill

- **If you are currently on a 21-day Pill:** start Femodene 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 Femodene.

- **If you are currently on a 28-day Pill:** start taking Femodene 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 Femodene.
- **Or, if you are taking a progestogen-only Pill (POP or 'mini Pill'):** start Femodene 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 Femodene 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 Femodene 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 to start taking Femodene 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 Femodene 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, your body may not get its usual dose of hormones from that pill. If you are **better within 12 hours of taking Femodene**, follow the instructions in section 3.4 *A lost pill*, and take another pill. If you are still sick or have diarrhoea **more than 12 hours after taking Femodene**, 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 have 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 Femodene 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 have some vaginal 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 Femodene 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, Femodene 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 Femodene.

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)
- **pain or swelling in your leg**
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **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 Femodene:

- **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 cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex**.

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 Femodene.

4.2 Less serious side effects

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Femodene. If it continues, becomes heavy or starts again, contact your doctor
- **headaches**
- **feeling sick, being sick and stomach upsets**
- **sore breasts**
- **depressive moods, loss of interest in sex**
- **putting on weight or losing weight**
- **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Femodene for a number of months. Chloasma may be reduced by avoiding too much sunlight
- poor tolerance of contact lenses.

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

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Femodene, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Femodene 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 Femodene for a while
- carries on even after you've stopped taking Femodene.

5. How to store Femodene

Keep all medicines out of the reach and sight of children.

Do not use Femodene after the expiry date shown on the strip.

Do not store above 25°C and protect from light.

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 Femodene and who makes it

What is in Femodene

Each box of Femodene contains three strips of 21 white tablets containing 75 micrograms of the progestogen gestodene, and 30 micrograms of the oestrogen ethinylestradiol.

Femodene also contains the inactive ingredients:

Lactose, maize starch, povidone, magnesium stearate (E572), sodium calcium edentate, sucrose, macrogol 6000, calcium carbonate (E170), talc, montan glycol wax.

The company that holds the product licence for Femodene is:

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA.

Femodene is made by:

Bayer Pharma AG, Berlin, Germany
or Bayer Weimar GmbH & Co KG, Weimar, Germany
or Delpharm Lille SAS, Lys-Lez-Lannoy, France.

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