

**Package leaflet:** Information for the user |

## Femodene® ED

Bayer Schering Pharma

Gestodene

Ethinylestradiol

### **Five important things to know about the Pill.**

- ③ The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used in the long term.
- ③ The Pill will not protect you against sexually transmitted diseases. ③ This medicine can increase your risk of problems such as blood clots and breast cancer.
- ③ Some women should not take the Pill because of current medical problems or illnesses. Please read this leaflet to make sure Femodene ED is right for you. ③ To prevent pregnancy it is important to take Femodene ED 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.

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### **Read all of this leaflet carefully before you start taking this medicine.**

- ③ Keep this leaflet. You may need to read it again.
- ③ If you have any questions or need more advice, ask your doctor, family planning nurse or pharmacist.
- ③ This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- ③ **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 ED does

Femodene ED 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 ED is taken every day without a break. You take an 'active pill' each day for 21 days, followed by an 'inactive pill' each day for 7 days.

**The benefits of taking the Pill** include:

- ③ it is one of the most reliable reversible methods of contraception if used correctly
- ③ it doesn't interrupt sex
- ③ it usually makes your periods regular, lighter and less painful
- ③ it may help with pre-menstrual symptoms.

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

**Femodene ED needs to be taken as directed to prevent pregnancy.**

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## 2. Make sure Femodene ED 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 leaflet.

### **Before you start taking the Pill**

③ 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**

③ You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.

③ You should go for **regular cervical smear** tests.

③ **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. ③ **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.

③ **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.**

③ Of 100,000 women who are **not on the Pill** and not pregnant, about **5** will have a blood clot in a year.

③ Of 100,000 women **taking a Pill** such as Femodene ED, about **25** will have a blood clot in a year.

- ③ 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.

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### **You are more at risk of having a blood clot:**

- ③ as you get **older**
- ③ if you **smoke**
- ③ if you or any of your close family have had **blood clots** ③ if you are seriously **overweight**
- ③ if you have a **disorder of blood fat (*lipid*) metabolism**, or other **very rare blood disorders** that may increase your risk of thrombosis ③ if you have **high blood pressure**
- ③ if you have a **heart valve disorder** or an **irregular heartbeat (*atrial fibrillation*)**
- ③ if you have **recently had a baby** ③ if you have **diabetes mellitus**
- ③ if you have certain rare medical conditions such as **systemic lupus erythematosus, Crohn's disease** or **ulcerative colitis**
- ③ if you have **haemolytic uraemic syndrome** (HUS - a disorder where blood clots cause the kidneys to fail)
- ③ if you have **sickle cell disease**
- ③ if you have had a **subarachnoid haemorrhage** (bleeding from the blood vessels of the brain)
- ③ 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 ED may not be suitable for you.

### Signs of a blood clot include:

- ③ a **migraine** for the first time, a migraine that is worse than normal or unusually frequent or severe **headaches**
- ③ any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- ③ any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- ③ **pain or swelling in your leg** ③ **stabbing pain when you breathe** ③ **coughing** for no apparent reason ③ **pain and tightness in the chest**
- ③ sudden **weakness** or **numbness** in one side or part of your body ③ **dizziness** or **fainting**.

→ **See a doctor as soon as possible. Do not take any more Femodene ED** 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** -

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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:

- ③ Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- ③ 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.
- ③ Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.

- ③ 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:**

- ③ if you have a close relative (mother, sister or grandmother) who has had breast cancer
- ③ 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 noncancer 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 ED.

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

- ③ If you are **pregnant** or might be pregnant
- ③ 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 ③ If you have **vaginal bleeding** that has not been explained by your doctor ③ 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
- ③ 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*

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- ③ If you have **abnormal red blood cells (sickle-cell anaemia)** ③ If you have

**disorders of blood fat (lipid) metabolism** ③ If you have ever had a **severe liver disease**

③ If you have certain types of **jaundice** (*Dubin-Johnson* or *Rotor syndromes*) ③ If you have ever had **liver tumours**

③ If you have **severe diabetes affecting your blood vessels** ③ If you have ever had a **blister-like rash** called *herpes gestationis* ③ If you have had any of the following **problems while pregnant**:

③ **worsening a hearing problem** called *otosclerosis* ③ **persistent itching**

③ If you are **allergic** (*hypersensitive*) to any of the ingredients in Femodene ED.

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

## 2.4 Femodene ED 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 ED but

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

③ 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**

③ If you have **varicose veins**

③ If you have had **epilepsy** or **migraines**

③ If you have **asthma**

③ If you have had **severe depression**

③ If you are **overweight** (*obese*)

③ If you have any **gynaecological problems**, such as **fibroids**

③ If you have **inflamed veins** (*phlebitis*)

③ If you have an inherited form of deafness known as **otosclerosis**

③ If you have the disease of the nervous system called **multiple sclerosis**

③ If you have the inherited disease called **porphyria**

③ If you have **calcium deficiency with cramps** (*tetany*)

③ If you have the movement disorder called **Sydenham's chorea**

③ If you have ever had **breast problems**

③ If you have **diabetes**

③ If you have **an intolerance to contact lenses**

③ If you have **systemic lupus erythematosus**

③ If you have ever had **kidney** or **liver problems**, or have had **gall stones** in

the  
past

③ If you have **brown patches on your face or body** (*chloasma*)

③ If you have **any disease that is prone to worsen during pregnancy**

③ If anyone in your family has had **breast cancer**.

→ **Tell your doctor or family planning nurse if any 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 ED

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## 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 ED. 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 ED from working properly - for example:

- ③ **some medicines used to treat epilepsy**
- ③ **griseofulvin** (an anti-fungal medicine) ③ **phenylbutazone** (an anti-inflammatory medicine) ③ **certain antibiotics**
- ③ **certain sedatives** (called *barbiturates*) ③ **St. John's Wort** (a herbal remedy).

If you do need to take one of these medicines, Femodene ED 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 ED 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 ED. Your doctor will tell you if this is necessary.

## 2.6 Taking Femodene ED with food and drink

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

## 2.7 Pregnancy and breast-feeding

**Do not use Femodene ED** 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 ED.

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



## **2.8 Driving and using machines**

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

## **2.9 Femodene ED contains lactose**

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

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# **3. Taking Femodene ED**

## **3.1 How to take it**

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

This pack is designed to help you remember to take your pills. Your pack contains 3 foil memo strips with 3 sets of 7 self-adhesive strips showing the days of the week. Each foil memo strip contains 28 tablets: 21 small active tablets in 3 rows and 7 larger inactive tablets in the last row.

### **Take Femodene ED every day for 28 days**

- ③ Find the set of self-adhesive strips. Each strip starts with a different day of the week. Peel off a strip that starts with your starting day.
- ③ For instance, if you start the tablets on a Wednesday, use a strip that starts with 'Wed'.
- ③ Stick the strip along the top of the foil memo-strip so that the first day is above the pill marked 'start'.
- ③ You can now see on which day you have to take each tablet. ③ Take your pill at the same time every day.
- ③ Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 28 pills.
- ③ Swallow each pill whole, with water if necessary. Do not chew the pill.

### **Then start your next strip**

Start taking your next strip of Femodene ED the next day. Do not leave a gap between packs.

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

### **3.2 Starting Femodene ED**

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

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

③ **If you are currently taking a 21-day Pill:** start Femodene ED 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 ED.

③ **If you are taking a 28-day Pill:** start taking Femodene ED 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 ED.

③ **Or, if you are taking a progestogen-only Pill (POP or 'mini Pill'):** start Femodene ED on the first day of bleeding, even if you have already taken the

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progestogen-only Pill for that day. You will have contraceptive cover straight away.

#### **Starting Femodene ED 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 ED 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 ED 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 ED and for the first 7 days of pill taking.

**If you have missed any of the pills in a strip, and you do not bleed while taking the large inactive pills, you may be pregnant. Contact your doctor or family**

**planning clinic, or do a pregnancy test yourself.**

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If you start a new strip of pills late, 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 condoms, for seven days.

### **3.4A lost pill**

If you lose an **active pill**,

**Either** take the last active 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 taking the large white inactive pills 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. 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.

If you lose an **inactive pill**, don't worry, just continue taking the remaining tablets at the correct time. Your contraceptive protection won't be affected.

### **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 ED**, follow the instructions in section 3.4 *A lost pill*. If you are still sick or have diarrhoea **more than 12 hours after taking Femodene ED**, 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 ED 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.

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### **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 ED 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 ED 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 ED.

### **4.1 Serious side effects - see a doctor straight away**

#### **Signs of a blood clot:**

- ③ a **migraine** for the first time, a migraine that is worse than normal, or unusually frequent or severe **headaches**
- ③ any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- ③ any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- ③ **pain or swelling in your leg** ③ **stabbing pain when you breathe** ③ **coughing** for no apparent reason ③ **pain and tightness in the chest**

③ sudden **weakness** or **numbness** in one side or part of your body ③ **dizziness** or **fainting**.

**Signs of a severe allergic reaction to Femodene ED:**

③ **swelling** of the **face, lips, mouth, tongue or throat**.

**Signs of breast cancer include:**

③ **dimpling** of the skin

③ **changes in the nipple** ③ any **lumps** you can see or feel.

**Signs of cancer of the cervix include:**

③ **vaginal discharge** that smells and/or contains blood ③ unusual **vaginal bleeding**

③ **pelvic pain**

③ **painful sex**.

**Signs of severe liver problems include:**

③ **severe pain in your upper abdomen** ③ **yellow skin or eyes (jaundice)** ③ **inflammation of the liver (hepatitis)**

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③ 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 ED.

**4.2 Less serious side effects**

③ **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 ED. If it continues, becomes heavy or starts again, contact your doctor

③ **headaches**

③ **feeling sick, being sick and stomach upsets** ③ **sore breasts**

③ **depressive moods, loss of interest in sex** ③ **putting on weight or losing weight**

③ **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Femodene ED for a number of months. Chloasma may be reduced by avoiding too much sunlight

③ 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 ED. Also tell them if any existing conditions get worse while you are taking Femodene ED.

#### **4.3 Bleeding between periods should not last long**

A few women have a little unexpected bleeding or spotting while they are taking Femodene ED, 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 ED 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:

③ carries on for more than the first few months ③ starts after you've been taking Femodene ED for a while ③ carries on even after you've stopped taking Femodene ED.

### **5.How to store Femodene ED**

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

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

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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 ED and who makes it**

### **What is in Femodene ED**

Each box of Femodene ED contains three strips of 28 tablets with three sets of 7 self-adhesive strips showing the days of the week.

Each strip of Femodene ED contains 21 white sugar-coated tablets containing 75 micrograms of the progestogen gestodene and 30 micrograms of the oestrogen ethinylestradiol and 7 larger, white, inactive tablets.

Femodene ED also contains the inactive ingredients:

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