

INFORMATION FOR THE PATIENT

Femulen®

etynodiol diacetate

Please read this leaflet carefully before you start taking your pills. The leaflet can't tell you everything about Femulen. So if you have any questions or are not sure about anything, ask your doctor, clinic or pharmacist.

Some information about Femulen

The name of your medicine is Femulen. It contains etynodiol diacetate, a type of hormone called a 'progestogen'. Femulen is a progestogen-only contraceptive pill, or 'POP' for short. The only hormone it contains is progestogen, unlike the combined contraceptive pill which contains two types of hormones - oestrogen and progestogen.

What is in Femulen?

Each Femulen pill contains:

- 500 micrograms of etynodiol diacetate (the 'active' ingredient); and
- calcium phosphate, maize starch, polyvinylpyrrolidone, sodium phosphate, calcium acetate and hydrogenated castor oil (the 'inactive' ingredients).

Femulen pills are white and have 'SEARLE' written on each side. They are packed in blister strips and supplied in packs of 84 pills.

The active ingredient in this medicine is **etynodiol** diacetate. This is the new name for **ethynodiol** diacetate. The ingredient itself has not changed.

Who supplies Femulen?

Femulen is supplied by:

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ, UK

Who makes Femulen?

Femulen is made by:

Piramal Healthcare UK Limited
Whalton Road
Morpeth
Northumberland NE61 3YA
United Kingdom

What is Femulen for?

Femulen helps to prevent you becoming pregnant. It does this in several ways. It thickens the fluid at the entrance to your womb. This makes it hard for sperm to travel through and enter the womb. It also changes the lining of your womb so that a fertilised egg cannot grow there. Sometimes it stops your ovaries releasing an egg.

Before you take Femulen

Femulen may not be suitable for all women. Before you start to take Femulen make sure your doctor knows if you have ever had:

- cancer of the breast, cervix, vagina, or womb;
- malignant or benign liver tumours;
- liver problems, for example jaundice (yellowing of the skin or eyes);
- pruritus (itching all over your body) or jaundice while you were pregnant;
- high levels of fat in your blood;
- vaginal bleeding for which your doctor could not find the cause;
- amenorrhoea (lack of periods);
- thrombophlebitis (inflamed veins), heart disease, blood clots, or a stroke;
- a disease of your red blood cells, such as sickle cell anaemia; or
- an allergic reaction to any of the ingredients in Femulen.

Also, please tell your doctor if you could be pregnant. If you become pregnant while you are taking this type of pill there is a slightly higher chance that it could be an ectopic pregnancy (a pregnancy developing outside of the womb).

Some diseases may get worse when you are taking the contraceptive pill. Your doctor may need to check you more closely if you suffer from:

- epilepsy; • migraine;
- heart or kidney problems; • depression;
- diabetes; • varicose veins;
- gallstones; • asthma;
- high blood pressure; • tetany (muscle twitches);
- multiple sclerosis; • porphyria (a rare inherited blood disease); or
- otosclerosis (an inherited form of deafness which sometimes gets worse during pregnancy).

If any of these get worse, or if you get them for the first time, your doctor may tell you to stop taking Femulen.

Your doctor or clinic will give you regular checkups while you are taking Femulen. Your blood pressure will be checked before you start the pill and then at regular intervals whilst you are on the pill. If your blood pressure goes up, your doctor may tell you to stop taking

Femulen. They may also check your breasts and reproductive organs, including taking a cervical smear at regular intervals, if this is considered necessary by the doctor.

Breast Cancer

Every woman is at risk of breast cancer whether or not she takes the pill. Breast cancer is rare under 40 years of age but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the pill than in women of the same age who do not take the pill. If women stop taking the pill, this reduces the risk, so that 10 years after stopping the pill, the risk of finding breast cancer is the same as for women who have never taken the pill. Breast cancer seems less likely to have spread when found in women who take the pill than in women who do not take the pill.

It is not certain whether the pill causes the increased risk of breast cancer. It may be that women taking the pill are examined more often, so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the pill, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

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

The possible small extra risk of being diagnosed with breast cancer has to be weighed against the known benefits of taking the progestogen-only pill.

Taking any medicine carries some risk. You can use the information in this leaflet, and the advice your doctor or clinic has given you to weigh up the risks of taking the pill. Don't be embarrassed, ask as many questions as you need to.

Other medicines and Femulen

Some medicines may stop Femulen from working properly. These include some drugs that treat epilepsy, arthritis, tuberculosis and some antibiotics and sedatives. If you take any other medicines while you are taking Femulen, make sure that your doctor knows. They will tell you whether you need to use other contraceptives while you are taking the medicine.

The herbal remedy St John's wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you already take a St John's wort preparation, stop taking the St John's wort and mention it to your doctor.

Smoking

Smoking increases the risk to your health and increases some of the risks of the combined pill. It is not known if these risks also apply to the progestogen-only pill. It is best to stop smoking anyway.

How to take Femulen

You should take one pill each day. Start on the first day of your next period. This is 'day one' of your cycle, the day when bleeding starts. The pack is marked with the days of the week to help you remember to take your pills.

Follow the direction of the arrows on the pack and take a pill every day until the pack is empty. When you finish the first pack, start a new pack on the next day. This means that you will be taking pills through your period. There must be no breaks between packs.

For the first seven days of the first pack you should also use a condom, or a cap and spermicide.

You can take the pill at a time that suits you. But you must take it at about the same time each day. Swallow the pill whole with some water. **If you are three or more hours late taking your pill, follow the instructions under 'What do I do if I forget to take a pill?'**

What do I do if my periods are different?

This is quite normal with the progestogen-only pill. Your periods may be irregular and you may have some bleeding between periods. You may even have no periods at all. Make a note of what happens so that you can tell the doctor or nurse at your next checkup.

What do I do if I forget to take a pill?

If you are more than three hours late taking your pill you may not be protected from pregnancy. Take the pill as soon as you remember, and take the next one at the normal time. This may mean taking two pills in one day. Continue to take your pills as normal but also use a condom for the next seven days.

What do I do if I miss a period?

This may happen with this type of pill. If you have taken all your pills properly, you are very unlikely to be pregnant. Take your next pack as normal. If you miss a second period see your doctor or clinic at once.

What do I do if I am changing pill brands?

Take the first pill of your new pack on the day after you finish your old pack. Do not leave any break at all.

What do I do if I have a stomach upset or I am sick?

Femulen may not work if you are sick or have diarrhoea. Continue to take your pills as normal but use a condom while you are ill and for the next seven days.

What do I do if I am having an operation?

Your doctor may take you off the pill for a while if you are going to have an operation, or if you are ill or injured and they think there is a risk of blood clots.

What do I do if I have just had a baby?

You can use Femulen after having a baby whether you are breast feeding or not. You can start taking the pill from day 21 after childbirth. This protects you as soon as you have taken the first pill. If you start later than this you may not be protected until you have taken the pill for another seven days. If you have had a miscarriage or abortion you can start taking the pill straightaway and will be protected immediately.

What do I do if I want a baby?

If you want to have a baby it is helpful to wait until your regular periods return before you try to get pregnant. You can use another type of contraceptive, such as a condom until then. Once you have had one period it will be easier to work out when the baby is due. However, if you get pregnant as soon as you stop taking Femulen, this is not harmful.

Overdose

If you take too many pills or you find out that someone else has taken a lot of pills, contact a doctor immediately.

Does Femulen have side effects?

All medicines can sometimes cause problems. If you are worried about side effects, talk to your doctor. These effects should become less of a problem as your body gets used to the pills.

Some women find that their periods are different. Sometimes the time between periods, and the length of the periods, is different. There may be bleeding between periods, called 'break-through bleeding'. This tends to happen more in the first few months of taking Femulen. If your periods seem different do not stop taking Femulen but mention it to the doctor or nurse at your next checkup.

Other side effects that you might have include:

- feeling or being sick; • stomach upsets;
 - chloasma (brown patches on your skin); • changes in your weight;
 - swollen or sore breasts; • headaches;
 - changes in sex drive; • migraines;
 - changes in appetite; • feeling dizzy;
 - an increase in body or facial hair;
 - colitis (problems with the intestines);
 - gall bladder problems;
 - an increase in the size of fibroids (fibrous tissue) in the womb;
 - changes in the way your body breaks down sugars, fats or vitamins; or
 - changes in your eyes which make it uncomfortable for you to wear contact lenses.
- Femulen may also affect the results of liver function, thyroid and hormone tests.
- Reasons to get medical help immediately•

Stop taking the pills at once and tell your doctor if:

- you become jaundiced (your skin or the whites of your eyes look yellow).

Also, follow this advice if:

- you have a sudden, severe pain in your chest;

- you suddenly become short of breath;
 - you have an unusual, severe or long headache;
 - your sight is affected in any way;
 - you find it difficult to speak;
 - you collapse or faint;
 - any part of your body suddenly feels weak or numb; or
 - you have a severe pain in one of your calves.
- These could be warning signs of thrombosis (a blood clot).

How to store Femulen

Store your Femulen pills in a dry place, away from light and below 30oC. Make sure children cannot see or reach them.

Don't take Femulen after the 'expiry date' shown on the box. If your pack is out of date, take it to your pharmacist who will get rid of the pills safely.

Femulen is a contraceptive. It will not protect against sexually-transmitted diseases including AIDS. For safer sex, use a condom as well as your usual contraceptive.

This leaflet was last updated 03/2012

If you have any comments on the way this leaflet is written, please write to Medical Information at Pfizer.

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