

## Consumer Medicine Information

# FEMODENE<sup>®</sup> 28

*Gestodene 0.075 mg and Ethinylestradiol 0.03 mg tablets*

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## What is in this leaflet

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Please read this leaflet carefully before you start using FEMODENE 28. It will advise you about how to take FEMODENE 28 properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

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## What is FEMODENE 28 used for and how does it work

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FEMODENE 28 is a combined oral contraceptive (often called "the Pill") consisting of 21 hormonal tablets and 7 non-hormonal tablets. Each small white hormonal tablet contains a small amount of two different female hormones. These are gestodene (a progestogen) and ethinylestradiol (an estrogen). Because of the small amount of hormones, FEMODENE 28 is considered to be a low-dose combined oral contraceptive preparation. FEMODENE 28 also contains 7 large white non-hormonal tablets that do not contain any active ingredients.

### How does FEMODENE 28 work?

Combined oral contraceptive Pills, such as FEMODENE 28, provide one of the most effective reversible methods of contraception known. Usually, when FEMODENE 28 is taken according to the instructions, the egg cells (normally released by the ovary each month) are prevented from maturing to the point where they can be fertilized. In addition, the cervical mucus remains thick, so it is more difficult for a man's sperm to enter the womb. Also, the lining of the womb is not prepared sufficiently for a fertilized egg to grow in.

### What is FEMODENE 28 used for?

FEMODENE 28 is used to prevent pregnancy. Combined oral contraceptives are a very effective method of birth control. When taken correctly (without missing tablets) the chance of becoming pregnant is very low (approximately 1% per year). The failure rate may increase when tablets are missed or taken incorrectly.

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## Before you use FEMODENE 28

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Do not use FEMODENE 28 if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use FEMODENE 28. Your doctor may advise you to use a different type of hormonal contraception or an entirely different (non-hormonal) method of birth control.

## **You must not use FEMODENE 28 if:**

- you have, or have ever had a disorder affecting the blood circulation. In particular, those conditions relating to thrombosis. Thrombosis is the formation of a blood clot. This may occur in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), the brain (stroke), or other parts of the body. (See also the section later in this leaflet called "FEMODENE 28 and thrombosis").
- you have or have ever had a stroke caused by a rupture of a blood vessel in the brain
- you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischemic attack or small reversible stroke)
- you have a history of migraine accompanied by visual symptoms or speech disability or weakness or numbness in any part of your body
- you have diabetes mellitus with blood vessel damage
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances)
- you have or have had pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- you have jaundice (yellowing of the skin) or severe liver disease, as long as liver function test results have not returned to normal
- you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- you have or have had a benign or malignant liver tumor
- you have any unexplained vaginal bleeding
- you are pregnant or think you might be pregnant
- you are allergic (hypersensitive) to any of the ingredients of FEMODENE 28

If any of these conditions appear for the first time while using FEMODENE 28, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures.

## **Tell your doctor if:**

If FEMODENE 28 is used in the presence of any of the conditions listed below or they appear for the first time, recur or worsen during treatment, you may need to be kept under close observation. Your doctor can explain this to you. You should tell your doctor if:

- you smoke
- you have diabetes
- you are overweight
- you have high blood pressure
- you have a heart valve disorder or a certain heart rhythm disorder
- you have an inflammation of your veins (superficial phlebitis)
- you have varicose veins
- anyone in your immediate family has had thrombosis, a heart attack or a stroke
- you suffer from headaches
- you suffer from epilepsy

- anyone in your immediate family has had breast cancer
- you have liver, kidney or gallbladder disease
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body)
- you have hemolytic uremic syndrome (HUS; a blood clotting disorder causing failure of the kidneys)
- you have sickle cell disease
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- you have hereditary angioedema; taking estrogens may induce or exacerbate symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.

## **What else you should know**

**FEMODENE 28 does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

In this leaflet, several situations are described where you should stop taking FEMODENE 28, or where the reliability of FEMODENE 28 may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because FEMODENE 28 alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

- **FEMODENE 28 and thrombosis**

Thrombosis is the formation of a blood clot which may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Deep venous thrombosis is a rare occurrence. The risk is highest during the first year a woman ever uses the Pill.

Venous thrombosis can develop whether or not you are taking the Pill. It can also happen if you become pregnant. The risk is higher in Pill users than in non-users, but not as high as during pregnancy.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely, blood clots can occur in the liver, gut, kidney or eye.

Very occasionally a thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke.

**When using FEMODENE 28 you should stop smoking, especially if you are older than about 35 years of age.**

If you develop high blood pressure while using FEMODENE 28, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilization (for example, when you have your leg or legs in plaster or splints). In women who use the Pill (such as FEMODENE 28) the risk may be even higher. Tell your doctor you are using FEMODENE 28 well in advance of any expected hospitalization or surgery. Your doctor may tell you to stop taking FEMODENE 28 several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start taking FEMODENE 28 again after you are back on your feet.

If you notice possible signs of thrombosis, stop taking the Pill and consult your doctor immediately. (See also the section called "*Tell your doctor if:*").

- **FEMODENE 28 and cancer**

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the ten years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In rare cases, benign, and even more rarely, malignant liver tumors have been reported in users of the Pill. These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

The most important risk factor for cervical cancer is persistent human papilloma virus infection. Some studies have indicated that long-term use of the Pill may further contribute to this increased risk, but there continues to be controversy about the extent to which this finding is attributable to other factors, e.g. cervical screening and sexual behavior including use of barrier contraceptives.

- **FEMODENE 28 and other medicines**

Some medicines may stop FEMODENE 28 from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate and felbamate); tuberculosis (e.g. rifampicin and rifabutin) and HIV infections (e.g. ritonavir and nevirapine); antibiotics (e.g. penicillins, tetracyclines and griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (primarily used for the treatment of depressive moods).

The Pill may also interfere with the working of other medicines (e.g. medicines containing cyclosporin or the anti-epileptic lamotrigine).

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed.

Always tell the doctor who prescribes FEMODENE 28 which medicines you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use FEMODENE 28. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

- **FEMODENE 28 and breast-feeding**

FEMODENE 28 is generally not recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please seek the advice of your doctor.

- **FEMODENE 28 and pregnancy**

**FEMODENE 28 must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are using FEMODENE 28 you should see your doctor as soon as possible.**

- **FEMODENE 28 and ability to drive and use Machines**

There are no observed effects.

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## **How to use FEMODENE 28 properly**

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When you follow the starting instructions and continue to take FEMODENE 28 correctly, the contraceptive protection provided by FEMODENE 28 is continuous. This includes the week when you take the non-hormonal tablets.

Additional contraceptive precautions are only required when special circumstances (e.g. forgetting tablets) reduce the reliability of the preparation.

Remember that FEMODENE 28 has been prescribed for you personally. Do not share it with others.

## **When and how to take the tablets**

The FEMODENE 28 pack contains 21 small round white hormonal tablets and 7 large white non-hormonal tablets. On the pack each tablet is marked with the day of the week on which it is to be taken. Take your tablet at about the same time each day, with some water if necessary. Follow the direction of the arrows until all 28 tablets have been taken. A period (the withdrawal bleed) should begin during the 7 days of taking the large white non-hormonal tablets. Start taking your next pack on the very next day after you have completed your last pack even if your period continues. This means that you will always start new packs on the same day of the week, and also that you will have your withdrawal bleed on or about the same day each month.

### **Starting your first pack of FEMODENE 28**

- **When no hormonal contraceptive has been used in the past month**

Start taking FEMODENE 28 on the first day of your cycle, i.e. the first day of menstrual bleeding. Take your first tablet from the green section marked with that day of the week. For example, if your period starts on a Monday, take the tablet marked Monday from the green section of the pack. Then follow the days in order of the directional arrows. When you start taking FEMODENE 28 your very first cycle may be shorter than usual. FEMODENE 28 will work immediately, it is not necessary to use an additional contraceptive method.

You may also start taking FEMODENE 28 on days 2-3 of your cycle, but in this case make sure that you use an additional barrier contraceptive method (such as condoms) for the first 7 days of tablet-taking in the first cycle.

- **When changing from a combined Pill, vaginal ring or transdermal (contraceptive) patch**

You can start taking FEMODENE 28 the day after you take the last tablet from your present Pill pack (this means no tablet-free break). Take your first tablet from the green section marked with that day of the week. If your present Pill pack also contains non-hormonal tablets you can start FEMODENE 28 on the day after taking the last hormonal tablet (if you are not sure which this is, ask your doctor or pharmacist).

You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last non-hormonal tablet of your present Pill). In case you have used a vaginal ring or transdermal patch, you should start using FEMODENE 28 preferably on the day of removal, but at the latest when the next application would have been due. If you follow these instructions, it is not necessary to use an additional contraceptive method.

- **When changing from a progestogen-only Pill (minipill)**

You can stop taking the minipill any day and start taking FEMODENE 28 the next day, at the usual time. Take your first tablet from the green section marked with that day of the

week. But make sure you also use an additional barrier contraceptive method for the first 7 days of tablet-taking when having intercourse.

- **When changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD)**

Start using FEMODENE 28 when your next injection is due or on the day that your implant or IUD is removed. Take your first tablet from the green section marked with that day of the week. But make sure you also use an additional barrier contraceptive method for the first 7 days of tablet-taking when having intercourse.

- **After having a baby**

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking FEMODENE 28. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take FEMODENE 28, you should discuss this first with your doctor.

- **After a miscarriage or an abortion**

Your doctor will advise you.

## **Special circumstances**

The following describes special circumstances that could alter the way you take FEMODENE 28. In all situations where the reliability of FEMODENE 28 is reduced (such as missing tablets) additional contraceptive precautions are required following the advice given below. This advice should also be followed in situations where other medicines may stop FEMODENE 28 from working properly and in the case of vomiting or severe diarrhea after taking FEMODENE 28.

## **If you forget to take your tablets**

If you forget to take your tablets, follow the instructions below. This is often called the "7 day rule". The more tablets you have missed, the higher the risk that the contraceptive effect is decreased. There is a particularly high risk of becoming pregnant if you miss tablets just before or immediately after taking the non-hormonal tablets.

### **WHAT TO DO IF .....**

#### **..... you forget tablets**

- If you have forgotten to take one or more of the **large white non-hormonal tablets** - there is no need to be concerned, simply take your next tablet, the next day as usual. However to make sure that you do not change your Pill taking rhythm, which is important for the contraceptive reliability of your Pill, you should proceed with your next tablet the next day at the normal time and discard the forgotten non-hormonal tablet(s) to avoid any confusion.

- If you are **less than 12 hours late** in taking one of the small hormonal FEMODENE 28 tablets, you are still protected against pregnancy. Take the tablet as soon as you remember and take the next one at your usual time. This may mean that you are taking 2 tablets in one day.
- If you are **more than 12 hours late** in taking one of your small hormonal FEMODENE 28 tablets, you will not be protected. Take the last tablet as soon as you remember and take the next one at your normal time. This may mean taking 2 tablets in one day. You must take extra contraceptive precautions and you must follow the 7 day rule. Read the section on "*Extra contraceptive precautions*" and "*The 7 day rule*" carefully.
- If you forget tablets in the first week after taking the large non-hormonal tablets and had intercourse in the seven days before, consult your doctor as the possibility of pregnancy should be considered.
- If you have forgotten to take your small hormonal FEMODENE 28 tablets for a few days, consult your doctor to be sure you are not pregnant, then discard the missed tablets and follow the 7 day rule.

### **Extra contraceptive precautions**

When you need extra contraceptive precautions, either:

- don't have sex; or
- use a cap plus spermicide; or
- use a condom

Do not use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives alter the usual menstrual cycle changes, such as changes in temperature and cervical mucus.

### **The 7 day rule**

- Continue taking your Pills
- You will not be protected from pregnancy until you have taken your daily small hormone Pill for the next 7 days in a row
- Use another method of contraception (*Extra contraceptive precautions*) such as condoms or do not have sexual intercourse for these next 7 days
- If there are fewer than 7 small hormone Pills left before the non-hormonal pills, go straight on to the small hormone Pills in the green section of the next pack. This means you miss out the large white non-hormonal pills. You may not have a period until the end of the next pack. This is not harmful.

### **If you vomit or have severe diarrhea after taking FEMODENE 28**

If you vomit or have severe diarrhea within 3 to 4 hours after taking your FEMODENE 28 hormonal tablets, the active ingredients may not have been completely absorbed. This is like missing a tablet. Therefore, follow the advice for missed tablets. If vomiting or diarrhea occurs while taking the non-hormonal tablets, this does not have an influence on the contraceptive reliability.

## **If you are taking medicines that affect FEMODENE 28**

Some medicines may stop FEMODENE 28 from working properly. These medicines are listed in an earlier section. For the time that you are taking the medicine and for the next 7 days follow the advice for missed tablets. If you are taking rifampicin, or you are taking these medicines continuously, your doctor will advise you on the length of time you need to take extra contraceptive precautions.

## **If you want to delay a period**

You can delay your period if you miss out the large non-hormonal tablets and go straight to the small hormonal tablets in the green section of your next pack. Continue with this pack until this pack is empty. Your period will start while you are taking the large white non-hormonal tablets in the next pack. You may have some breakthrough bleeding or spotting while you are taking the small hormonal tablets.

## **If you want to change the starting day of your period**

If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the duration of taking the non-hormonal tablets. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should start your next pack 3 days sooner than you usually do, discard the 3 remaining large white tablets of your previous pack and then continue with the next pack without having a break between the packs. If you make the duration of taking the large non-hormonal tablets very short (e.g. 3 days or less), you may not have bleeding during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

## **If you have unexpected bleeding**

As with other Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) with FEMODENE 28 between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to FEMODENE 28 (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

## **If you have missed a period**

If you have taken all of your tablets at the right time, and you have not vomited, had severe diarrhea or used other medicines, then you are very unlikely to be pregnant. Continue to take FEMODENE 28 as usual.

If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of FEMODENE 28 until your doctor has checked that you are not pregnant.

## **When you want to stop taking FEMODENE 28**

You can stop taking FEMODENE 28 at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

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## Overdosage

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There have been no reports of serious harmful effects from taking too many FEMODENE 28 tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken FEMODENE 28, ask your doctor for advice. Taking the large white non-hormonal tablets is harmless because they do not contain any active ingredients.

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## When using FEMODENE 28

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### **Tell your doctor immediately if:**

**You should stop treatment and see your doctor immediately if you get a blood clot, heart attack or stroke while you are taking FEMODENE 28. Warning signs for a blood clot, heart attack or stroke to look out for are:**

- an unusual cough
- severe pain in the chest which may reach the left arm
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain or swelling in either of your legs

### **Tell your doctor if:**

#### **Contact your doctor as soon as possible if:**

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet; do not forget about the items related to your immediate family. (See also the section called "*Before you use FEMODENE 28*").
- you feel a lump in your breast
- you are going to use other medications. (See also the section called "*FEMODENE 28 and other medicines*").
- you are to be immobilized or are to have surgery (consult your doctor at least four weeks in advance)
- you have unusual, heavy vaginal bleeding

- you forgot tablets in the first week after taking the large non-hormonal tablets and had intercourse in the seven days before
- you have severe diarrhea
- you have missed your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor)

## Regular check-ups

When you are using FEMODENE 28, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

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## Side effects

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Tell your doctor if you notice any unwanted side effects, especially if severe or persistent, or if there is a change in your health that you think might be caused by FEMODENE 28.

### Serious side effects

Serious side effects associated with the use of combined oral contraceptives such as FEMODENE 28, as well as the related symptoms, are described in the following sections "*The Pill and thrombosis*" and "*The Pill and cancer*". Please read these sections for additional information and consult your doctor at once where appropriate.

### Other possible side effects

The following side effects have been reported in users of combined oral contraceptives such as FEMODENE 28, although they may not be caused by the contraceptive Pill. Such side effects that occur in the first few months that you are using FEMODENE 28 will probably lessen with time.

| System Organ Class                 | Common<br>( $\geq 1/100$ ) | Uncommon<br>( $\geq 1/1000$ and<br>$< 1/100$ ) | Rare<br>( $< 1/1000$ )     |
|------------------------------------|----------------------------|--|----------------------------|
| Eye Disorders                      |                            |  | Contact lens intolerance   |
| Gastrointestinal Disorders         | Nausea, abdominal pain     | Vomiting, diarrhea                             |                            |
| Immune System Disorders            |                            |  | Hypersensitivity reactions |
| Investigations                     | Weight gain                |  | Weight loss                |
| Metabolism and Nutrition Disorders |                            | Fluid retention                                |                            |
| Nervous System Disorders           | Headache                   | Migraine                                       |                            |

|  |                                |                    |   |
|--|--------------------------------|--------------------|---|
| Psychiatric Disorders                    | Depression, mood changes       | Increased libido   | Decreased libido  |
| Reproductive System and Breast Disorders | Breast pain, breast tenderness | Breast enlargement | Vaginal discharge, breast discharge                       |
| Skin and Subcutaneous Tissue Disorders   |                                | Rash, hives        | Skin reactions (erythema nodosum and erythema multiforme) |

If you have hereditary angioedema, taking estrogens may induce or exacerbate symptoms of angioedema. (See also "*Before you start to use FEMODENE 28*").

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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## Storage

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Do not use after the expiry date stated on the package.

Store all medicines properly and keep them out of reach of children.

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## Further information

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Like other combined oral contraceptive Pills, FEMODENE 28 may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. As a result, the risk of anemia may be lower. Your period pains may become less severe or may completely disappear.
- Some serious disorders have been reported to occur less frequently in users of "high-dose" oral contraceptive Pills. These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants outside of the womb) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for "low-dose" Pills such as FEMODENE 28, but so far this has only been confirmed for endometrial and ovarian cancer.

### **FEMODENE 28 tablets contain:**

*active substances (per tablet):*

gestodene (0.075 mg) and ethinylestradiol (0.03 mg)

*other substances:*

lactose monohydrate, maize starch, povidone 25 000, sodium calcium edetate, magnesium stearate, sucrose, povidone 700 000, macrogol 6000, calcium carbonate, purified talc, montanglycol wax

**If you have any further questions please consult your doctor or pharmacist.**

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## **Name and Address**

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## **Date of Preparation**

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1st February 2007