

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using FEMME-TAB ED 20/100?

FEMME-TAB 20/100 contains the active ingredients Levonorgestrel (a progestogen) and Ethinylestradiol (an oestrogen). FEMME-TAB 20/100 is used to prevent pregnancy. FEMME-TAB ED 20/100 may also have non-contraceptive health benefits like your period may be lighter and shorter. As a result, the risk of anaemia may be lower. Your period pains may become less severe or may completely disappear.

For more information, see Section [1. Why am I using FEMME-TAB ED 20/100?](#) in the full CMI.

### 2. What should I know before I use FEMME-TAB ED 20/100?

Do not use if you have ever had an allergic reaction to Levonorgestrel and/or Ethinylestradiol or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use FEMME-TAB ED 20/100?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FEMME-TAB ED 20/100 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use FEMME-TAB ED 20/100?

- The FEMME-TAB ED 20/100 pack contains 21 round white to off-white active tablets and 7 red-brown inactive 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 red-brown inactive 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.

More instructions can be found in Section [4. How do I use FEMME-TAB ED 20/100?](#) in the full CMI.

### 5. What should I know while using FEMME-TAB ED 20/100?

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>• If you vomit within 3 to 4 hours or have severe diarrhoea after taking a white to off-white active tablet, the active ingredients may not have been completely absorbed. This should be treated as missing a tablet. Follow the advice above for missed tablets.</li> <li>• FEMME-TAB ED 20/100 does not protect you from sexually transmitted diseases (STDs), such as HIV-AIDS, Chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis. You will need additional barrier contraceptives (e.g. condoms) to protect yourself from STDs.</li> <li>• When you are using FEMME-TAB ED 20/100, your doctor will tell you to return for regular check-ups, including a pap smear test. Your doctor will advise how often you need to take the test.</li> <li>• Stop taking FEMME-TAB ED 20/100 and see your doctor immediately if you get a blood clot, heart attack or stroke: you become pregnant while taking the medicine or if you miss your period twice in a row.</li> <li>• Call your doctor straight away if you develop high blood pressure while taking the medicine.; if you have unexpected bleeding and it continues, becomes heavy, or occurs again. if you have any concerns for a missed period. It is very unlikely to be pregnant if you have been taking the medicine correctly, provided that you have taken the white to off-white active tablets at the right time, you have not been taking any other medicines that may interfere with FEMME-TAB ED 20/100, and you have not vomited or had severe diarrhoea during the cycle.</li> </ul>
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<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking FEMME-TAB ED 20/100, or do not take a tablet every day.</li> <li>• Do not use FEMME-TAB ED 20/100 for other purposes unless advised by your doctor.</li> <li>• Do not give your medicine to anyone else.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep the medicine in the original packaging in a cool and dry place below 25 °C.</li> <li>• Do not take the tablets out from the blister until it is time to take them.</li> <li>• Follow the instructions in the carton on how to take care of your medicine properly.</li> </ul>

For more information, see Section [5. What should I know while using FEMME-TAB ED 20/100?](#) in the full CMI.

## 6. Are there any side effects?

**Less serious side effects:** Gastrointestinal (nausea), Reproductive System and Breast Disorders (breast tenderness or pain, hirsutism, Skin (acne, alopecia), Metabolism and nutrition disorders (weight gain). **Speak to your doctor if you have any of these less serious side effects and they worry you.**

**Serious side effects:** Blood and Lymphatic System Disorders (possible signs of a thrombosis: chest pain, which may increase with deep breathing; breathlessness and/or difficulty breathing; painful swelling in your leg(s); weakness, numbness or bad ‘pins and needles’ of an arm or leg; pain or tenderness in the leg which may only be felt when standing or walking; increased warmth in the affected leg, red or discoloured skin on the leg; severe, sudden stomach pains; severe light-headedness or dizziness; rapid or irregular heartbeat; a bad fainting attack or you collapse; unusual headaches or migraines that are worse than usual; sudden problems with your speech or eyesight, or motor coordination; sudden coughing which may result in you coughing up blood; pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; feeling of being full, having indigestion or choking; sweating, nausea, vomiting or dizziness). Reproductive System and Breast Disorders (breast lumps, unexplained vaginal bleeding). Liver (Eyes/skin turning yellow (jaundice)). **Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FEMME-TAB ED 20/100

Active ingredient(s): [Levonorgestrel 100 µg / Ethinylestradiol 20 µg]

## Consumer Medicine Information (CMI)

This leaflet provides important information about using FEMME-TAB ED 20/100. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FEMME-TAB ED 20/100.**

Where to find information in this leaflet:

- [1. Why am I using FEMME-TAB ED 20/100?](#)
- [2. What should I know before I use FEMME-TAB ED 20/100?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FEMME-TAB ED 20/100?](#)
- [5. What should I know while using FEMME-TAB ED 20/100?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using FEMME-TAB ED 20/100?

FEMME-TAB ED 20/100 contains the active ingredients **Levonorgestrel 100 µg and Ethinylestradiol 20 µg**. FEMME-TAB ED 20/100 is a combined oral contraceptive (often called "the Pill") consisting of 21 white to off white active tablets and 7 red-brown inactive (placebo) tablets. Each white to off white round film-coated tablet contains a small amount of two different female hormones. These are Levonorgestrel (a progestogen) and Ethinylestradiol (an oestrogen). Because of the small amount of hormones, FEMME-TAB ED 20/100 is considered to be a low-dose combined oral contraceptive preparation. The red-brown inactive tablets do not contain any active ingredients.

**FEMME-TAB ED 20/100 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.

Like other combined oral contraceptive pills, FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100, but so far this has only been confirmed for endometrial and ovarian cancer.

## 2. What should I know before I use FEMME-TAB ED 20/100?

### Warnings

**Do not use FEMME-TAB ED 20/100 if:**

- You are allergic (hypersensitive) to Levonorgestrel and/or Ethinylestradiol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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 "FEMME-TAB ED 20/100 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., cancer of the breast or the genital organs)
- You have or have had a benign or malignant liver tumour.
- You have any unexplained vaginal bleeding.
- You are pregnant or think you might be pregnant.

## Check with your doctor if you:

- Have 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 haemolytic 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.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100 you should see your doctor as soon as possible.

FEMME-TAB ED 20/100 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.

## FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100, or where the reliability of FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100 alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

## FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100 you should stop smoking, especially if you are older than about 35 years of age.**

If you develop high blood pressure while using FEMME-TAB ED 20/100, 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 FEMME-TAB ED 20/100) the risk may be even higher. Tell your doctor you are using FEMME-TAB ED 20/100 well in advance of any expected hospitalization or surgery. Your doctor may tell you to stop taking FEMME-TAB ED 20/100 several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start taking FEMME-TAB ED 20/100 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 "Stop taking FEMME-TAB ED 20/100 and see your doctor immediately ")

### **FEMME-TAB ED 20/100 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 tumours have been reported in users of the Pill. These tumours 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 (HPV) 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 behaviour including use of barrier contraceptives.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

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

#### **Some medicines may interfere with FEMME-TAB ED 20/100 and affect how it works.**

Some medicines may stop FEMME-TAB ED 20/100 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).

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 FEMME-TAB ED 20/100 which medicines you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use FEMME-TAB ED 20/100. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FEMME-TAB ED 20/100.**

### **4. How do I use FEMME-TAB ED 20/100?**

#### **How much to take / use**

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information in this leaflet.
- When you follow the directions correctly, the contraceptive protection provided by FEMME-TAB ED 20/100 is continuous. This includes the week when you take the inactive tablets.
- Additional contraceptive precautions are only required when special circumstances (e.g. forgetting tablets) reduce the reliability of the preparation.
- Remember that FEMME-TAB ED 20/100 has been prescribed for you personally. Do not share it with others.

#### **When and how to take FEMME-TAB ED 20/100**

The FEMME-TAB ED 20/100 pack contains 21 round white to off-white active tablets and 7 red-brown inactive 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 red-brown inactive 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 FEMME-TAB ED 20/100**

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

Start taking FEMME-TAB ED 20/100 on the first day of your cycle, i.e. the first day of menstrual bleeding. Take your first tablet from the red section marked with that day of the week. For example, if your period starts on a Monday, take the tablet marked Monday from the red section of the pack. Then follow the days in order of the directional arrows. When you start taking FEMME-TAB ED 20/100 your very first cycle may be shorter than usual. FEMME-TAB ED 20/100 will work immediately, it is not necessary to use an additional contraceptive method.

##### **When changing from a combined Pill, or vaginal ring**

You start taking FEMME-TAB ED 20/100 the day after you take the last active tablet from your present Pill pack (this means no tablet-free break or taking of the inactive tablets). Take your first tablet from the red section marked with that day of the week. If you are not sure which are the active tablets in your present Pill pack, ask your doctor or pharmacist.

Where you have used a vaginal ring, you should start using FEMME-TAB ED 20/100 on the day of removal. 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 FEMME-TAB ED 20/100 the next day, at the usual time. Take your first tablet from the red section marked with that day of the week. 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 system (IUS)**

Start using FEMME-TAB ED 20/100 when your next injection is due or on the day that your implant or IUS is removed. Take your first tablet from the red section marked with that day of the week. 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 FEMME-TAB ED 20/100. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take FEMME-TAB ED 20/100, 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 FEMME-TAB ED 20/100. In all situations where the reliability of FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100 from working properly and in the case of vomiting or severe diarrhoea after taking FEMME-TAB ED 20/100.

#### **If you forget to use FEMME-TAB ED 20/100**

FEMME-TAB ED 20/100 should be used regularly at the same time each day. If you miss your dose at the usual time, review the case as the following instructions:

- If you forget to take a red-brown inactive tablet, take it as soon as you remember and continue to take the medicine as usual. As the inactive tablets do not contain any active ingredients, you are still protected against pregnancy.
- If you missed a white to off-white active tablet and remembered to take the missed tablet within 12 hours, you will be protected against pregnancy.

**If you missed a white to off-white tablet for more than 12 hours, follow the detailed instructions below:**

**If you have been taking the white to off-white active tablets for 7 uninterrupted days before your missed tablet:**

- **Take the missed tablet as soon as you remember and continue to take the medicine as usually, even if this means taking 2 tablets in one day.**
- After missing a white to off-white active tablet, the chance of pregnancy depends on when you missed the tablet. The risk of pregnancy is higher if you missed a tablet at the beginning or end of a pack.
- *If after taking your missed tablet you have less than 7 white to off-white tablets left in the blister pack, you should continue to finish the white to off-white tablets in that blister but skip the red-brown inactive tablets and start to take the white to off-white active tablets from the next pack corresponding to the correct day of the week.*
- This is the best way to maintain protection against pregnancy. You may not have a period until the end of the white to off-white tablets in the second blister pack. You may have spotting or breakthrough bleeding during the days of taking the active tablets.

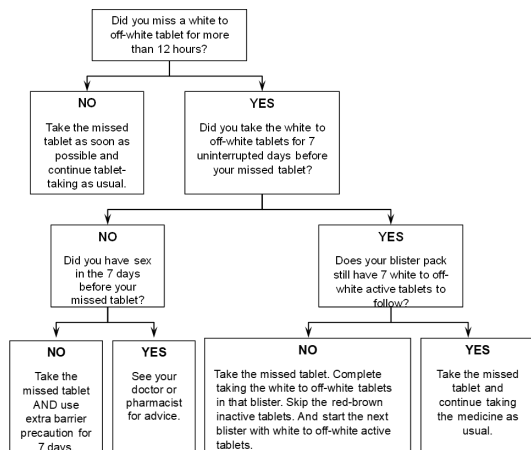
**If you have been taking the white to off-white active tablets for less than 7 uninterrupted days before your missed tablet:**

**Take the missed tablet as soon as you remember and continue to take the medicine as usually, even if this means taking 2 tablets in one day. You should also use additional barrier contraceptive precautions for the next 7 days:** Either don't have sex or use a cap plus spermicide or 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. If you have sex during that time, it is possible to get pregnant and you may need emergency contraception.

*If you have had sex in the week before the missed tablet, it is possible to get pregnant. See your doctor or pharmacist for advice.*

**If you forget to take more than one white to off-white active tablet, see your doctor or pharmacist for advice.**

Please refer to the below diagram for a summary of advice if you missed a white to off-white active tablet. Please ask your doctor or pharmacist if you have any questions regarding how to take this medicine.



### If you vomit or have severe diarrhoea after taking FEMME-TAB ED 20/100

If you vomit or have severe diarrhoea within 3 to 4 hours after taking your FEMME-TAB ED 20/100 active 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 diarrhoea occurs while taking the inactive tablets, this does not have any influence on the contraceptive reliability.

### If you are taking medicines that affect FEMME-TAB ED 20/100

Some medicines may stop FEMME-TAB ED 20/100 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 red-brown inactive tablets and go straight to the white to off-white active tablets in the red section of your next blister pack. Continue with this pack until this pack is empty. Your period will start while you are taking the red-brown inactive tablets in the next pack. You may have some breakthrough bleeding or spotting while you are taking the white to off-white active 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 red-brown inactive 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 red-brown 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 inactive 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 FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100 (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 diarrhoea or used other medicines, then you are very unlikely to be pregnant. Continue to take FEMME-TAB ED 20/100 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 FEMME-TAB ED 20/100 until your doctor has checked that you are not pregnant.

### When you want to stop taking FEMME-TAB ED 20/100

You can stop taking FEMME-TAB ED 20/100 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.

### If you use too much FEMME-TAB ED 20/100

There have been no reports of serious harmful effects from taking too many FEMME-TAB ED 20/100 tablets at one time. If you think that you have used too much FEMME-TAB ED 20/100, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while using FEMME-TAB ED 20/100?

### Things you should do

**If you vomit within 3 to 4 hours or have severe diarrhoea after taking a white to off-white active tablet**, the active ingredients may not have been completely absorbed. This should be treated as missing a tablet. Follow the advice above for missed tablets.

FEMME-TAB ED 20/100 does not protect you from sexually transmitted diseases (STDs), such as HIV-AIDS, Chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B,

human papilloma virus and syphilis. **You will need additional barrier contraceptives (e.g. condoms) to protect yourself from STDs.**

#### **Have regular check-ups with your doctor.**

When you are using FEMME-TAB ED 20/100, your doctor will tell you to return for regular check-ups, including a pap smear test. Your doctor will advise how often you need to take the test.

#### **Stop taking FEMME-TAB ED 20/100 and see your doctor immediately:**

- if you get a blood clot, heart attack or stroke. 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.
- if you become pregnant while taking the medicine.
- if you miss your period twice in a row. You may be pregnant. Do not start the next pack of FEMME-TAB ED 20/100 until your doctor has checked that you are not pregnant.

#### **Call your doctor straight away if you:**

- if you develop high blood pressure while taking the medicine. You may be advised to stop taking it.
- if you have unexpected bleeding and it continues, becomes heavy, or occurs again. When taking this pill for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection but continue to take your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.
- if you have any concerns for a missed period. It is very unlikely to be pregnant if you have been taking the medicine correctly, provided that you have taken the white to off-white active tablets at the right time, you have not been taking any other medicines that may interfere with FEMME-TAB ED 20/100, and you have not vomited or had severe diarrhoea during the cycle.

Remind any doctor, dentist, or pharmacist you visit that you are using FEMME-TAB ED 20/100:

- Before you have any treatments or tests

- Before you start any new medicines
- Before any surgeries. The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). The excess risk of thrombosis is highest during the first year a woman takes a combined oral contraceptive. Your doctor may tell you to stop taking the medicine several weeks before surgery, or at the time of immobilisation, and when you can start taking the medicine again.

#### **Things you should not do**

- Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking FEMME-TAB ED 20/100, or do not take a tablet every day.
- Do not use FEMME-TAB ED 20/100 for other purposes unless advised by your doctor.
- Do not give your medicine to anyone else.

#### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how FEMME-TAB ED 20/100 affects you.**

#### **Looking after your medicine**

- Keep the medicine in the original packaging in a cool and dry place below 25 °C.
- Do not take the tablets out from the blister until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

- Do not store the medicine in the bathroom, near a sink or on a windowsill.
- Do not leave the medicine in the car.

**Keep it where young children cannot reach it.**

#### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

There is a risk of developing venous thromboembolism and arterial thromboembolism with use of this product. The degree of risk associated with developing these conditions will depend on your familial history and personal circumstances. Your doctor will discuss these risk factors with you.

## Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>nausea</li> </ul> <b>Reproductive System and Breast Disorders:</b> <ul style="list-style-type: none"> <li>breast tenderness or pain</li> <li>hirsutism</li> </ul> <b>Skin-related:</b> <ul style="list-style-type: none"> <li>acne</li> <li>alopecia</li> </ul> <b>Metabolism and nutrition disorders</b> <ul style="list-style-type: none"> <li>weight gain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<b>Blood and Lymphatic System Disorders:</b> possible signs of a thrombosis: <ul style="list-style-type: none"> <li>chest pain, which may increase with deep breathing.</li> <li>breathlessness and/or difficulty breathing.</li> <li>painful swelling in your leg(s)</li> <li>weakness, numbness or bad 'pins and needles' of an arm or leg.</li> <li>pain or tenderness in the leg which may only be felt when standing or walking.</li> <li>increased warmth in the affected leg, red or discoloured skin on the leg.</li> <li>severe, sudden stomach pains</li> <li>severe light-headedness or dizziness.</li> <li>rapid or irregular heartbeat</li> <li>a bad fainting attack or you collapse.</li> <li>unusual headaches or migraines that are worse than usual.</li> <li>sudden problems with your speech or eyesight, or motor coordination</li> <li>sudden coughing which may result in you coughing up blood.</li> <li>pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm or below the breastbone.</li> <li>discomfort radiating to the back, jaw, throat, arm, stomach.</li> <li>feeling of being full, having indigestion or choking.</li> <li>sweating, nausea, vomiting or dizziness.</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Reproductive System and Breast Disorders:</b> <ul style="list-style-type: none"> <li>breast lumps</li> <li>unexplained vaginal bleeding.</li> </ul> <b>Liver-related:</b> <ul style="list-style-type: none"> <li>Eyes/skin turning yellow (jaundice)</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What FEMME-TAB ED 20/100 contains

<b>Active ingredients (main ingredients)</b>	Levonorgestrel 100 µg Ethinylestradiol 20 µg
<b>Other ingredients (inactive ingredients)</b>	Each white to off-white active tablet also contains: <ul style="list-style-type: none"> <li>Lactose monohydrate</li> <li>Maize starch</li> <li>Gelatine</li> <li>Magnesium stearate</li> <li>Hypromellose (3cps)</li> <li>Macrogol 4000</li> <li>Titanium dioxide (E171).</li> </ul> Each red-brown inactive tablet contains: <ul style="list-style-type: none"> <li>Lactose monohydrate</li> <li>Maize starch</li> <li>Gelatine</li> <li>Magnesium stearate</li> <li>Hypromellose (3cps)</li> <li>Macrogol 4000</li> <li>Titanium dioxide (E171)</li> <li>Iron oxide red (E172)</li> </ul>
<b>Potential allergens</b>	Levonorgestrel Ethinylestradiol

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What FEMME-TAB ED 20/100 looks like**

FEMME-TAB ED 20/100 is comes in a box containing 1, 3 or 4 blister packs.

Each blister pack contains 21 white to off-white active tablets and 7 red-brown inactive tablets.

The blister is marked with the days of the week for each tablet.

AUST R 170389.

### **Who distributes FEMME-TAB ED 20/100**

AFT Pharmaceuticals Pty Ltd

113 Wicks Road

North Ryde

Sydney, NSW 2113

Email: [customer.service@aftp pharm.com](mailto:customer.service@aftp pharm.com)

This leaflet was prepared in September 2023.