

# TRIFEME®

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## 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.

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### 1. Why am I using TRIFEME?

TRIFEME contains two active ingredients, levonorgestrel and ethinylestradiol. TRIFEME is used to prevent pregnancy.

For more information, see Section [1. Why am I using TRIFEME?](#) in the full CMI.

### 2. What should I know before I use TRIFEME?

Do not use if you have ever had an allergic reaction to levonorgestrel, ethinylestradiol, any other oral contraceptives 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 TRIFEME?](#) in the full CMI.

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

Some medicines may interfere with TRIFEME 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 TRIFEME?

- Take one tablet at the same time every day, regardless of how often you have sex.
- See the full CMI for instructions on how to start taking TRIFEME for the first time or how to change to TRIFEME from a different contraceptive.

More instructions can be found in Section [4. How do I use TRIFEME?](#) in the full CMI.

### 5. What should I know while using TRIFEME?

Things you should do	
	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using TRIFEME.</li><li>• Tell your doctor immediately if you</li></ul>

	<p>become pregnant while taking TRIFEME.</p> <ul style="list-style-type: none"> <li>• See your doctor if you have not taken your tablets correctly and have missed a period.</li> <li>• Have regular check-ups from your doctor, including a Pap smear.</li> <li>• Perform regular breast self-examination.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine or change the dosage, without checking with your doctor.</li> </ul> <p>If you stop taking TRIFEME or do not take a tablet every day without using another form of contraception, you may become pregnant.</p>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Make sure you know how TRIFEME affects you before you drive or use machines. TRIFEME may cause dizziness in some people.</li> </ul>

### Looking after your medicine

- Keep TRIFEME in a cool, dry place where the temperature stays below 25°C and is away from light.
- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack, they may not keep well.

For more information, see Section [5. What should I know while using TRIFEME?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include changes to your bleeding patterns, painful periods, breast tenderness, changes in sex drive, abdominal pain, cramps or bloating, changes to your mood, headaches, weight changes, swelling of the hands, ankles or feet, acne, loss of scalp hair, increase in body hair. More serious side effects include blood clots, worsening or new onset of migraines/headaches, jaundice (yellowing of skin or eyes), significant rise in blood pressure, worsening of existing conditions, e.g. epileptic seizures.

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.



# TRIFEME®

**Active ingredient(s):** *levonorgestrel and ethinylestradiol*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using TRIFEME. **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 TRIFEME.**

**Where to find information in this leaflet:**

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

## 1. Why am I using TRIFEME?

TRIFEME contains two active ingredients, levonorgestrel and ethinylestradiol, which are similar to the hormones that your body normally produces. TRIFEME is an oral contraceptive, commonly known as a "birth control pill" or "the Pill".

**TRIFEME is used to prevent you from becoming pregnant if taken correctly:**

- By preventing ovulation (the release of an egg from the ovary) during each menstrual cycle
- It changes the cervical mucus consistency making it difficult for the sperm to reach the egg
- It changes the lining of the uterus making it less suitable for implantation.

Your doctor may have prescribed TRIFEME for another reason.

Ask your doctor if you have any questions about why TRIFEME has been prescribed for you.

## **2. What should I know before I use TRIFEME?**

### **Warnings**

#### **Do not use TRIFEME if:**

1. You are allergic to levonorgestrel or ethinylestradiol, or any other similar medicines (such as other oral contraceptives) or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing

- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

2. You have, or have had a blood clot in the:

- legs (thrombophlebitis or deep vein thrombosis (DVT)) or lungs (pulmonary embolism (PE))
- heart (heart attack)
- brain (stroke)
- eyes
- other parts of the body

3. You are at increased risk of a blood clot in the legs (DVT) or lungs (PE) due to any of the following:

- A family history of blood clots (DVT or PE) or you have been advised that you have an increased risk of blood clots
- Major surgery and have been confined to bed for long periods of time, including any surgery to the legs or pelvis, neurosurgery, or major trauma
- Biochemical factors, such as Activated Protein C resistance (including Factor V Leiden), antithrombin-III deficiency, protein C deficiency, protein S deficiency
- Cancer, systemic lupus erythematosus (SLE), haemolytic uraemic syndrome (HUS) (a disorder of blood coagulation causing failure of the kidneys), chronic inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Sickle cell disease

- Obesity, age above 35 years, high cholesterol
  - Smoking, particularly if you are a heavy smoker (15 or more cigarettes per day) and are aged over 35 years
  - Pregnancy
4. You have, or have had, blood clots in the arteries (known as arterial thromboembolism (ATE)).  
Examples of these include:
- Stroke
  - Angina (chest pain)
  - Transient ischaemic attack or "mini stroke"
5. You are at increased risk of ATE, including:
- A family history of ATE or you have been advised that you have an increased risk of ATE, including if you have a condition called antiphospholipid syndrome (a condition that makes your blood more likely to clot), or hyperhomocysteinaemia (a high level of a substance called homocysteine in the blood).
  - History of migraine, accompanied by blurred vision, difficulty in speaking, muscle weakness, or increased sensitivity to light, sound, or noise
  - Multiple risk factors for ATE or a serious risk factor for ATE that include:
    - Uncontrolled high blood pressure
    - Diabetes with blood vessel damage
    - Severe lipid disease
    - Sickle cell anaemia.
6. You have or have had any of the following conditions:
- Disease in any blood vessel(s)

- Inflammation of the pancreas, which is associated with very high blood levels of triglycerides (fatty substances)
  - Liver tumour or liver disease
  - Yellowing of the whites of the eyes or the skin (jaundice) during pregnancy or during previous use of an oral contraceptive
  - Vaginal bleeding, the cause of which is unknown
  - Cancer or suspected cancer of the breast or genital organs (e.g. cervix, vagina, ovaries, endometrium, womb) and known or suspected estrogen-dependent tumours
7. You are pregnant or you think you are pregnant. Pregnancy must be excluded before you start taking TRIFEME.
8. You are taking anti-viral hepatitis C virus (HCV) medicinal products such as those containing glecaprevir, pibrentasvir, ombitasvir, paritaprevir, ritonavir and dasabuvir with or without ribavirin. If you are not sure about your anti-HCV medication, tell your doctor.
9. Do not give this medicine to a child who has not had their first period. You have already experienced menopause.

### **Check with your doctor if you:**

- Take any medicines for any other condition
- Have any other medical conditions or health problems, such as:

- Heart disease including heart valve disorders or certain heart rhythm disorders
- High blood pressure, a history of high blood pressure, or high blood pressure during pregnancy
- High cholesterol
- Hepatitis C
- Diabetes
- Migraine or other headaches
- Hyperhomocysteinemia
- Breast lumps, abnormal breast X-ray or mammogram
- Epilepsy
- Depression
- Gallbladder disease
- Fluid retention or kidney disease
- Asthma
- Fibroids
- Yellowing of the whites of the eyes or skin (jaundice) during pregnancy or during previous oral contraceptive use
- Hereditary angioedema (swelling of the face, lips, mouth, tongue or throat).

If you have any of these conditions, you should have regular check-ups with your doctor to make sure that taking TRIFEME is not making the conditions worse.

- Are over 35 years of age or are overweight.
- Recently had a baby, lost a baby in the second trimester or had an abortion

- Are planning a long-haul plane flight (greater than 4 hours).
- Are intolerant to some sugars, or your doctor has told you so. TRIFEME contains lactose.
- You are allergic to any foods, dyes, preservatives or any other medicines.

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**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss the risks and benefits involved with you.

## **Blood clots**

You must tell your doctor if you or anyone in your immediate family has, or has had, blood clots in the legs or lungs or anywhere else in the body

Blood clots are a rare occurrence when taking an oral contraceptive.

The risk of a blood clot is highest during the first year of taking an oral contraceptive for the first time or if you are re-starting the "pill" after a break of 4 weeks or more.

The risk of having a blood clot is higher in oral contraceptive users than in non-users but is not as high as during pregnancy.

## **Stroke**

You must tell your doctor if you or anyone in your immediate family has, or has had, a stroke or heart attack.

Taking oral contraceptives is linked with an increased risk of having a heart attack, angina, stroke or a "mini stroke".

## **Medical check-ups**

Before you start to take TRIFEME, you must have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine test.

### **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.

**Some medicines may interfere with TRIFEME and affect how well it or the other medicine works. This may lead to unwanted side effects, reduce the effect of TRIFEME and/or the other medicine.**

**These medicines include:**

- Atorvastatin, used to treat high cholesterol
- Indinavir for the treatment of HIV infection
- Anti-fungal agents such as itraconazole and fluconazole
- Paracetamol
- Ascorbic acid (Vitamin C)
- Ciclosporin, used to prevent organ rejection
- Theophyllines, used for asthma and other breathing difficulties
- Corticosteroids
- Lamotrigine, for seizures
- Medicines for high blood pressure
- Medicines for epilepsy
- Medicines used to "thin the blood" (anticoagulants)
- Medicines for diabetes or high blood sugar levels

**Medicines that may reduce the effect of TRIFEME include:**

- Anti-viral hepatitis C virus (HCV) medicines such as glecaprevir, pibrentasvir, ombitasvir, paritaprevir, ritonavir and dasabuvir
- Rifampicin and rifabutin for the treatment of tuberculosis
- Antibiotics such as ampicillin, other penicillins and tetracyclines
- Anti-fungal agents such as griseofulvin
- Barbiturates (certain types of medicines prescribed for epilepsy, such as phenobarbitone)
- Medicines for epilepsy (such as phenytoin, primidone, carbamazepine and topiramate)

- Ritonavir for the treatment of HIV infection
- Modafinil used to treat excessive daytime sleepiness
- St. John's wort, an ingredient in many medicines you can buy without a prescription from a pharmacy, health food shop or supermarket
- Corticosteroids such as dexamethasone

**While you are taking any of these medicines and for the next 7 days after stopping them, you must use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods).**

**If you come to the end of the yellow tablets during this time, start the next pack straight away. Skip the 7 red tablets.**

**If you take rifampicin and some other medicines, you may need to use additional non-hormonal contraception for four weeks after finishing the course of treatment.**

Ask your doctor or pharmacist about how long you need to use additional non-hormonal contraception.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking TRIFEME.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRIFEME.**

## 4. How do I use TRIFEME?

### How much to take

- Take one tablet every day.
- Follow the instructions provided and use TRIFEME until your doctor tells you to stop.

### When to take TRIFEME

- TRIFEME should be taken every day, regardless of how often you have sex.
- TRIFEME will work best if you do not miss any tablets and take it at the same time each day. Taking your tablet at the same time each day will also help you remember when to take the tablets.
- It does not matter if you take TRIFEME before or after food.
- If you are concerned about this, please speak to your doctor or pharmacist.

### How to take TRIFEME

- Swallow one tablet whole with a full glass of water.
- Each blister pack of TRIFEME contains 21 active tablets: 6 tablets are brown, 5 tablets are white and 10 tablets are yellow in colour; and 7 inactive tablets which are red. Each blister strip of TRIFEME provides a month of tablets. It is important that you take the tablets in the correct order. Following the arrows on the blister strip will assist you.

## **How to start taking TRIFEME for the first time**

1. On the first day of your menstrual period, take a tablet that matches the day of the week from the shaded section of the blister pack. If your period starts between Monday and Friday, your first tablet is red. If your period starts on a Saturday or Sunday, your first tablet is brown.

**You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until you have taken a brown or white tablet in the correct order every day for 7 days without a break.**

2. Then take one tablet each day; following the arrows so that you are taking the correct tablet for the day of the week until all tablets have gone.
3. You will have a 'withdrawal' bleed, similar to having a period, during the week of the red tablets.

**If you do not have a period while you are taking the red tablets, and there is any chance that you have not followed all the instructions in this leaflet, contact your doctor to check if you are pregnant.**

## **Going on to further blister packs**

1. On the day after the last tablet in your previous blister pack, begin the next pack by taking a tablet from the shaded section of the blister pack. If the day of the week when you start your new pack is between Monday and Friday, your first tablet is red. If it is

Saturday or Sunday, your first tablet is brown. Do this even if you are still bleeding.

2. Each new pack is started with a red or brown tablet on the same day as the first pack, so that you have 6 days on brown tablets, 5 days on white tablets, 10 days on yellow tablets and 7 days on red tablets. There is no break between packs.
3. If you start taking your new pack late, you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until you have taken a brown or white tablet in the correct order every day for 7 days without a break.

## **Switching to TRIFEME from a different oral contraceptive**

**Follow these steps if your current oral contraceptive contains an estrogen and a progestogen:**

1. Stop taking your current oral contraceptive after you have taken the last active tablet. If your current oral contraceptive pack also contains inactive, or reminder tablets, do not take them.
2. The next day, take the first tablet from the shaded section that matches the day of the week. If the day of the week is between Monday and Friday, your first tablet is red. If the day of the week is Saturday or Sunday, your first tablet is brown.

**You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until you have taken a brown or white**

**tablet in the correct order every day for 7 days without a break.**

3. Then take one tablet each day, following the arrows so that you are taking the correct tablet for the day of the week until all of the tablets have gone.
4. You will have a 'withdrawal' bleed, similar to having a period, during the week of red tablets.

**If you do not have a period while you are taking the red tablets, and there is any chance that you have not followed all of the advice in this leaflet, contact your doctor to check if you are pregnant.**

**If your current oral contraceptive only contains a progestogen:**

- You can stop taking a progestogen-only contraceptive tablet any day and start taking TRIFEME the next day, at the same time.
- If you have been using a progestogen-only implant, start taking TRIFEME on the day the implant is removed.
- If you have been using a progestogen-only injection, start taking TRIFEME on the day the next injection would be due.
- In all cases start TRIFEME by taking a red or brown tablet from the shaded section that matches the day of the week.
- You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until you have taken a brown or white tablet in the correct order every day for 7 days without a break.

## **If you forget to take TRIFEME**

TRIFEME should be used regularly at the same time each day. If you miss your dose at the usual time, it may not work as well in protecting you from becoming pregnant.

**Do not take a double dose to make up for the dose you missed.**

**If you miss one active tablet (brown, white or yellow tablet):**

- If it is less than 12 hours late, take the missed tablet immediately. Take the next tablet at your usual time, even if this means taking two active tablets in one day.

**If you do not take the missed tablet within 12 hours, TRIFEME may not work as well in protecting you from becoming pregnant.**

- If you remember your missed tablet more than 12 hours late, take the last missed tablet as soon as you remember and the next tablet at the usual time.

Continue to take your tablets at the usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until you have taken an active tablet in the correct order every day for 7 days without a break. If you come to the end of the yellow tablets during this time, start the next pack straight away. Skip the 7 red tablets.

**If you miss two active tablets (brown, white or yellow tablets):**

- Take the last missed tablet as soon as you remember and then the next tablet at the usual time.
- Continue to take your tablets at the usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until you have taken an active tablet in the correct order every day for 7 days without a break. If you come to the end of the yellow tablets during this time, start the next pack straight away. Skip the 7 red tablets.
- You may not have a withdrawal bleed until the end of this new pack, but you may have spotting or breakthrough bleeding when taking the active tablets. If you do not have a withdrawal bleed at the end of the new pack, contact your doctor, who must make sure that you are not pregnant before you start the next pack.

**If you miss three or more active tablets (brown, white or yellow tablets):**

- Contact your doctor for advice on what to do.

**If you miss a red tablet:**

- If you miss one or more inactive, red tablets, leave them in the pack and do not worry.
- However, if you miss red tablets and then forget to start the next pack on time, start as soon as you remember by taking a brown tablet that matches the day of the week. You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until you have taken a brown or white tablet

in the correct order every day for 7 days without a break.

- If you are not sure what to do, ask your doctor or pharmacist.

If you are having trouble remembering to take TRIFEME, ask your pharmacist for some hints.

### **If you vomit or have diarrhoea after taking TRIFEME**

If you have vomiting or diarrhoea within 4 hours of taking an active tablet (brown, white or yellow tablet), you must use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until you have taken an active tablet in the correct order every day for 7 days without a break. If you come to the end of the yellow tablets during this time, start the next pack straight away. Skip the 7 red tablets.

The tablet may not have time to be absorbed properly and may not protect you from becoming pregnant.

If you have vomiting or diarrhoea after taking a red tablet, do not worry.

### **If you take too much TRIFEME**

If you think that you have taken too much TRIFEME, 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.**

Symptoms of an overdose may include:

- Feeling sick or vomiting
- Dizziness
- Feeling sleepy or tired
- Women may also experience menstrual bleeding.

## **5. What should I know while using TRIFEME?**

### **Things you should do**

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking TRIFEME.
- If you are about to start taking any new medicines, tell the doctor or pharmacist that you are taking TRIFEME.

If you are about to have any blood tests, tell your doctor you are taking TRIFEME. It may interfere with the results of some tests.

- Tell your doctor you are taking TRIFEME at least 4 weeks before any planned hospitalisation or surgery.

Your doctor may tell you to stop taking TRIFEME several weeks before surgery or at the time of immobilisation. Your doctor will tell you when you can start taking TRIFEME after you are back on your feet.

To avoid pregnancy during this time you must use a non-hormonal method of contraception such as condoms or a diaphragm.

## **Missed periods**

- If you miss a period and you have taken your tablets correctly, continue taking your tablets as you would normally.
- Sometimes you might not have a menstrual period while taking TRIFEME.
- If you miss a period and you have not taken your tablets correctly, keep taking your tablets and see your doctor immediately.

Not taking your tablets correctly includes missing one or more tablets or starting a new pack later than you should have.

- If you miss two menstrual periods, stop taking your tablets and see your doctor, even if you have taken the tablets correctly. You must use a non-hormonal method of contraception, (such as condoms or a diaphragm) during this time.
- Your doctor should make sure you are not pregnant before you start taking TRIFEME again.

## **Medical check up**

- Have regular check-ups from your doctor, including a Pap smear.
- Oral contraceptives should not be prescribed for longer than one year without your doctor carrying out a check-up. Your doctor will advise you how often

you need a Pap smear. A Pap smear can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cervical cancer. The most important risk factor for cervical cancer is persistent human papillomavirus (HPV) infection. However, cervical cancer has been reported to occur more often in women using an oral contraceptive for a long time. This finding may not be caused by the oral contraceptive but may be related to sexual behaviour and other reasons.

## **Breast cancer risk**

- Perform regular breast self-examination.
- Risk factors for the development of breast cancer include increasing age, family history, obesity, never having had a baby, and late age for first full-term pregnancy. Breast cancer has also been found slightly more often in women who take oral contraceptives than in women of the same age who do not. This slight increase in the number of breast cancer cases gradually disappears during the course of the 10 years after stopping use of oral contraceptives. It is not known whether the oral contraceptive causes the difference. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

## **Sexually Transmitted Disease (STD)**

- If you are concerned about contracting a sexually transmitted disease (STD), ask your partner to wear a condom when having sexual intercourse with you.

- TRIFEME will not protect you from HIV-AIDS or any other sexually transmitted diseases (STDs) such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis. To help protect yourself from STDs, you need to use a barrier contraceptive such as a condom.

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

- Become pregnant, or think you may have become pregnant, while taking TRIFEME.

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

- Do not take TRIFEME if the packaging is torn or shows signs of tampering. If it is expired or is damaged, return it to your pharmacist for disposal. TRIFEME may have no effect at all, or worse, have an entirely unexpected effect, if you take it after the expiry date.
- Do not take TRIFEME to treat any other complaints unless your doctor tells you to.
- Do not give TRIFEME to anyone else.
- Do not stop taking TRIFEME, or change the dosage, without checking with your doctor.

If you stop taking TRIFEME or do not take a tablet every day, without using another form of contraception, you may become pregnant.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TRIFEME affects you.**

TRIFEME may cause dizziness in some people.

## **Drinking alcohol**

No information is available.

## **Looking after your medicine**

- Keep your tablets in a cool, dry place where the temperature stays below 25°C and is away from light.
- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack, they may not keep well.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

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

## **After stopping TRIFEME**

If your periods do not return within 2 to 3 months of stopping TRIFEME, tell your doctor.

Some women have short-term problems getting pregnant after stopping TRIFEME, especially if they had irregular menstrual cycles before starting to use an oral contraceptive.

If you are planning to become pregnant after stopping TRIFEME, use a non-hormonal method of contraception such as condoms or a diaphragm for 3 months before trying to get pregnant.

Ask your doctor or pharmacist for advice about taking folate if you plan to become pregnant.

## **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.

## Side effects

Side effects	What to do
<p data-bbox="204 432 735 533"><b>Reproductive or breast problems:</b></p> <ul data-bbox="204 568 774 1727" style="list-style-type: none"><li data-bbox="204 568 746 792">• Changes in bleeding patterns, including breakthrough bleeding/spotting</li><li data-bbox="204 808 568 860">• Painful periods</li><li data-bbox="204 875 711 1211">• Missed periods, but if you have not taken TRIFEME as directed you should check whether you are pregnant</li><li data-bbox="204 1227 759 1339">• Changes in mucus from the vagina</li><li data-bbox="204 1355 715 1406">• Changes in the cervix</li><li data-bbox="204 1422 770 1473">• Vaginal thrush (candida)</li><li data-bbox="204 1489 770 1653">• Breast pain, tenderness, enlargement, possible milk secretion</li><li data-bbox="204 1668 699 1720">• Changes in sex drive</li></ul> <p data-bbox="204 1749 778 1850"><b>Stomach problems, such as:</b></p> <ul data-bbox="204 1886 767 1998" style="list-style-type: none"><li data-bbox="204 1886 767 1998">• Abdominal pain, cramps or bloating</li></ul>	<p data-bbox="810 432 1337 645"><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Changes in appetite</li> <li>• Nausea or vomiting</li> </ul> <p><b>Difficulties thinking or working because:</b></p> <ul style="list-style-type: none"> <li>• Mood changes, including depression</li> <li>• Headache, including migraines</li> <li>• Nervousness</li> <li>• Dizziness</li> <li>• Contact lenses becoming uncomfortable to wear</li> </ul> <p><b>Changes to your appearance such as:</b></p> <ul style="list-style-type: none"> <li>• Weight change (increase or decrease)</li> <li>• Swelling of the hands, ankles or feet</li> <li>• Acne, rash</li> <li>• Darkening of the skin, which may persist after stopping TRIFEME</li> <li>• Loss of scalp hair</li> <li>• Increase in body hair</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Worsening of conditions that you may already have, such as:</b></p> <ul style="list-style-type: none"> <li>● Chorea (involuntary muscle spasm)</li> <li>● Porphyria</li> <li>● Systemic lupus erythematosus (Lupus)</li> <li>● Varicose veins</li> <li>● Gallbladder disease</li> <li>● Hereditary angioedema (swelling of the face, lips, mouth tongue or throat)</li> </ul>	<p><b>Call your doctor straight away if you notice any of these.</b></p>
<p><b>Pain or discomfort:</b></p> <ul style="list-style-type: none"> <li>● Fever</li> <li>● Unexplained or persistent pains in the head, chest, arm or below the breastbone</li> <li>● Severe pain, swelling or discolouration in either of your legs</li> <li>● Sudden weakness or numbness in any part of</li> </ul>	<p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>your body, especially on one side of the body</p> <ul style="list-style-type: none"> <li>● Discomfort radiating to the back, jaw, throat or stomach</li> <li>● Sudden trouble walking, dizziness, loss of balance or coordination</li> </ul> <p><b>Digestive system problems:</b></p> <ul style="list-style-type: none"> <li>● Bloody diarrhoea</li> <li>● Rectal bleeding</li> <li>● Abdominal pain</li> <li>● Feeling of indigestion or choking</li> <li>● Loss of appetite or weight loss</li> </ul> <p><b>Problems with your eyes or eyesight:</b></p> <ul style="list-style-type: none"> <li>● Blurred or double vision</li> <li>● Partial or complete loss of sight</li> <li>● Eye protrusion, swelling of the eye or eye lesions</li> </ul> <p><b>Migraines:</b></p> <ul style="list-style-type: none"> <li>● Migraine headaches for the first time</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● More frequent migraines if you already suffer from them</li> </ul> <p><b>General feelings of unwellness, including:</b></p> <ul style="list-style-type: none"> <li>● Feeling tired</li> <li>● Sudden onset of shortness of breath or rapid breathing</li> <li>● Rapid or irregular heartbeat</li> <li>● Severe dizziness or fainting, sometimes with loss of balance</li> <li>● Sweating, nausea or vomiting</li> <li>● An unusual cough</li> <li>● Loss of consciousness of fainting with or without seizure</li> </ul> <p><b>Changes to your body:</b></p> <ul style="list-style-type: none"> <li>● You are an epileptic and your fits become more frequent</li> <li>● Confusion, trouble speaking or understanding</li> <li>● Breast lumps</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Jaundice or a yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements. Taking oral contraceptives has been associated with an increased risk of having a benign liver tumour, and in very rare cases, liver cancer. The risk appears to increase the longer oral contraceptives are taken.</li> <li>● Rise in blood pressure. You may experience headache, blurred vision or palpitations. Sometimes your blood pressure may rise without you experiencing any of these symptoms. It is important to keep your routine doctor's appointments so that</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>your blood pressure can be checked.</p> <ul style="list-style-type: none"> <li>• Swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing with an itchy rash</li> </ul> <p>Whilst these side effects are rare, they are serious. You may need urgent medical attention or hospitalisation.</p>	

**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 TRIFEME contains**

<b>Active ingredients (main ingredients)</b>	Each brown tablet contains: <ul style="list-style-type: none"><li>• 50 micrograms of levonorgestrel</li><li>• 30 micrograms of ethinylestradiol</li></ul> Each white tablet contains: <ul style="list-style-type: none"><li>• 75 micrograms of levonorgestrel</li><li>• 40 micrograms of ethinylestradiol</li></ul> Each yellow tablet contains: <ul style="list-style-type: none"><li>• 125 micrograms of levonorgestrel</li><li>• 30 micrograms of ethinylestradiol</li></ul>
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	Each red tablet contains no active ingredients.
<b>Other ingredients (inactive ingredients)</b>	<p>The brown, white, yellow and red tablets also contain the following inactive ingredients:</p> <ul style="list-style-type: none"> <li>• Lactose monohydrate</li> <li>• Maize starch</li> <li>• Povidone</li> <li>• Purified talc</li> <li>• Magnesium stearate</li> <li>• Sucrose</li> <li>• Macrogol 6000</li> <li>• Calcium carbonate</li> <li>• Glycerol (brown and yellow tablets only)</li> <li>• Glycol montanate</li> </ul> <p>The brown tablets also contain:</p> <ul style="list-style-type: none"> <li>• Iron Oxide Yellow</li> <li>• Iron Oxide Red</li> <li>• Titanium dioxide</li> </ul> <p>The yellow tablets also contain:</p> <ul style="list-style-type: none"> <li>• Iron Oxide Yellow</li> <li>• Titanium dioxide</li> </ul>

The red tablets also contain:

- Brilliant scarlet 4R
- Erythrosine

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

TRIFEME does not contain gluten, tartrazine or any other azo dyes.

## **What TRIFEME looks like**

TRIFEME comes in a 16-week box containing 4 blister packs.

Each blister pack contains 4 different types of tablets:

- 6 brown active tablets
- 5 white active tablets
- 10 yellow active tablets
- 7 red inactive tablets

The blister pack is marked with days of the week next to each tablet to ensure they are taken in the correct order. (AUST R 40133)

## **Who distributes TRIFEME**

Pfizer Australia Pty Ltd

Sydney NSW

Toll free number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

This leaflet was prepared in June 2023.