

## 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 Minulet?

Minulet contains two active ingredients, gestodene and ethinylestradiol. Minulet is used to prevent pregnancy.

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

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

Do not use if you have ever had an allergic reaction to gestodene 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 Minulet?](#) in the full CMI.

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

Some medicines may interfere with Minulet 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 Minulet?

- 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 Minulet for the first time or how to change to Minulet from a different contraceptive.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or dentist and pharmacist you visit that you are using Minulet.</li><li>• Tell your doctor immediately if you become pregnant while taking Minulet.</li><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>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or change the dosage, without checking with your doctor. If you stop taking Minulet or do not take a tablet every day without using another form of contraception, you may become pregnant.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Make sure you know how Minulet affects you before you drive or use machines. Minulet may cause dizziness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Minulet in a cool, dry place where the temperature stays below 25°C, away from moisture, heat or sunlight.</li></ul>

For more information, see Section [5. What should I know while using Minulet?](#) 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), increase in epileptic seizures or significant rise in blood pressure. For full list of side effects and further information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Minulet®

Active ingredient(s): *gestodene and ethinylestradiol*

## Consumer Medicine Information (CMI)

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

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

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

### 1. Why am I using Minulet?

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

Minulet is used to prevent you from becoming pregnant in several ways, if taken correctly:

- It inhibits the egg release by stopping it maturing
- 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 Minulet for another reason.

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

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

#### Warnings

**Do not take Minulet if:**

1. You are allergic to gestodene 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 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 (deep vein thrombosis (DVT))
- lungs (pulmonary embolism (PE))
- heart (heart attack)
- brain (stroke)

- 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
    - Prolonged immobilisation, major surgery, 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, haemolytic uraemic syndrome, 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
  4. You have, or have had, blood clots in the arteries (known as arterial thromboembolism (ATE)).

Examples of these include:

- Stroke
  - Angina
  - Transient ischaemic attack or "mini stroke"
5. You are at increased risk of arterial thromboembolism (ATE), including:
    - A family history of ATE or you have been advised that you have an increased risk of ATE
    - 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 (fatty materials) disease, such as cholesterol or triglyceride issues
      - History of migraine, accompanied by blurred vision, difficulty in speaking, muscle weakness, or increased sensitivity to light, sound or noise.
      - Biochemical factors, such as hyperhomocysteinaemia and antiphospholipid antibodies (e.g. anticardiolipin antibodies and lupus anticoagulant)
  6. You have 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)
    - Breast cancer or cancer of the lining of the womb, cervix or vagina, or you think you have these conditions
    - Unexplained vaginal bleeding
    - Liver tumour or liver disease
    - Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of an oral contraceptive
    - Severe skin itchiness during pregnancy
    - A history of herpes in pregnancy, known as herpes gestationis
    - A history of a hearing problem known as otosclerosis, which is worse during pregnancy

7. You are pregnant or you think you are pregnant. Pregnancy must be excluded before you start taking Minulet.
8. You are under 18 years of age or are post-menopausal.
9. 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.

#### 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
  - Hereditary angioedema

If you have any of these conditions you should have regular check-ups with your doctor to make sure that taking Minulet is not making the conditions worse. If you are not certain whether any of the above may apply to you, check with your doctor.

- Are over 35 years of age or are overweight
- Are intolerant to some sugars, or your doctor has told you so, speak to your doctor before taking it.

Minulet contains lactose.

- 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.

Minulet is not recommended during pregnancy. Pregnancy must be excluded before you start taking Minulet.

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

Minulet is not recommended while you are breastfeeding. Small amounts of oral contraceptives have been found in breast milk. It is not known what effect this may have on the baby. A decrease in milk supply may also occur.

#### Children

Do not give this medicine to a child under 18 years.

#### 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.
- 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.

Tell your doctor if you have, or have had, any of the following conditions as these are risk factors for developing blood clots:

- Cancer
- Systemic lupus erythematosus (SLE) - a type of inflammatory disease caused when the immune system attacks its own tissues
- Haemolytic uraemic syndrome (HUS) - a disorder of blood coagulation causing failure of the kidneys
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- Sickle cell disease
- Smoking particularly if you are a heavy smoker (15 or more cigarettes per day) and are aged over 35 years
- Have had any recent surgery or trauma
- Recently had a baby
- Lost a baby in the second trimester
- Are pregnant
- Had major surgery and have been confined to bed for long periods of time

Also tell your doctor if you are planning a long-haul plane flight (greater than 4 hours).

#### 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 Minulet, 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 Minulet and affect how it or the other medicine works.**

**Some medicines may increase the levels of Minulet in your blood, which may lead to unwanted side effects.**

**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)

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

- Rifampicin and rifabutin for the treatment of infections, including tuberculosis
- Antibiotics such as ampicillin, other penicillins and tetracyclines
- Anti-fungal agents such as griseofulvin
- Barbiturates (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 also 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 white tablets during these 7 days, 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.

**Minulet may also affect how well some other medicines work.**

**These medicines include:**

- Anti-viral hepatitis C virus (HCV) medicines such as glecaprevir, pibrentasvir, ombitasvir, paritaprevir, ritonavir and dasabuvir
- Ciclosporin, used to prevent organ rejection
- Theophylline, used for asthma and other breathing difficulties
- Corticosteroids
- Lamotrigine, used for seizures

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

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

## 4. How do I use Minulet?

### How much to take

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

### When to take Minulet

- Minulet should be taken at the same time every day, regardless of whether you have sex.
- Minulet 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 Minulet before or after food.

- If you are concerned about this, please speak to your doctor or pharmacist.

### How to take Minulet

- Swallow Minulet with a glass of water.

### How to start taking Minulet for the first time

1. On the first day of your menstrual bleed, take a white tablet that matches the day of the week from the purple shaded section of the blister pack.
2. Then take one white tablet each day, following the arrows so that you are taking the correct tablet for the day of the week until all 21 white tablets have gone.
3. Then take one red tablet each day for the next 7 days.
4. You will have a 'withdrawal' bleed, similar to having a period, during the week of red tablets.

Minulet is effective from the first day of use if begun as instructed. Your first cycle is likely to be shorter than usual, approximately 23 to 24 days long. Thereafter, your cycles should be about 28 days long.

If you do not bleed 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

On the day after your last red tablet, begin the next pack with a white tablet from the purple shaded section of the blister pack that matches the day of the week. Do this even if you are still bleeding.

Each new pack is started with a white tablet on the same day as the first pack, so that you have 21 days on white tablets, then 7 days on red tablets. There is no break between packs.

If you start the new pack later than the day after your last red tablet, you may have started a normal fertile cycle.

**If you start 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 a white tablet has been taken daily for 7 days without a break.**

### How to change to Minulet from a different combined 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 tablet in the pack.
2. If your current oral contraceptive is a 28 day pack, start Minulet the next day by taking take the first white tablet from the purple shaded section that matches the day of the week. If your current oral contraceptive is a 21 day pack, wait 7 days from when the last tablet was taken. On the 8th day, start Minulet by taking take the first white tablet from the purple 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 a white tablet has been taken daily for 7 days without a break.**

3. Then take one white tablet each day following the direction of the arrows until all 21 white tablets have gone.

4. Then take one red tablet each day for the next 7 days.
5. You will have a 'withdrawal' bleed, similar to having a period, during the week of red tablets.

If you do not bleed 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.

### **How to change to Minulet from a progesterone-only contraceptive**

You can stop taking a progestogen-only contraceptive tablet any day and start taking Minulet the next day, at the same time.

If you have been using a progestogen-only implant, start taking Minulet on the day the implant is removed.

If you have been using a progestogen-only injection, start taking Minulet on the day the next injection would be due.

In all cases start Minulet by taking a white tablet from the purple 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 a white tablet has been taken daily for 7 days without a break.**

### **After having a baby**

If you have just had a baby, talk to your doctor before you start taking Minulet.

### **After a miscarriage or abortion**

Your doctor will advise you how to take Minulet after a miscarriage or abortion.

### **How long to take Minulet**

Your doctor may prescribe Minulet for long periods, until you no longer need or want contraception.

If you are not sure how long you should be taking Minulet, ask your doctor.

### **If you forget to use Minulet**

Minulet 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.**

### **Forgetting one white tablet**

- If you forget one white tablet but 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 tablets in one day.

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

- If one white tablet is missed and is more than 12 hours late, skip the missed white tablet and take the next white tablet at the usual time.
- Continue to take tablets at your 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 a white tablet has been taken daily for 7 days without a break. If you come to the end of the white tablets during the 7 days

after a missed tablet, start the next pack straight away. Skip the 7 red tablets.

### **Forgetting more than one white tablet**

Contact your doctor for advice on what to do.

### **Forgetting a red tablet**

- If you miss one or more 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 white tablet that matches the day of the week from the purple shaded section.

**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 a white tablet has been taken daily 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 Minulet, ask your pharmacist for some hints.

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

- If you have vomiting or diarrhoea within 4 hours of taking a white 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 a white tablet has been taken daily for 7 days without a break. If you come to the end of the white tablets during these 7 days, 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 use too much Minulet**

If you think that you have used too much Minulet, 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.**

If you take too much Minulet, some of the symptoms you may have include:

- Feeling sick or vomiting
- Dizziness
- Feeling sleepy or tired.

Women may also experience menstrual bleeding.

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

### **Things you should do**

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

- If you become pregnant while taking Minulet, see your doctor immediately.
- Tell your doctor you are using Minulet at least 4 weeks before any planned hospitalisation or surgery.

Your doctor may tell you to stop taking Minulet several weeks before surgery or at the time of immobilisation. Your doctor will tell you when you can start taking Minulet 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.

- If you are scheduled for any laboratory tests, tell your doctor you are taking Minulet.

Some blood tests may be affected by taking Minulet.

### 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 Minulet.

- 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 Minulet again.

### Pap smear

- 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 use oral contraceptives than in women of the same age who do not use them. 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.

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### 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.
- Minulet will not protect you from HIV-AIDS or any other sexually transmitted diseases 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.

### Things you should not do

- Do not take this medicine if the expiry date (EXP) printed on the pack has passed.

Minulet may have no effect at all, or worse, an entirely unexpected effect, if you take it after the expiry date.

- Do not take this medicine if the packaging is torn or shows signs of tampering.

If this is the case, take the tablets back to your pharmacist.

- Do not give Minulet to anyone else.
- Do not use Minulet to treat any other complaints unless your doctor tells you to.
- Do not stop taking Minulet, or change the dosage, without checking with your doctor.

If you stop taking Minulet 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 Minulet affects you.

Minulet may cause dizziness in some people.

### Drinking alcohol

No information available.

### Looking after your medicine

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

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.

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

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### After stopping Minulet

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

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

If you are planning to become pregnant after stopping Minulet, 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.

#### When to discard your medicine

If your doctor tells you to stop taking Minulet, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

#### 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

Common side effects	What to do
<p><b>Reproductive or breast problems:</b></p> <ul style="list-style-type: none"> <li>• Changes in bleeding patterns, including breakthrough bleeding/spotting</li> <li>• Painful periods</li> <li>• Missed periods, but if you have not taken Minulet as directed you should check whether you are pregnant.</li> <li>• Changes in mucus from the vagina</li> <li>• Changes in the cervix</li> <li>• Vaginal thrush (candida)</li> <li>• Breast pain, tenderness, enlargement, possible milk secretion</li> <li>• Changes in sex drive</li> </ul> <p><b>Stomach problems such as:</b></p> <ul style="list-style-type: none"> <li>• Nausea or vomiting</li> <li>• Abdominal pain, cramps or bloating.</li> </ul> <p><b>Difficulties thinking or working because of:</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> </ul>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you.</b></p>

Common side effects	What to do
<ul style="list-style-type: none"> <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) or changes in appetite</li> <li>• Swelling of the hands, ankles or feet</li> <li>• Acne</li> <li>• Rash</li> <li>• Darkening of the skin, which may persist after stopping your medicine</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 your existing conditions, such as:</b></p> <ul style="list-style-type: none"> <li>• Chorea</li> <li>• Porphyria</li> <li>• Systemic lupus erythematosus</li> <li>• Varicose veins</li> <li>• Gallbladder disease</li> <li>• Hereditary angioedema</li> </ul> <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>• Weakness or numbness in any part of your body</li> <li>• Discomfort radiating to the back, jaw, throat or stomach</li> <li>• Abdominal pain</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> <li>• Swelling around eyes or mouth</li> </ul> <p><b>Migraines:</b></p> <ul style="list-style-type: none"> <li>• Migraine headaches for the first time</li> <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>• Shortness of breath</li> <li>• Rapid or irregular heartbeat</li> <li>• Dizziness or fainting, sometimes with loss of balance</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. You may need urgent medical attention or hospitalisation.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Sweating, nausea or vomiting</li> <li>An unusual cough</li> </ul> <p><b>Changes to your body:</b></p> <ul style="list-style-type: none"> <li>Confusion, trouble speaking or understanding</li> <li>Breast lumps</li> <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.</li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>Rise in blood pressure. You may experience headache, blurred vision or palpitations.</li> </ul> <p>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 your blood pressure can be checked.</p> <ul style="list-style-type: none"> <li>If you have epilepsy and your fits become more frequent</li> <li>Itchy rash</li> </ul> <p><b>Digestive system problems:</b></p> <ul style="list-style-type: none"> <li>Feeling of indigestion or choking</li> <li>Rectal bleeding, or blood on your underwear or when going to the bathroom.</li> <li>Bloody diarrhoea</li> <li>Loss of appetite or weight loss</li> </ul>	

**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 Minulet contains

<b>Active ingredient</b>	Each white active tablet contains: <ul style="list-style-type: none"> <li>75 micrograms of gestodene</li> </ul>
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<b>(main ingredient)</b>	<ul style="list-style-type: none"> <li>30 micrograms of ethinylestradiol</li> </ul> <p>The red tablets do not contain active ingredients.</p>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>Lactose monohydrate</li> <li>Maize starch</li> <li>Povidone</li> <li>Magnesium stearate</li> <li>Sucrose</li> <li>Calcium carbonate</li> <li>Purified talc</li> <li>Macrogol 6000</li> <li>Glycol montanate</li> </ul> <p>The white active tablets also contain:</p> <ul style="list-style-type: none"> <li>Sodium calcium edetate</li> </ul> <p>The red inactive tablets also contain:</p> <ul style="list-style-type: none"> <li>Brilliant scarlet 4R CI 16255</li> <li>Erythrosine CI 45430</li> </ul>

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

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

#### What Minulet looks like

Minulet comes in a 12 week box containing 3 blister packs. Each blister pack contains 21 white active tablets and 7 red inactive tablets. The white active tablets are round, biconvex tablets, approximately 6 mm in diameter. The red inactive tablets are round, biconvex coated tablets. The blister pack is marked with days of the week next to each tablet.

(AUST R 296803)

#### Who distributes Minulet

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

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

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