MINULET®

Gestodene and Ethinyloestradiol Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Minulet. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Minulet against the benefits this medicine is expected to have for you.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Minulet is used for

Minulet is an oral contraceptive. Minulet tablets contain two hormones (gestodene and ethinyloestradiol), which prevent you from becoming pregnant if taken correctly. They are similar to the hormones that your body normally produces.

Minulet prevents pregnancy in several ways:

- 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.

Minulet is not habit-forming.

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

Before you take Minulet

When you must not take Minulet

Do not take Minulet if:

1. **You are allergic to any of the ingredients found in Minulet**

The ingredients found in Minulet are listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

2. **You have or have had any medical conditions, especially the following:**

- Blood clots in the legs (thrombophlebitis or deep vein thrombosis), lungs (pulmonary embolism) or eyes
- Heart valve or heart rhythm disorders that may be associated with the formation of blood clots
- Heart attack or stroke
- Chest pain (angina pectoris)
- High blood pressure which is uncontrolled
- Some severe types of headache or migraine, including migraine with partial paralysis
- Diabetes with blood vessel damage
- 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
- High blood levels of cholesterol or triglycerides (fatty substances)
- Sickle cell anaemia
- Severe skin itchiness during pregnancy
- A history of herpes in pregnancy
- A history of a hearing problem known as otosclerosis, which is worse during pregnancy
- Inflammation of the pancreas, which is associated with very high blood levels of triglycerides (fatty substances).

If you are not certain whether these may apply to you, or you are worried by anything in this list, tell your doctor.

3. **If you are pregnant or you think you are pregnant.**

Pregnancy must be excluded before you start taking Minulet.

4. **Minulet is not for use in children or in postmenopausal women.**
5. **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.

6. **The packaging is torn or shows signs of tampering.**

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

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.

You must tell your doctor if:

1. **You are allergic to any foods, dyes, preservatives or any other medicines.**
2. **You smoke.**

Oral contraceptives increase your risk of having a stroke or heart attack. The risk of serious side effects on the heart and blood vessels is even greater if you smoke and take oral contraceptives. The risk increases with age and with heavy smoking (15 or more cigarettes per day), especially in women older than 35 years. If you take Minulet, you should not smoke.

3. **You have any other health problems, especially:**

- Breast lumps, abnormal breast X-ray or mammogram
- Diabetes
- Heart disease
- High cholesterol or blood fats
- High blood pressure or you have a history of high blood pressure, including high blood pressure during pregnancy
- Migraine or other headaches
- 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.

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.

4. **Anyone in your family has had blood clots in the deep veins of the legs, a stroke or heart attack or you have any of the following conditions:**

- Obesity
- Recent surgery or trauma
- Recently had a baby
- Lost a baby in the second trimester
- Confined to bed rest for long periods.

The risk of developing blood clots in the deep veins of your legs, which can break away and block a blood vessel elsewhere in your body, are increased if you have any of these conditions and use an oral contraceptive. Blood clots are a rare occurrence and can develop whether or not you are taking an oral contraceptive. They can also happen during pregnancy. The risk of having a blood clot is higher in oral contraceptive users than in non-users, but not as high as during pregnancy.

5. **You plan to become pregnant or you think you are pregnant.**

Like most medicines, Minulet is not recommended during pregnancy.

6. **You are breast-feeding or plan to breast-feed**

Like most medicines, Minulet is not recommended while you are breast-feeding. 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.

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

Taking other medicines

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

Some medicines may stop Minulet from working properly. These include medicines such as:

- Rifampicin and rifabutin for the treatment of 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.

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 and ascorbic acid (Vitamin C).

Minulet may also affect how well some other medicines work. These medicines include:

- Cyclosporin used to prevent organ rejection
- Theophyllines 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.

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

Some blood tests may be affected by taking Minulet.

How to take Minulet

Follow the directions on the blister pack.

If your doctor has prescribed Minulet for some other purpose than contraception, follow their directions closely, even if they are not the same as on the pack.

When to take Minulet

You must take Minulet every day, even if you do not have sex very often.

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.

Starting a hormonal contraceptive for the first time

To start taking Minulet follow these steps:

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

1. 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.
2. 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.
3. 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.

Switching from a different combined oral contraceptive

Follow these steps if your current oral contraceptive contains an oestrogen 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 advice in this leaflet, contact your doctor to check if you are pregnant.

Switching from a progestogen-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 take your tablets

If you forget to take Minulet every day it may not work as well in protecting you from becoming pregnant.

Do not try to make up for missed doses by taking more than one tablet at a time.

FORGETTING ONE WHITE TABLET

1. **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.

2. **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

1. **If you miss one or more red tablets, leave them in the pack and do not worry.**
2. **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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Minulet. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

While you are taking Minulet

Things you must 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.

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.

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.

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.

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.

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.

Things you must not do

Do not give Minulet to anyone else even if they have the same condition as you.

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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Minulet.

When used correctly, Minulet is an effective contraceptive, but may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask your doctor or pharmacist to answer any questions you have.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- Sharp chest pain, coughing of blood, or sudden shortness of breath
- Pain in the calf muscle area
- Crushing chest pain or heaviness in the chest
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg
- Sudden changes or loss of vision
- Breast lumps
- Severe pain or tenderness in the stomach area
- 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.

- Migraine headaches for the first time
- More frequent migraines if you already suffer from them
- Itchy rash
- You are an epileptic and your fits become more frequent
- Rise in blood pressure
- Swelling around eyes or mouth
- Bloody diarrhoea, abdominal pain or tenderness, fever, nausea or vomiting.

Whilst these side effects are rare, they are serious. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reproductive or breast problems such as:

- Changes in bleeding patterns, including breakthrough bleeding/ spotting
- Painful periods
- Missed periods, but if you have not taken Minulet as directed you should check whether you are pregnant
- Changes in mucus from the vagina
- Changes in the cervix
- Vaginal thrush (candida)
- Breast pain, tenderness, enlargement, possible milk secretion
- Changes in sex drive.

Stomach problems such as:

- Nausea or vomiting
- Abdominal pain, cramps or bloating.

Difficulties thinking or working because of:

- Mood changes, including depression
- Headache, including migraines
- Nervousness
- Dizziness
- Contact lenses becoming uncomfortable to wear.

Changes to your appearance such as:

- Weight change (increase or decrease) or changes in appetite
- Swelling of the hands, ankles or feet
- Acne
- Rash
- Darkening of the skin, which may persist after stopping Minulet
- Loss of scalp hair
- Increase in body hair.

Worsening of conditions you may already have such as:

- Chorea
- Porphyria
- Systemic lupus erythematosus
- Varicose veins
- Gallbladder disease
- Hereditary angioedema.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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.

After taking Minulet

Storage

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.

Keep Minulet in a cool, dry place where the temperature stays below 25°C and is away from light.

Do not store Minulet or any other medicine, in a bathroom or near a sink.

Do not leave Minulet in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep Minulet where children cannot reach it.

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

Disposal

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.

Product description

What it looks like

Minulet comes in a 12 week box containing 3 blister packs. Each blister pack contains 21 white hormone tablets and 7 red non-hormonal tablets. The blister pack is marked with days of the week next to each tablet.

Ingredients

Each white tablet contains 75 micrograms of gestodene and 30 micrograms of ethinyloestradiol as the active ingredients.

Each red tablet contains no active ingredients.

The white and red tablets also contain the following inactive ingredients:

- Lactose
- Maize starch
- Povidone
- Sodium calcium edetate
- Magnesium stearate
- Sucrose
- Calcium carbonate
- Talc
- Macrogol 6000
- Glycol montanate.

The red tablets also contain the colouring agents:

- Brilliant scarlet 4R CI 16255
- Erythrosine CI 45430.

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

Supplier

Minulet is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll Free Number 1800 675 229

Australian Registration Number: AUST R 47377

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