

Package leaflet: Information for the patient

TRI-MINULET TABLETS

gestodene and ethinylestradiol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet you may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Tri-Minulet is and what it is used for**
2. **What you need to know before you take Tri-Minulet**
3. **How to take Tri-Minulet**
4. **Possible side effects**
5. **How to store Tri-Minulet**
6. **Contents of the pack and other information**

1. What Tri-Minulet is and what it is used for

The name of your medicine is Tri-Minulet Tablets.

Tri-Minulet is an oral contraceptive.

Important things to know about combined hormonal contraceptives (CHCs):

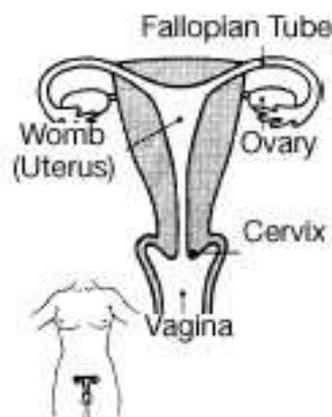
- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks

Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 “Blood clots”).

How the female reproductive system works

Once a month, an egg (or ovum) is released from one of the ovaries and passes along the Fallopian tube to the womb. Fertilisation (the joining together of the male's sperm with the female's egg) usually takes place while the egg is still in the Fallopian tube. The fertilised egg embeds itself in the wall of the womb, which has been specially prepared to receive it, and it grows into a baby.

If fertilisation does not take place, then the egg is shed in the next menstrual period.



What do your tablets do?

Tri-Minulet is a combined hormonal contraceptive, one of a group of medicines often referred to as the Pill. It contains two types of hormone: an estrogen, ethinylestradiol, and a progestogen, gestodene. Tri-Minulet is a triphasic contraceptive. This means that there are three levels of hormones in each pack which reflect the changing levels in your normal cycle. These hormones stop the ovary from releasing an egg each month (ovulation). They also thicken the fluid (mucus) at the neck of the womb (cervix) making it more difficult for the sperm to reach the egg, and alter the lining of the womb to make it less likely to accept a fertilised egg.

Medical research and vast experience have shown that, if taken correctly, the Pill is an effective reversible form of contraception.

2. What you need to know before you take Tri-Minulet

General notes

Before you start using Tri-Minulet you should read the information on blood clots (thrombosis) in section 2. It is particularly important to read the symptoms of a blood clot – (see section 2 “Blood clots”).

Do not take Tri-Minulet:

Do not take Tri-Minulet if you have any of the following conditions, listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- If you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs
- If you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies
- If you need an operation or if you are off your feet for a long time (see section ‘Blood clots’)
- If you have ever had a heart attack or a stroke
- If you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms)
- If you have any of the following diseases that may increase your risk of a clot in the arteries:
 - severe diabetes with blood vessel damage
 - very high blood pressure
 - a very high level of fat in the blood (cholesterol or triglycerides)
 - a condition known as hyperhomocysteinaemia
- If you have (or have ever had) a type of migraine called ‘migraine with aura’
- If you have known or suspected breast cancer
- If you have cancer of the lining of the womb, cervix or vagina
- If you have a liver tumour (non-cancerous or cancerous)
- If you have liver disease and your liver is not yet back to normal
- If you have unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- If you are or could be pregnant or you are breast feeding
- If you are allergic to any of the ingredients of this medicine (listed in section 6)
- If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see section 2 ‘Other medicines and Tri-Minulet’).

Warnings and precautions

When should you contact your doctor?

Seek urgent medical attention:

- If you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clot' (thrombosis) section below).

For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

Talk to your doctor, pharmacist or nurse before taking Tri-Minulet if any of the following conditions apply to you.

If the condition develops, or gets worse while you are using Tri-Minulet, you should also tell your doctor.

- If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- If you have systemic lupus erythematosus (SLE –; a disease affecting your natural defence system);
- If you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- If you have sickle cell anaemia (an inherited disease of the red blood cells);
- If you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- If you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots');
- If you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Tri-Minulet.
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins;
- If you have breast nodules, fibrocystic disease of the breast, or an abnormal breast X-ray or mammogram;
- If you have severe headaches or epilepsy;
- If you suffer from depression;
- If you have gallbladder, heart or kidney disease
- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

Psychiatric disorders

Some women using hormonal contraceptives including Tri-Minulet have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Tri-Minulet increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of having a harmful blood clot due to Tri-Minulet is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> • swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> • pain or tenderness in the leg which may be felt only when standing or walking • increased warmth in the affected leg • change in colour of the skin on the leg e.g. turning pale, red or blue 	Deep vein thrombosis
<ul style="list-style-type: none"> • sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat • severe pain in your stomach; <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a ‘common cold’).</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> • immediate loss of vision or • painless blurring of vision which can progress to loss of vision 	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> • chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone; • fullness, indigestion or choking feeling; • upper body discomfort radiating to the back, jaw, throat, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety, or shortness of breath; • rapid or irregular heartbeats 	Heart attack
<ul style="list-style-type: none"> • sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; 	Stroke

<ul style="list-style-type: none"> • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. <p>Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	
<ul style="list-style-type: none"> • swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen) 	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Tri-Minulet your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with Tri-Minulet is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains ethinylestradiol and gestodene such as Tri-Minulet between about 9 and 12 women will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see 'Factors that increase your risk of a blood clot' below).

	Risk of developing a blood clot in a year
Women who are not using a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing levonorgestrel, norethisterone or norgestimate	About 5-7 out of 10,000 women
Women using Tri-Minulet	About 9-12 out of 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with Tri-Minulet is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m²);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Tri-Minulet may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Tri-Minulet ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Tri-Minulet needs to be stopped.

If any of the above conditions change while you are using Tri-Minulet, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using Tri-Minulet is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Tri-Minulet you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure that is not controlled through treatment;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;

- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Tri-Minulet, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

- While you are receiving this medication you should see your doctor regularly for examination. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman.
- If you have any unusual symptoms such as unexplained pains in the chest, abdomen or legs you must consult your doctor immediately.

The Pill and Cancer

Every woman is at risk of breast cancer whether or not she takes the Pill. Breast cancer is rare under the age of 40 years, but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill this reduces the risk, so that 10 years after stopping the Pill the risk of finding breast cancer is the same as for women who have never taken the Pill. Breast cancer seems less likely to have spread when found in women who take the Pill than in women who do not take the Pill.

It is not certain whether the Pill causes the increased risk of breast cancer. It may be that women taking the Pill are examined more often so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the Pill but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

Cancer of the liver has rarely been reported in long-term users of the Pill. Non-malignant liver tumours have also been linked with Pill usage. Discontinuation of the Pill may be necessary with sudden or long-term disturbances of the liver, do not take the Pill until liver function has returned to normal.

Some research has shown an increased risk of cancer of the neck of the womb (cervix) in long term Pill takers, but it is unclear how much this increase is due to the Pill.

Chronic infection with the Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer.

These possible risks should also be considered together with the benefits of the Pill.

Ocular Lesions

There have been case reports of retinal thrombosis (closure of the central retinal artery causing sudden, usually nearly complete, loss of vision) with the use of oral contraceptives. Oral contraceptives should be discontinued if there is unexplained partial or complete loss of vision; rapid swelling of an eyeball; double vision or any sudden changes to your eyesight.

Gallbladder Disease

An increased relative risk of gallbladder disease in users of oral contraceptives and estrogens has been reported in some studies.

Bleeding Irregularities

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablet taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

If you have missed tablets and then do not get a withdrawal bleeding in the first normal tablet-free interval, the possibility of pregnancy must be considered.

If you have missed taking one (or more) pills, and have had unprotected sexual intercourse; you may be pregnant. Ask your doctor or pharmacist about emergency contraception.

Some women may experience post-pill amenorrhea (absence of menstrual period) or oligomenorrhea (infrequent or very light menstrual period), especially when such a condition was pre-existent.

Other conditions

Some conditions may be made worse by taking the Pill. Tell your doctor if you think any of the following problems get any worse while you are taking the Pill:

Severe depression; varicose veins; high blood pressure; diabetes; the disorder of metabolism known as porphyria; liver problems; systemic lupus erythematosus (SLE); heart disease; kidney disease; brown patches on the face and body like those that occur in pregnancy (chloasma); fibroids of the womb; problems wearing contact lenses; migraine; disturbance of vision; Sydenham's Chorea; pemphigoid gestationis; otosclerosis- related hearing loss; lipid disorders; calcium deficiency with muscle cramps (tetany); inflammation of the veins (phlebitis), swelling of face, eyes, mouth or difficulty breathing.

Tell your doctor as soon as possible if you suffer from any of the above for the first time while taking the Pill.

Make sure your doctor knows if you have any other disease.

Your doctor will have given you a check-up before prescribing Tri-Minulet and this should be repeated regularly. Blood pressure should be measured, and the check-up should include examination of your womb and surrounding organs, breasts, pelvis and abdomen. Your doctor should also note your family history.

A PAP smear should be performed if the patient has been sexually active or if it is otherwise indicated

Tri-Minulet should be stopped four weeks before planned operations, or during periods when you are unable to move (for example following accidents). You should not take Tri-Minulet for two weeks after surgery or during bed rest. This is because the risk of getting blood clots is increased by many surgical operations and by periods of inactivity. It may also be increased after injuries, such as fractures.

Other medicines and Tri-Minulet

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Several medicines may interfere with the way the Pill works. Medicines that increase the activity of your liver enzymes may prevent your Pill from working, and may cause breakthrough bleeding and irregular periods. These include:

- medicines used to treat epilepsy such as phenytoin, primidone, carbamazepine, oxycarbazepine, topiramate

- some medicines used to treat tuberculosis (rifabutin)
- phenylbutazone, dexamethasone (an anti-inflammatory medicine)
- some medicines used to treat HIV/AIDS (some protease inhibitors),
- some sedatives and tranquillisers (called ‘barbiturates’)
- griseofulvin (a medicine used to treat fungal infections)
- modafinil (for excessive daytime sleepiness)
- medicines that reduce gastrointestinal transit time
- certain antibiotics (e.g. rifampicin)
- the herbal remedy commonly known as St John’s wort (*hypericum perforatum*)

Other medicines that do not affect your liver enzymes, may also have this effect. These include medicines that speed up the passage of food through your body and certain antibiotics. You may have to use another method of contraception as well, such as the condom, while you are taking these medicines - and for a further seven days afterwards. Your doctor may advise you to use these extra precautions for even longer. In addition, follow the advice for "what to do if you forget to take your Pill" (see later).

The herbal remedy, St John’s wort (*Hypericum perforatum*) may prevent oral contraceptives from working properly and should not be taken at the same time as this medicine. If you are already taking a St John’s wort preparation, stop taking St John’s wort and tell your doctor at your next visit.

Some medicines may decrease the activity of your liver enzymes. This may cause the blood levels of the ingredients in your Pill to rise. Examples of these medicines include atorvastatin, indinavir, fluconazole and troleandomycin. Drugs that affect absorption of your Pill in your intestines (e.g. ascorbic acid (vitamin C) and paracetamol) may also have this affect.

Your Pill may affect the way that other medicines work, or increase the risk of potential side effects. These include some medicines that are broken down by your liver (e.g. ciclosporin and theophylline) and the medicines flunarizine and lamotrigine.

Do not use Tri-Minulet if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

Tri-Minulet can be restarted approximately 2 weeks after completion of this treatment. See section Do not take Tri-Minulet.

Before you have any blood tests

Tell your doctor that you are taking the Pill, because oral contraceptives interfere with some tests.

Sexually transmitted diseases

Tri-Minulet will not protect you against HIV infection (AIDS) or other sexually transmitted diseases. If you think you are at risk you should use a condom in addition to the Pill.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you become pregnant stop taking your tablets immediately and consult your doctor. Use another method of contraception, such as a condom, until the pregnancy is confirmed.

Small amounts of contraceptive steroids and/or metabolites have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jaundice and breast enlargement.

The use of the Pill is generally not recommended until the nursing mother has completely weaned her child.

Driving and using machines

Tri-Minulet has no known effect on the ability to drive or use machines.

Tri-Minulet contains lactose monohydrate and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tri-Minulet contains sodium calcium edetate

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tri-Minulet

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

About the pack:

The memo blister has been designed to help you to remember to take your tablets. Each pill is marked with a number. Start taking Tri-Minulet Tablets on the first day of menstrual bleeding by taking tablet 1 that is beside the word START. Press the blister pocket next to the day of the week on which you have taken the first tablet, ensuring that you break the foil on the other side. This will be your start day for every new pack.

Your start day (day 1) and days 8 and 15 always fall on the same day of the week. These have a square border so that you can check to see that you are taking the tablets correctly.

It will act as a reminder if you press the blister pocket indicating your start day on any other Tri-Minulet Tablets pack that you may have been prescribed.

Starting the first pack

When no hormonal contraceptive has been used in the past month

Take the first pill on the first day of your period. This is day one of your cycle, the day when bleeding starts. You will be protected at once.

If you start on any other day of your period, you should use another method of contraception as well, such as the condom, for the first seven pill-taking days, but this is only for the first pack.

You can take your pill at any time, but you should take it about the same time each day. You may find it easiest to take it either last thing at night or first thing in the morning. Take a pill every day in the order shown until you finish all 21 pills in the pack.

Once you have taken all 21 pills, stop for seven days. You will probably bleed during some of these seven days.

You do not need to use any other form of contraception during the seven-day break provided you have taken the 21 pills properly and you start the next pack on time.

The next pack

After seven pill-free days, start your next pack. Do this whether or not you are still bleeding. You will always start a new pack on the same day of the week.

Starting after childbirth or pregnancy

After a birth, abortion or miscarriage, your doctor should advise you about taking the Pill. After a miscarriage or abortion in the first three months of pregnancy you can start using Tri-Minulet immediately.

If you have had a baby, and had a normal delivery without any later complications, are fully mobile and are not breast-feeding or you have had an abortion in the second three months of pregnancy, you can start taking Tri-Minulet 28 days after delivery or abortion. Alternative contraception (such as the condom) must be used for the first 7 days of pill-taking. If you have had unprotected sex after day 21 you should not start Tri-Minulet until your period starts.

If you are breast feeding, the combined Pill is not recommended because it can reduce your flow of milk. If you have any questions about starting Tri-Minulet after childbirth or pregnancy, ask your doctor or pharmacist.

If you are changing to Tri-Minulet after taking another Pill:

If you are changing to Tri-Minulet after taking another Pill, follow your doctor's instructions.

When changing from another 21-day combined Pill, start taking Tri-Minulet the next day after the end of the previous course.

If you are changing from a 28-day combined pill start taking Tri-Minulet the day after you take the last active pill in the previous course.

In either of these cases a withdrawal bleed should not be expected until the end of the first course of Tri-Minulet. No additional contraception is required.

Switching from a progestin-only method of birth control (e.g. progestin only Pill, implant, intrauterine device (IUD), or an injection)

If you are changing from a progestogen only pill (POP), you can stop taking the POP any day and start taking Tri-Minulet on the next day at the same time. An additional form of contraception, such as the condom, should be used for the first seven days of pill-taking.

If you are changing from an injectable or implant contraceptive you can start using Tri-Minulet when your next injection is due or on the day after your implant is removed. An additional form of contraception, such as the condom, should be used for the first seven days of pill-taking.

Any pills left in packs after changing your Pill, should be returned to your pharmacist or doctor.

If you miss a period

If you have taken all your pills correctly it is unlikely you are pregnant. However, you should make sure that you are not pregnant before you start your next pack.

If you take more Tri-Minulet than you should

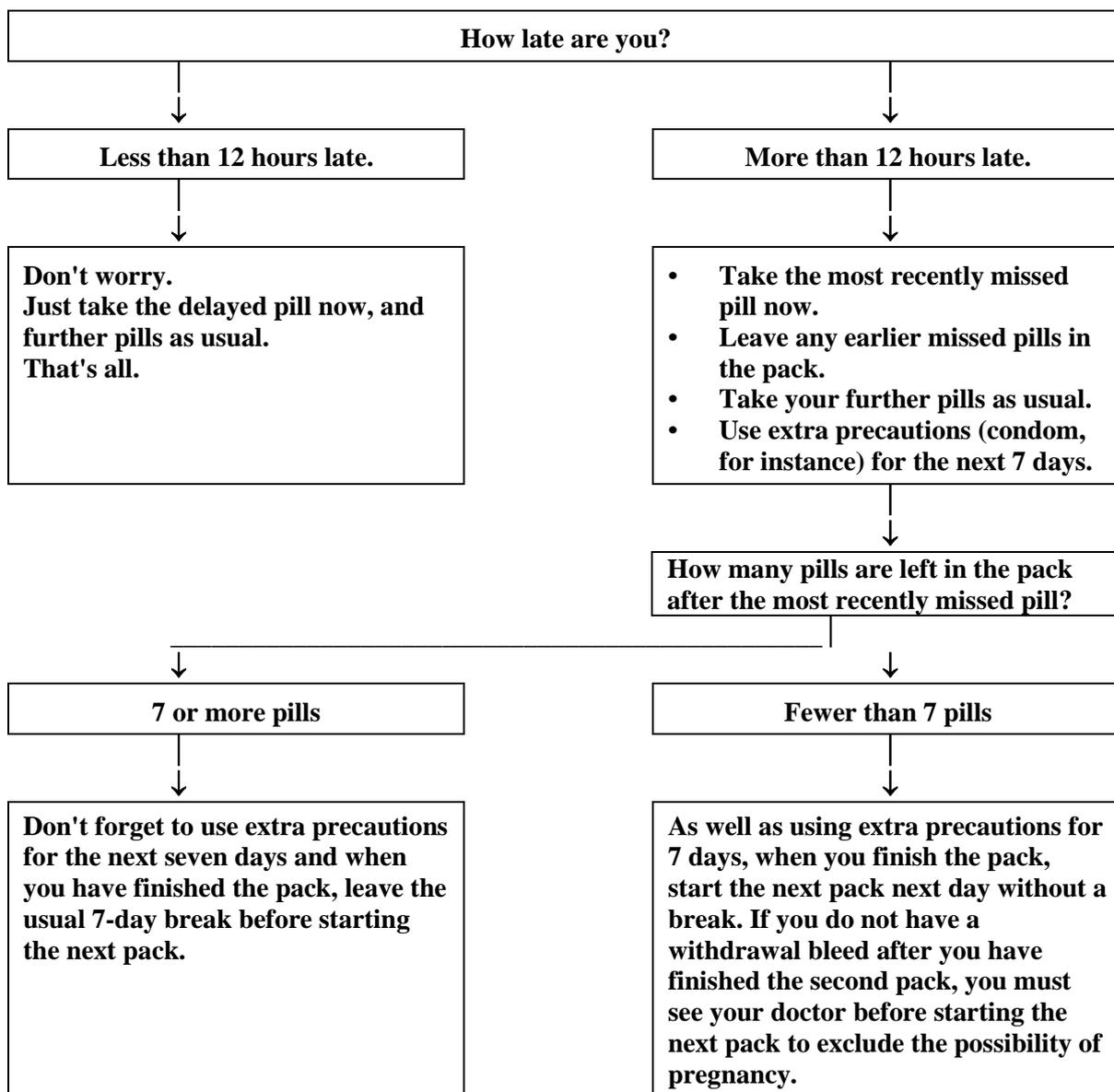
Taking too many tablets may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, and drowsiness/fatigue. Withdrawal bleeding may occur in females. In case of overdose, contact your doctor or pharmacist.

What to do if you forget to take Tri-Minulet

If you are **less than 12 hours late** in taking your pill, take it as soon as you remember, and further pills as usual.

If you are **more than 12 hours late** in taking one or more pills, take the last missed pill as soon as you remember, even if it means taking two pills in one day, continue to take further pills as usual and use extra contraception (condom, for instance) for the next 7 days. If these 7 days run beyond the end of the pack, start the next pack immediately, without a gap. In this case, a withdrawal bleed should not occur until the end of the second pack. If you do not have a withdrawal bleed, then, consult your doctor before starting the next pack.

This advice can be summarised by following the diagram below:



If you have a stomach upset

If you have been sick or had diarrhoea the Pill may not work. If the sickness or diarrhoea occurs within 4 hours after taking the Pill follow the instructions above for “If you are less than 12 hours late in taking your pill.” The extra tablet (of the same colour) should be taken from a back-up pack. If the sickness or diarrhoea occurs more than 4 hours after taking the pill, continue to take it, but you may not be protected from the first day of vomiting or diarrhoea. Use another method, such as a condom, for any intercourse during the stomach upset and until you start your next pack.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Tri-Minulet, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you use Tri-Minulet”.

TELL YOUR DOCTOR STRAIGHT AWAY IF YOU GET ANY OF THESE SYMPTOMS AFTER TAKING YOUR TABLETS:

- Severe sudden onset of rash
- Severe headache or migraine
- Difficulties in seeing or speaking
- Pain or swelling in the legs
- Fainting
- Pain in the chest or stomach
- Shortness of breath
- Numbness in an arm or leg
- Breast lumps
- Coughing with blood.

Serious side effects

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

Your doctor will probably stop Tri-Minulet if:

- You become jaundiced.
- Your blood pressure is raised.
- You have any condition which can worsen with the Pill, and shows signs of getting worse (see section 2).

If you have bleeding while you are taking the tablets

You may at first have some breakthrough bleeding, or spotting, whilst you are taking your tablets, but your periods should settle down after a few months. However, if the bleeding is heavy, continuous or keeps returning, see your doctor.

Tri-Minulet may cause some minor side effects. Tell your doctor if any of the following symptoms bother you:

Very common side effects (may affect more than 1 in 10 people)

- Headache, including migraines
- Breakthrough bleeding/spotting

Common side effects (may affect up to 1 in 10 people)

- Abdominal pain/cramps
- Feeling or being sick, changes in appetite
- Changes in body weight
- Changes in interest in sex (libido)
- Depressive moods, nervousness
- Dizziness
- Headaches
- Tender breasts or breast secretion
- Skin problems such as acne or rash, brown patches on the face and body, like those that occur in pregnancy (chloasma), itching.
- Irregular bleeding or missed bleeds
- Fluid retention or bloating
- Changes in vaginal discharge, vaginal infections such as thrush

- Hair thinning or unusual hairiness
- Problems with contact lenses

Uncommon side effects (may affect up to 1 in 100 people)

- Increase in blood pressure
- Changes in serum lipid levels

Rare side effects (may affect up to 1 in 1,000 people)

- Angioedema
- Glucose intolerance
- Erythema nodosum
- Decrease in serum folate levels
- Harmful blood clots in a vein or artery for example:
 - in a leg or foot (i.e. DVT)
 - in a lung (i.e. PE)
 - heart attack
 - stroke
 - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
 - blood clots in the liver, stomach/intestine, or kidneys.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

Very rare side effects (may affect up to 1 in 10,000 people)

- Harmful blood clots in a vein or artery for example:
 - In the eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).
- Gallbladder disease (including gallstones),
- Pancreatitis (inflammation of the pancreas), a blood disorder called haemolytic uremic syndrome – HUS (a disorder where blood clots cause the kidneys to fail)
- Exacerbation of systemic lupus erythematosus – SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs), porphoria and chorea (a movement disease)
- Optic neuritis inflammation of the optic nerve (may lead to partial or complete loss of vision)
- Aggravation of varicose veins
- Hepatic adenomas (benign liver tumours)
- Hepatocellular carcinomas (cancer of the liver)
- Erythema multiforme (fever and rash of the face, arms and legs).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tri-Minulet

Do not use this medicine after the expiry date, which is stated on the blister pack and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C.

Keep this medicine out of the sight and reach of children. Your tablets could harm them.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tri-Minulet contains

The active substances are:

6 beige tablets containing 50 micrograms of gestodene and 30 micrograms of ethinylestradiol;
5 dark brown tablets containing 70 micrograms of gestodene and 40 micrograms of ethinylestradiol;
10 white tablets containing 100 micrograms of gestodene and 30 micrograms of ethinylestradiol.

The other ingredients are lactose monohydrate, maize starch, povidone, sodium calcium edetate, magnesium stearate, sucrose, macrogol 6000, calcium carbonate, talc, glycerol, titanium dioxide (E171), ferric oxide yellow (E172) and wax E. (see section 2 'Tri-Minulet contains lactose monohydrate and sucrose' and 'Tri-Minulet contains sodium calcium edetate')

What Tri-Minulet looks like and contents of the pack

Tri-Minulet is supplied in a carton containing three blister packs of 21 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland

Manufacturer:

Pfizer Ireland Pharmaceuticals
Little Connell
Newbridge
Co. Kildare
Ireland

Company Contact Address

For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.
Telephone: 1800 633 363.

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