PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Minulet®

Coated tablets

Each coated tablet contains:
Ethinylestradiol 0.03 mg
Gestodene 0.075 mg

Inactive ingredients and allergens in this medicine: see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to a doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Minulet® is intended for birth control and belongs to a group of medicines called "contraceptive pills".
Each tablet contains two female hormones, estrogen (ethinylestradiol) and progestogen (gestoden).

Therapeutic group: combined oral contraceptive pills, an estrogen and progestogen combination.

A few important things to know about combined Pills:

- When used correctly, they are one of the most reliable reversible methods of contraception.
- They slightly increase the risk of having a thrombosis (blood clots) in the veins and arteries, especially in the first year or when restarting after 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 "Minulet® and thrombosis (blood clots)").
- Like other contraceptive pills, Minulet® does not protect you against HIV infection (AIDS) or other sexually transmitted diseases. If you think you are at risk, you should use a condom as well as the Pill.

2. BEFORE USING THE MEDICINE

Before you start taking Minulet® you should read the information on thrombosis (blood clots) in section 2. It is particularly important to read the part about symptoms of thrombosis (see section 2 "Minulet® and thrombosis (blood clots)").

Do not use the medicine if:

you have any of the following conditions. 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.

- you are sensitive (allergic) to ethinylestradiol, gestodene or any of the ingredients of this medicine (listed in section 6).
- you have (or have ever had) a blood clot in a blood vessel in your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or other organs.
- 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.
- you are about to have surgery or if you will be off your feet for a long time (see "Minulet® and thrombosis (blood clots)").
- you have ever had a heart attack or a stroke.
- 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).
- you have any of the following diseases that may increase your risk of develop a blood clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- you have (or have ever had) an inflammation of the pancreas (pancreatitis) with high levels of fat/triglycerides in the blood.
- you have (or have ever had) a type of migraine called 'migraine with aura'.
- you have known or suspected breast cancer.
- you have cancer of the lining of the womb, cervix or vagina.
- you have a liver tumor (non-cancerous or cancerous).
- you have a liver disease and your liver function is not yet back to normal.
- you have unexplained vaginal bleeding (until a diagnosis is reached by your doctor).
- you are or could be pregnant.
- you are breastfeeding.
- you have hepatitis C (viral liver inflammation) and are taking medicines containing: ombitasvir, paritaprevir, ritonavir, and dasabuvir or glecaprevir/pibrentasvir (see "Other medicines and Minulet®").

Special warnings regarding use of the medicine:

Seek immediate medical attention:

- **if you notice possible symptoms of a blood clot that may mean you are suffering from a blood clot in the leg (that is a deep vein thrombosis), a blood clot in the lung (pulmonary embolism), a heart attack or a stroke (see "Minulet® and thrombosis (blood clots)").**

For a description of the symptoms of these serious side effects please go to section 2 "How to recognize symptoms of a blood clot".

Talk to your doctor before taking Minulet® if any of the following conditions apply to you.
You should also consult your doctor if any of the conditions develop, or get worse while you are taking Minulet®:

- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE – a disease affecting your immune system)
- if you have hemolytic uremic syndrome (HUS - a disorder of the blood clotting system which causes kidney failure)
- if you have sickle cell anemia (an inherited disease of the red blood cells)

- if you have elevated levels of fat in the blood (hypertriglyceridemia) or a family history of this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).
- if you are about to have surgery, or you will be off your feet for a long time (see in section 2 'Minulet® and thrombosis (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 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
- hypertension
- diabetes
- a metabolic disorder called porphyria
- liver problems
- brown patches that appear on your face and body like those that occur during pregnancy (chloasma)
- fibroids of the womb (benign (non-cancerous) tumors that grow from the muscle layers of the womb)
- problems wearing contact lenses
- migraines
- disturbances of vision
- Sydenham's chorea (a disease characterized by rapid, uncoordinated jerking movements affecting primarily the face, feet and hands)
- pemphigoid gestationis (a blistering skin disease that occurs during pregnancy)
- otosclerosis-related hearing loss
- blood lipid disorders (high or low levels of fat in your blood)
- calcium deficiency with muscle cramps
- inflammation of the veins (phlebitis)
- swelling of face**,** eyes**,** mouth or difficulty breathing
- **Psychiatric disorders**
  Some women using hormonal contraceptives including 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.

Minulet® and thrombosis (blood clots)

Using a combined hormonal contraceptive such as Minulet® increases your risk of developing a blood clot compared with women who are not using such contraceptives. In rare cases, a blood clot can block a blood vessel and cause serious problems.
Blood clots can develop:

- in veins [venous thrombosis, venous thromboembolism (VTE)]
- in the arteries [arterial thrombosis, arterial thromboembolism (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 using Minulet® is small.

How to recognize a blood clot?

Refer to a doctor urgently if you notice any of the following symptoms:

Are you experiencing any of these signs?	What are you possibly suffering from?
swelling of one leg or along a vein in the leg or foot especially when accompanied by: • pain or tenderness in the leg which may be felt only when standing or walking • a sensation of warmth in the affected leg • change in colour of the skin on the leg, for example turning pale, red or blue	Deep vein thrombosis
• 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 • light headedness or dizziness • rapid or irregular heartbeats If you are unsure, talk to your doctor as some of these signs 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).	Pulmonary embolism
Signs which most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in a blood vessel in the eye)
• 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
• 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 • sudden, severe or prolonged headache with no known cause • loss of consciousness or fainting with or without seizure 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	Stroke

• swelling and slight blue discoloration of an extremity • severe sudden pain in your stomach (acute abdomen)	Blood clot blocking other blood vessels

Blood clots in a vein

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

- The use of the combined hormonal contraceptives has been connected with an increase in the risk of developing blood clots in the veins (venous thrombosis). However, this side effect is rare. Most frequently, it occurs 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 as before 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 taking 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 (deep venous thrombosis or pulmonary embolism) with Minulet® is small.

- Out of 10,000 women who are not using a combined hormonal contraceptive and are not pregnant, about two women 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 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 contraceptive (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 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 Minulet® is small but some conditions will increase the risk.

Your risk is higher:

- if you are overweight (BMI over 30 kg/m^2)
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. under the age 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 Minulet® may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop using Minulet® ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years)
- if you gave birth a few weeks ago

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

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

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 Minulet® needs to be stopped.

If any of the above conditions change while you are using 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 Minulet® is very small but can increase:

- with increasing age (beyond about 35 years)
- **if you smoke.** When using a combined hormonal contraceptive like 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 medication
- if a member of your immediate family has had a heart attack or stroke at a young age (under the age of 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 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.

The Pill and Cancer

Every woman is at risk of breast cancer whether or not she takes the Pill. Breast cancer is rare in women 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 who do not take the Pill.
If a woman stops taking the Pill the result is that 10 years after stopping the Pill her risk of breast cancer diagnosis is the same as for a woman who has never taken the Pill.
Breast cancer seems less likely to have spread when it was found in women who took the Pill than in those women who did not take the Pill.

It is not clear 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.

Cancerous tumors in the liver have rarely been reported in long-term users of the Pill. Non-malignant liver tumors have been observed in women taking the Pill. Discontinuation of the Pill may be necessary with sudden or long-term disturbance in liver function. Do not take the Pill until liver function has returned to normal.

Some studies suggest that oral contraceptives may increase your risk of cancer of the cervix, although this may be due to differences in sexual behavior, rather than the Pill. All women should have regular cervical smear tests. Chronic infection with the Human Papilloma virus (HPV) is the most important risk factor for cervical cancer.

You should consider these possible risks alongside the benefits of taking the Pill.

Vision disorders

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

As 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 suitable sanitary protection but keep taking your Pills 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 forget a Pill and then do not get a withdrawal bleeding in the 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.

Smoking
Tell your doctor if you start smoking while you are taking Minulet®.
The risk of arterial thrombosis and heart attack or stroke while using Minulet® increases if you smoke. When using a combined hormonal contraceptive like 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.

Check-ups, follow up, and lab tests
Your doctor will give you a check-up before prescribing Minulet® and this should be repeated regularly. Check-up frequency and nature must be based on guidelines and practical experience and adjusted for the individual woman. 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 must be performed if the patient has been sexually active or if it is otherwise indicated.

Before you have a blood test, tell the doctor that you are taking the Pill because this medicine may affect the test results.

Drug interactions
If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Certain medicines may interfere with the way the Pill works. Some medicines may prevent your Pill from working and may cause breakthrough bleeding (bleeding in between periods) and irregular periods. These include:
- medicines used to treat epilepsy (such as phenytoin, primidone, carbamazepine, oxcarbazepine, topiramate)
- some medicines used to treat tuberculosis (rifabutin)
- phenylbutazone, dexamethasone (anti-inflammatory medicines)
- modafinil (for excessive daytime sleeping problems)
- some medicines used to treat HIV/AIDS (protease inhibitors)
- certain tranquillizers and sleeping medicines (called 'barbiturates')
- griseofulvin (a medicine used to treat fungal infections)
- medicines that reduce gastrointestinal transit time
- certain antibiotics (such as rifampicin)
- the herbal remedy commonly known as St John's wort (*Hypericum perforatum*)

You may have to use another method of contraception as well, such as a condom, while you are taking these medicines - and for a further 7 days afterwards. Your doctor may advise you to use these extra precautions for even longer. In addition, follow the advice in the sub section 'If you forget to take Minulet®' in section 3 of this leaflet.

St. John's wort *(Hypericum perforatum)*: Breakthrough bleeding and unintended pregnancies have been reported in women taking the Pill and St John's wort

(*Hypericum perforatum*) If the Pill and St. John's wort are used at the same time, a non-hormonal backup method of birth control is recommended such as a condom.

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.

Medicines that affect absorption of your Pill in your intestines (such as ascorbic acid (vitamin C) and paracetamol) may have a similar effect.

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. cyclosporine, theophylline, corticosteroids) and the medicines flunarizine and lamotrigine.

Do not use Minulet® if you have hepatitis C (viral liver inflammation) and are taking medicines that containing: ombitasvir, paritaprevir, ritonavir, and dasabuvir or glecaprevir/pibrentasvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme).
Your doctor will prescribe another type of contraceptive before you start treatment with these medicines.
Minulet® can be restarted about 2 weeks after completing treatment with these medicines. See the section **"Do not use this medicine if"**.

To prevent risks or inefficiency from interactions with other medicines, consult a doctor of pharmacist before taking any other medicine while you are using Minulet®.

Pregnancy, breastfeeding, and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are 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 side 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
Minulet® has no known effect on the ability to drive or use machines.

Important information regarding some of the ingredients of the medicine
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 medicine.

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

About the pack
The pack has been designed to help you remember to take your tablets on time.

Each pack contains 21 tablets. On the back of the strip, each tablet is marked with the day of the week and an arrow indicating the direction of progression.
Take the first pill on the first day of your menstrual bleeding according to the day of the week marked on the pack. This will be the day you start for every new pack. Continue taking the tablets in the direction of the arrows until you have used up all the tablets.
The usual dosage is generally: one tablet, every day, **at a fixed time**, from the first day of your menstrual bleeding and for 21 consecutive days, followed by a 7-day Pill free break. Your period will usually appear during this break.

Swallow the tablet whole. There is no information about crushing, splitting, or chewing the tablets.

The dosage and treatment regimen will be determined by the doctor only.

Do not exceed the recommended dose.

Your doctor will decide how long you will take this treatment.

Starting the first pack

How to start your first pack when you have not used a hormonal contraceptive in the past month:
Take the first tablet 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 7 pill-taking days, but this is only for your first pack.
You can take your Pill at any time, but you should take it at the same time each day. It is usually easiest to take the tablet before bed or first thing in the morning.
Once you have taken all 21 tablets in the pack, stop taking the tablets for 7 days. You will probably bleed during some of these days.
You do not need to use any other form of contraception during the 7-day break provided you have taken all the 21 tablets properly and you start the next pack on time.

The next pack
After 7 pill-free days, start your next pack. Do this whether or not you are still bleeding. This way 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 will advise you about taking the Pill. After a miscarriage or abortion in the first 3 months of pregnancy you can start using Minulet® immediately.

If you have had a normal delivery without any later complications, and are fully mobile and are not breastfeeding, and you have not had an abortion in months four, five or six of pregnancy, you can start taking Minulet® 28 days after delivery or abortion. Additional contraception (such as a 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 Minulet® until your period starts.
If you are breastfeeding, the combined Pill is not recommended because it can reduce your flow of milk. If you have any questions about starting Minulet® after childbirth or pregnancy, ask your doctor or pharmacist*.*

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

When changing from another 21-day combined estrogen-progesterone Pill to Minulet®, start taking Minulet® the day after you finish the course of the previous Pill.

If you are changing from a 28-day combined estrogen-progesterone Pill, start taking Minulet® the day after you take the last **active** tablet of the previous Pill.

In either of these cases a withdrawal bleed is not expected until the end of the first course of Minulet®. No additional contraception is required in these cases.

Switching from a progesterone-only Pill, or injected or implanted contraceptives to Minulet®:
If you are changing from a progesterone-only Pill you can stop taking the progesterone-only Pill on any day and start taking Minulet® the next day at the same time.
Use an additional form of contraception, such as the condom, for the first seven days of the first pack.

If you are changing from an injectable or implant contraceptive you can start using Minulet® on the day your implant is removed or the day your next injection is due.
Use an additional form of contraception, such as the condom, for the first seven days of the first pack.

If there is no bleed after you finish the pack
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 have accidentally taken a higher dose of Minulet®
Taking too many tablets of Minulet® might cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, and drowsiness/fatigue. Withdrawal bleeding may occur in some women. In case of overdose, contact your doctor or pharmacist.

If a child has accidentally swallowed some of the medicine, immediately contact a doctor or proceed a hospital emergency room and bring the package of the medicine with you.

If you forget to take Minulet®:
If you are less than 12 hours late in taking your Pill, take a tablet as soon as you remember, and carry on taking your next tablets as usual.
If you are more than 12 hours late in taking your Pill, take the last missed tablet as soon as you remember and continue taking the rest of the tablets as usual, even if it means taking 2 tablets in one day.
Continue to take Minulet® as usual until you finish the pack, and use extra contraception (condom, for instance) for the next 7 days.
If the 7 days in which you require extra contraception run beyond the end of the present pack, start the next pack the day after you have taken the last tablet in the present pack, without a break. In this case, a withdrawal bleed (period) will occur only at the end of the second pack. If you do not get a period when you finish the second pack, consult your doctor immediately before starting the new pack.

If you are suffering from diarrhea or vomiting
The Pill may not work. If vomiting or diarrhea happens **within 4 hours** after taking the Pill, follow the instructions under “If you forget to take Minulet®” for “If you are less than 12 hours late in taking your pill”. The extra tablet should be taken from a back-up pack.
If the vomiting or diarrhea happens **more than 4 hours** after taking the Pill, continue taking it as usual, but you may not be protected from the first day of vomiting or diarrhea. Use another contraception method, such as a condom, during the vomiting and diarrhea and until you start your next pack.

If you want to stop taking this medicine
You can stop using Minulet® any time. If you do not want to get pregnant, consult your doctor about other effective contraception.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Minulet® may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you get any side effect, particularly if severe and persistent, or you experience any change in your health that you think may be due to using Minulet®, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information see section 2 'Before using this medicine'.

Tell your doctor straight away if you experience any of these symptoms:
- Swelling of the face, lips or throat which makes it difficult to swallow or breathe, as well as itching and rash. This could be a sign of a severe allergic reaction to Minulet®.
- 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
- Coughing with blood
- Breast lumps.

Your doctor will probably stop your Minulet® treatment if:
- You become jaundiced
- Your blood pressure is raised
- You have any condition which can get worse with Pill use and it shows signs of getting worse (see section 2 'Before using this medicine').

If you have bleeding while you are taking the tablets
You may at first have some breakthrough bleeding or spotting while 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, consult your doctor.

Minulet® may cause some minor side effects. Tell your doctor if the following symptoms bother you:

Very common side effects - may affect more than 1 in 10 users:
- Headache, including migraines
- Breakthrough bleeding/spotting

Common side effects - may affect 1-10 in 100 users:
- Abdominal pain/stomach cramps
- Nausea and vomiting
- Changes in body weight
- Changes in interest in sex
- Depressive moods, nervousness
- Dizziness
- Tender breasts or discharge from your breasts
- Acne
- Irregular bleeding or painful bleeding or missed bleeds
- Fluid retention or bloating
- Changes in vaginal discharge, vaginal infections such as thrush

Uncommon side effects - may affect 1-10 in 1,000 users:
- Changes in appetite
- Rash, brown patches on the face and body like those that occur in pregnancy (chloasma), itching
- Hair thinning or unusual hairiness
- Increase in blood pressure
- Changes lipid levels in the blood
- Abdominal cramps, bloating

Rare side effects - may affect 1-10 in 10,000 users:
- Severe allergic reactions including angioedema and urticaria (swelling of skin accompanied by itching and hives)
- Glucose intolerance
- Problems with contact lenses
- Erythema nodosum
- Decrease in serum folate levels
- Cholestatic jaundice (abnormal bile flow in the liver causing yellowing of the skin)
- Harmful blood clot in a vein or artery, for example
  - in a leg or foot (deep venous thrombosis)
  - in a lung (pulmonary embolism)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischemic attack
  - blood clots in the liver, stomach/intestine, kidneys.

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

Very rare side effects - may affect less than 1 in 10,000 users:
- 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 of the other conditions that increase this risk (see section 2 for more information about conditions that increase the risk of blood clots and the symptoms of a blood clot).
- Gallbladder disease (including gallstones)
- Pancreatitis (inflammation of the pancreas), a blood disorder called hemolytic uremic syndrome - HUS (a disorder where blood clots cause kidney failure)
- Exacerbation of systemic lupus erythematosus – SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs), porphyria, and chorea (a movement disease)
- Inflammation of the optic nerve (may lead to partial or complete loss of vision)

- Aggravation of varicose veins
- Ischemic colitis (inflammation due to inadequate blood flow to large intestine)
- Benign liver tumors
- Cancer of the liver
- Fever and rash of the face, arms, and legs

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link 'Reporting Side Effects of Drug Treatment' found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store this medicine below 25°C. Keep the pack in the carton in order to protect from light.

6. FURTHER INFORMATION

In addition to the active ingredients, this medicine also contains:
Lactose Monohydrate, Sucrose, Maize Starch, Calcium Carbonate, Talc, Macrogol 6000, Povidone K-25, Magnesium Stearate, Povidone K-90, Sodium Calcium Edetate, Wax E Pharma, Purified Water (q.s.).

Each tablet contains: 37.5 mg lactose monohydrate and 19.7 mg sucrose.
It also contains sodium.

What the medicine looks like and contents of the package:

- A carton containing one blister tray with 21 white tablets.
- A carton containing 3 blister trays, each blister tray containing 21 white tablets.

Not all package sizes may be marketed.

Registration holder: Pfizer PFE Pharmaceuticals Israel, 9 Shenkar Street, Herzlia Pituah, 46725.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
050-50-25757

Revised in 08/2021 according to MOH guidelines.