PACKAGE LEAFLET: INFORMATION FOR THE USER

MILLINETTE® 30/75

microgram coated tablets

ethinylestradiol / gestodene

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").

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT MILLINETTE IS AND WHAT IT IS USED FOR

Millinette is a combined hormonal contraceptive, one of a group of drugs often referred to as the Pill. It contains two types of hormone: an oestrogen, ethinylestradiol, and a progestogen, gestodene. 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.

Remember, combined hormonal contraceptive pills like Millinette will not protect you against sexually-transmitted diseases (such as AIDS). Only condoms can help to do this.

You and the pill

How your body gets ready for pregnancy (the menstrual cycle).

You can usually become pregnant (conceive) from the time you start to have periods (usually in your teens), until your periods stop (the menopause). Every menstrual cycle takes about 28 days. About halfway through this cycle, an egg is released from one of your ovaries into a Fallopian tube. This is called ovulation.
The egg travels down the Fallopian tube towards your womb. When you have sex, your partner's penis releases millions of sperm into your vagina. Some of these sperm travel up through your womb into your Fallopian tubes. If there is an egg in one of these tubes and a sperm reaches it, you can become pregnant. This is called 'conception'.
A fertilised egg settles in the lining of your womb and takes nine months to grow into a baby. As an egg can live for up to two days, and sperm for up to five days, you can become pregnant if you have had sex up to five days before ovulation and for some time afterwards. If a sperm does not fertilise an egg, you will lose the egg at the end of your menstrual cycle along with the lining of your womb. This is called a 'period'.

How do natural hormones work?

Your menstrual cycle is controlled by two sex hormones made by your ovaries: oestrogen and progesterone (which is a progestogen). Your oestrogen levels increase during the first half of your menstrual cycle, and make your womb develop a thick lining, ready to receive the egg if conception happens. Progesterone comes later in your menstrual cycle and changes the lining of the womb to prepare it for pregnancy.
If you don't become pregnant, you will then make less of these hormones and this causes the lining of your womb to break down. As mentioned above, this womb lining leaves your body as a period. If you do become pregnant, your ovaries and placenta (this attaches the growing baby to the womb and gives it food) carry on making progesterone and oestrogen to stop any more eggs being released. This means that while you are pregnant you will not ovulate or have periods.

How does the pill work?

A combined contraceptive pill such as Millinette contains hormones which are like those that your body produces (oestrogen and progestogen). These hormones help to stop you from getting pregnant, just as your natural hormones would stop you conceiving again when you are already pregnant.

The combined contraceptive pill protects you against getting pregnant in three ways.
1. You won't release an egg to be fertilised by sperm.
2. The fluid in the neck of your womb thickens so it is more difficult for sperm to enter it.
3. The lining of your womb does not thicken enough for an egg to grow in it.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MILLINETTE

General notes
Before you start using Millinette 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 use Millinette
You should not use Millinette if you have any of the 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 (or have ever had) a type of migraine called 'migraine with aura';
- 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 ever had) an inflammation of the pancreas (pancreatitis) associated with very high level of fat in the blood;
- if you have (or have ever had) liver disease and liver function test have not yet returned to normal;
- if you have liver tumours or if you have ever had these;
- if you have (or have ever had) cancer affected by sex hormones (e.g. breast cancer or reproductive organ cancer);
- if you have unusual bleeding from your vagina;
- if you are allergic to gestodene or ethinylestradiol or any of the other ingredients of this medicine (listed in section 6).

Do not use Millinette if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section 'Other medicines and Millinette').

If you get any of these conditions while you are taking Millinette, do not take any more pills and contact your doctor immediately. In the meantime, use another method of contraception such as a condom or cap plus spermicide.

Warnings and precautions
Talk to your doctor or pharmacist before taking Millinette.

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.E3\e pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below).

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

Regular check-ups
Before you start taking Millinette, your doctor should take your medical history by asking you some questions about yourself and other members of your family. Your doctor will take your blood pressure and make sure you are not pregnant. Your doctor may also examine you. Once you have started taking Millinette, your doctor will see you again for regular check-ups. This will happen when you go back to your doctor for more pills.

Tell your doctor if any of the following conditions apply to you
If the condition develops, or gets worse while you are using Millinette, you should also tell your doctor.

Your doctor may tell you to stop using Millinette and advise you to use another method of contraception.
- 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.
- 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 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 Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- 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 Millinette.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins.

If you suffer from:
- high blood pressure (hypertension);
- yellowing of the skin (jaundice);
- itching of your whole body (pruritus);
- gallstones;
- the inherited disease called porphyria;
- the movement disorder called Sydenham's chorea;
- the rash known as herpes gestationis;
- the inherited form of deafness known as otosclerosis;
- disturbed liver function;
- diabetes;
- depression or mood changes;
- brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Millinette 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 any Millinette 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?

• 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;
  • 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

• 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. 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').	Pulmonary embolism
Symptoms 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 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 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 Millinette 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 Millinette 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 gestodene such as Millinette 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 Millinette	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 Millinette is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or 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. 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 Millinette may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Millinette 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 Millinette needs to be stopped.

If any of the above conditions change while you are using Millinette, 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 Millinette is very small but can increase:
- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Millinette 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;
- 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 Millinette, 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
Some studies have found that you may have an increased risk of cervical cancer if you use the pill in the long term. This increased risk may not be caused by the pill, because it could be due to the effects of sexual behaviour and other circumstances. The most important risk factor for cervical cancer is infection with human papilloma virus (HPV).

Every woman is at risk of breast cancer whether or not she takes the pill. Breast cancer is rare in women under 40. Breast cancer has been found slightly more often in women who take the pill than in women of the same age who don't take the pill. If you stop taking the pill, this reduces your 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.
Since breast cancer is a rare condition in women below 40 years of age, the increase in number of diagnosed cases of breast cancer in current and previous users of the pill is small compared to the risk of breast cancer during their entire life time.

Rarely, using the pill has led to liver diseases such as jaundice and benign liver tumours.
Very rarely, the pill has been associated with some forms of malignant liver tumours (cancer) in long-term users.
Liver tumours may lead to life-threatening intra-abdominal haemorrhage (bleeding in the abdomen). So, if you have pain in your upper abdomen that does not get better, tell your doctor. Also, if your skin becomes yellow (jaundiced), you must tell your doctor.

Psychiatric disorders
Some women using hormonal contraceptives including Millinette 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.

Migraine/headache
You should talk to your doctor immediately if your migraine worsens or if a recurrent, persistent, or severe headache develops (see also section 2 "Blood clots").

Children and adolescents
Millinette is not indicated before menarche (the first menstrual bleeding).

Other medicines and Millinette
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Also tell any other doctor or dentist who prescribes another medicine that you use Millinette. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Do not use Millinette 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 as this may cause increases in liver function blood test results (increase in ALT liver enzyme).

product name	labelling number	country code	design code	plant code	item code	version
MILLINETTE 30	K-152276-2.3	UK	-	-	-	v_01

colour: P Black; P 214; P 528
printing technology:
font (size [leading]): Cronos Pro (9 pt) [10.8 pt]
Studio: -
date: 2023.03.02.
made by: -

packaging material	size	technical drawing	supervised technical drawing by	date
UTAS-3	345 x 635 (±0,5)/40 x 86 (±1) mm	PIL_RTU_86x40_345x635_temp /Page01	-	2019.04.11.

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.
Millinette can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Millinette".

Some medicines can have an influence on the blood levels of Millinette and can make it **less effective in preventing pregnancy,** or can cause unexpected bleeding. These include medicines used for the treatment of:
- epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidone, felbamate, oxcarbazepine, topiramate);
- tuberculosis (e.g. rifampicin);
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapin, efavirenz);
- fungal infections (e.g. griseofulvin);
- medicine used for the treatment of pulmonary artery hypertension (bosentan);
- arthritis, arthrosis (etoricoxib)

The herbal remedy St. John's wort. If you want to use herbal products containing St. John's wort while you are already using Millinette you should consult your doctor first.

Millinette may influence the efficacy of other medicines, e.g.
- ciclosporin (medicine used for the treatment of suppression of tissue rejection following transplant surgery);
- theophyllin (a medicine for the treatment of asthma);
- lamotrigine (medicine for the treatment of epilepsy- this could lead to an increased frequency of seizures);
- tizanidine (medicine used to treat muscle pain and/or muscle cramps).

Ask your doctor or pharmacist for advice before taking any medicine.

Before you have any laboratory tests
Tell your doctor or the laboratory staff that you are taking an oral contraceptive, because oral contraceptives can affect the results of some tests.

Pregnancy and breast-feeding
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.

Pregnancy
If you think you might be pregnant, stop taking Millinette and talk to your doctor immediately. Until you have spoken to your doctor, use another method of contraception such as a condom or a cap plus spermicide.
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Ask your doctor or pharmacist for advice before taking Millinette. Millinette should not be taken during breast-feeding.

Driving and using machines
Millinette has no or only minor influence on the ability to drive and use machines.

Millinette contains lactose, sucrose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE MILLINETTE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. This pack is designed to help you remember to take your pills.

Starting the first pack
Take the first pill on the first day of your period. This is day one of your cycle – the day when bleeding starts. If you start on day 2-5 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.

Changing to Millinette from another combined hormonal contraceptive
You should start with Millinette on the day after the tablet-free period of your previous pill finishes (or after the last inactive tablet of your previous pill).

Changing to Millinette from progestogen-only preparations (progestogen-only pills, injection, implant, intrauterine system)
You may switch any day from the progestogen-only pill but you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

If you have had an injection, an implant or an intrauterine system, you can start to take Millinette on the day that your next injection is due, or on the day that your implant or intrauterine system is removed, but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

Starting after childbirth or miscarriage or abortion
After a birth, abortion or miscarriage, your doctor should advise you about taking the pill.
You can start using Millinette immediately after a miscarriage or abortion which occurs during the first three months of pregnancy. In this case it is not necessary to take further contraceptive measures.
If you have had a delivery or abortion which occurs during the second three months of pregnancy, you can start taking Millinette 21-28 days after giving birth or having abortion. If you are breast-feeding, the combined pill is not recommended because it can reduce your flow of milk. Alternative contraception (such as the condom) must be used for the first 7 days of pill-taking. If you have had unprotected sex you should not start Millinette until your period starts or you are sure you are not pregnant. If you have any questions about starting Millinette after childbirth or abortion, ask your doctor or pharmacist.

If you take more Millinette than you should
If you take more Millinette than you should, it is not likely that it will do you any harm, but you may feel sick, actually be sick or have some vaginal bleeding. If you have any of these symptoms, you should talk to your doctor who can tell you what, if anything, you need to do.

If you forget to take Millinette
If you forget to take a pill please follow these instructions.

If you forgot to take the tablet at the usual time and are **less than 12 hours late** in doing so, you should take it as soon as you remember. Then continue taking tablets at the usual time.

If you forgot to take the tablet at the usual time and are **more than 12 hours late** in doing so, or if you forgot to take **more than one tablet,** contraceptive protection may be reduced. You should take the last missed tablet as soon as you remember, even if this means taking two tablets in one day. Then continue taking tablets at the usual time. Additionally, a non-hormonal back-up birth control method should be used for the next 7 days (e.g., condoms or cervical cap with spermicide).

If you take the last tablet from the blister pack during this 7-day period, you should start taking tablets from a new blister pack as soon as the current pack is finished; no gap should be left between blister packs. It is unlikely you will experience a withdrawal bleed while taking tablets from the second blister pack, but you may experience blood spots or breakthrough bleeding. If you do not experience a withdrawal bleed after completing the second pack, you should talk to your doctor. The possibility of pregnancy should be excluded before resuming Millinette.

If you stop taking using Millinette
If you stop taking Millinette, you can become pregnant. You should discuss other methods of contraception with your doctor to avoid pregnancy.

What to do if you have a stomach upset?
If you have been sick or had diarrhoea within 3-4 hours after taking the pill, the active substances in the pill may not be fully absorbed into your body. In this case the advice concerning missed pills, described above should be followed. In case of vomiting or diarrhoea, use extra contraceptive precautions, such as a condom, for any intercourse during the stomach upset and for the next seven days.

What to do if you want to delay or to shift your period?
If you want to delay or to shift your period, you should contact your doctor for advice.

If you want to delay your period, you should continue the next pack of Millinette after taking the last tablet in the current pack, without a pill-free interval. You can take as many pills from this next pack as you want, until the end of the second blister pack. When you use the second pack, you may have breakthrough bleeding or spotting. Regular intake of Millinette is resumed after the usual 7 days tablet-free interval.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 Millinette, please talk to your doctor.

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").

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 Millinette".

The following is a list of the side effects that have been linked with the use of Millinette.

Very common side effects (may affect more than 1 in 10 people):
Headache, irregular bleeding and spotting between periods.

Common side effects (may affect up to 1 in 10 people):
Vaginitis, fungal infection of vagina, mood altered including depression, nervousness, dizziness, nausea, upper abdominal pain, acne, painful menstruation, changes in vaginal secretion, absence of menstruation, weight increase, breast tenderness, breast pain, breast swelling, breast discharge.

Uncommon side effects (may affect up to 1 in 100 people):
Migraine, fluid retention, changed appetite (increased or reduced), increase in blood pressure, vomiting, diarrhoea, rash, nettle-rash (urticaria), chloasma (yellowish-brown patches on the skin), excessive hair growth, hair loss, changes in serum lipid levels including hypertriglyceridemia, change in the interest in sex (reduced libido).

Rare side effects (may affect up to 1 in 1,000 people):
Anaphylactic reactions (reaction with very rare cases of hives, swelling of face, tongue, severe circulatory and respiratory disorders), glucose intolerance, jaundice, eye irritation when wearing contact lenses, general disease in ear and labyrinth, various skin diseases (such as erythema multiforme (characterized by rash with target-shaped reddening or sores), erythema nodosum (characterized by painful reddish skin nodules)), decrease in serum folate levels, other disease in the gastrointestinal tract, change in interest in sex (increased libido).
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, kidneys or 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).

Very rare side effects (may affect up to 1 in 10,000 people):
Benignus or malignant tumour of liver, aggravation of varicose veins, exacerbation of systemic lupus erythematosus -SLE (a disorder where blood clots cause the kidneys to fail), exacerbation of porphyria, exacerbation of chorea (an involuntary movement disorder), inflammation in the nerve of eye, blood clots in the blood vessels of the eye, weight decrease, pancreatitis (inflammation of the pancreas), inflammatory intestinal disorder (Crohn's disease, ulcerative colitis), gallbladder disorder, gall stones, blood disorder called haemolytic uraemic syndrome – HUS (a disorder where blood clots cause the kidneys to fail).

Not known (frequency cannot be estimated from available data):
Liver damage (such as hepatitis, abnormal liver function).

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 the Yellow Card Scheme: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MILLINETTE

Keep this medicine out of sight and reach of children.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 Millinette contains
The active substances are: 30 micrograms ethinylestradiol and 75 micrograms gestodene in one coated tablet.
The other ingredients are:
Tablet core: Sodium calcium edetate, Magnesium stearate, Silica colloidal anhydrous, Povidone K-30, Maize starch, Lactose monohydrate.
Tablet coat: Quinoline yellow (E 104), Povidone K-90, Titanium dioxide (E 171), Macrogol 6000, Talc, Calcium carbonate (E 170), Sucrose.

What Millinette looks like and contents of the pack
Yellow, round, biconvex sugar-coated tablets, both sides are without imprinting.

Packaging:
Blister: PVC/PVDC/aluminium.
Blister: PVC/PVDC/aluminium in PETP/aluminium/PE bag.
Pack sizes: 1×21 tablets; 3×21 tablets, 6×21 tablets, 13×21 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Gedeon Richter Plc.,
Gyömrői út 19-21,
1103 Budapest,
Hungary

This leaflet was last revised in March 2023.

GEDEON RICHTER

K-15276-2.3

MILLINETTE® 30/75

00000000

MILLINETTE® 30/75

00000000

product name	labelling number	country code	design code	plant code	item code	version	
MILLINETTE 30	K-15276-2.3	UK	-	-	-	v_01	

colour	printing technology	font (size [leading]):	Studio
P Black P 214 P 528		Cronos Pro (9 pt) [10.8 pt]	- date: 2023.03.02. made by: -

packaging material	size	technical drawing	supervised technical drawing by	date
UTAS-3	345 x 635 (±0,5)/40 x 86 (±1) mm	PIL_RTU_86x40_345x635_temp /Page02	-	2019.04.11.