

- 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.

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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: 1x21 tablets; 3x21 tablets, 6x21 tablets, 13x21 tablets.

Not all pack sizes may be marketed.

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

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