

# MILLINETTE® 20/75

## microgram coated tablets

ethinylestradiol / gestodene



### Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

### In this leaflet:

1. What Millinette is and what it is used for
2. Before you take Millinette
3. How to take Millinette
4. Possible side effects
5. How to store Millinette
6. Further information

### 1. WHAT MILLINETTE IS AND WHAT IT IS USED FOR

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

### 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. BEFORE YOU TAKE MILLINETTE

#### Do not take 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 may then decide that Millinette is not suitable for you and advise you to use another method of contraception.

#### Tell your doctor if:

- you have ever had a disorder affecting your blood circulation known as thrombosis (for example, blood clots in your legs, lungs, heart, brain, eyes or in any other part of your body);
- you have ever had a heart attack or angina (severe chest pain) or a stroke (such as sudden weakness or tingling in one side of your body);
- you or any member of your close family have any medical condition which makes you more at risk of developing blood clots (see also the section 'The pill and thrombosis');
- you have diabetes with changes to the blood vessels;
- you have or have ever had an eye disorder due to circulatory disease;
- you have high blood pressure (hypertension);
- you have liver disease or if you have ever had this;
- you have liver tumours or if you have ever had these;
- you have breast cancer or other cancer, for example ovarian cancer, cervical cancer, or cancer of the uterus (womb);
- you have unusual bleeding from your vagina;
- you have or have ever had migraine;
- you are allergic (hypersensitive) to gestodene, ethinylestradiol or any of the other ingredients of Millinette;
- you are pregnant or think you might be.

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.

#### Take special care with Millinette:

##### 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 immediately if...

you have any of the following conditions while you are taking Millinette. Also, do not take any more pills until you have spoken to your doctor. In the meantime, use another method of contraception such as a condom or cap plus spermicide.

- If you get a migraine for the first time, or if you already have migraines but they get worse or happen more often than before.
- Symptoms of a blood-clot formation. (See also the section - 'The pill and thrombosis.')
- These symptoms include:
  - unusual pain or swelling in your legs;
  - sudden sharp pains in your chest which may reach your left arm;
  - sudden shortness of breath or difficulty in breathing;
  - sudden coughing for no apparent reason;
  - any unusual, severe or long-lasting headache;
  - any sudden changes to your eyesight (such as loss of vision or blurred vision);
  - slurred speech or any other difficulties affecting your speech;
  - vertigo (spinning sensation);
  - dizziness, fainting or fits;
  - sudden weakness or numbness in one side or part of your body;
  - difficulties in moving around (known as motor disturbances); or
  - severe pain in your abdomen (known as acute abdomen).
- Surgery or immobilisation (not being able to move around as normal). You must stop taking Millinette at least four weeks before a planned major operation (for example, stomach surgery), or if you are having any surgery to your legs. Also, if you are immobilised for a long time (for example, you are in bed after an accident or operation, or you have a plaster cast on a broken leg). The pill should not be resumed until 2 weeks after complete remobilisation. Your doctor will tell you when you can start taking Millinette again.
- If you think you may be pregnant.

#### Tell your doctor before starting to take Millinette if...

you know you suffer from any of the following conditions. You need to tell your doctor if this is the case as these conditions may get worse while you are taking the pill. If any of these conditions do get worse or you have them for the first time, tell your doctor as soon as you can. Your doctor may tell you to stop using Millinette and advise you to use another method of contraception.

- If you, or any member of your family, have a blood-fat (lipid) disorder called hypertriglyceridaemia, as this disorder can increase your risk of getting a disease of your pancreas, called pancreatitis.
- 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;
  - systemic lupus erythematosus - SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs);
  - a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail);
  - 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;
  - Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases);
  - brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps.

#### The pill and thrombosis

Some studies have suggested that the risk of developing various blood-circulation disorders is slightly greater in women who take the combined pill than in those who do not. This can lead to a thrombosis. A thrombosis is when you have a blood clot which may block a blood vessel. The clot may form in the veins (venous thrombosis) or in the arteries (arterial thrombosis). Most blood clots can be treated, with no long-term danger. However, a thrombosis can cause serious permanent disabilities or could even kill you, though this is very rare. Blood clots sometimes form in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a 'pulmonary embolism'.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

In extremely rare cases, blood clots can form in other places such as the liver, gut, kidney or eye.

A blood clot can develop whether or not you are taking the pill. It can also happen if you become pregnant. The risk is higher in people who take the pill than in people

who don't take the pill, but it isn't as high as the risk during pregnancy. A thrombosis is most likely in the first year of taking any combined pill.

For Millinette there are about 30 to 40 cases of thrombosis for every 100,000 women each year.

In pregnant women, there are about 60 cases of thrombosis for every 100,000 pregnancies each year.

Symptoms of a blood-clot formation are listed under 'Tell your doctor immediately if.'

**If you notice possible signs of a thrombosis, stop taking the pill and contact your doctor immediately. In the meantime, use another method of contraception such as a condom or cap plus spermicide.**

You should also remember that certain conditions can increase your risk of thrombosis. They include:

- age (the risk of having a heart attack or stroke increases as you get older);
- smoking (with heavier smoking and increasing age, your risk of thrombosis increases). **When using the pill stop smoking, especially if you are over 35;**
- if any member of your close family has ever had any illness caused by blood clots, or a heart attack, or a stroke;
- being very overweight (obese);
- having a disorder of blood-fat (lipid) metabolism, or other very rare blood disorders;
- having high blood pressure (hypertension);
- having a heart-valve disorder or a certain heart-rhythm disorder;
- having given birth recently (you will have an increased risk of thrombosis after giving birth);
- having diabetes mellitus;
- having systemic lupus erythematosus - SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs);
- having a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail);
- having Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases);
- having sickle cell disease;
- getting a migraine for the first time, or if you already have migraines but they get worse or happen more often than before;
- having a major operation, any surgery to your legs or not being able to move around as normal.

Your risk of having a deep venous thrombosis temporarily increases after an operation or any time when you can't move around as normal (for example, when you have your leg or legs in plaster or splints). If you are on the pill, this risk could be higher. Tell your doctor you are using the pill well before you expect to go into hospital or have an operation. Your doctor may tell you to stop taking the pill several weeks before or after an operation. If there is no time for this, your doctor may give you a medicine to reduce your risk of thrombosis. Your doctor will also tell you when you can start taking the pill again, once you are back on your feet.

#### 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.

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.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking and have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may stop Millinette from working properly.

If you are taking any other medicine while you are taking Millinette, be sure to tell your doctor (or dentist, if they have prescribed antibiotics). Your doctor (or dentist) can tell you whether you should use extra contraceptive precautions and for how long.

Medicines which can sometimes stop Millinette from working properly are:

- antibiotics (such as ampicillin, tetracycline and rifampicin);
- medicines used to treat epilepsy or other illnesses of nervous system, such as primidone, carbamazepine, oxcarbazepine, topiramate, hydantoin or barbiturates (such as phenobarbitone);
- rifonavir (a medicine used to treat HIV infections);
- griseofulvin (a medicine used to treat fungal infections);
- 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 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.

If you are taking antibiotics, always ask your doctor's advice about extra precautions. Always mention you are on the combined pill if you are prescribed any medicines.

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.

Millinette may influence the effect of other medicines, such as cyclosporine, lamotrigine, therefore in such case you should consult your doctor.

#### **Pregnancy and breast-feeding**

##### *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.

#### **Important information about some of the ingredients of Millinette**

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

#### **Before you have any blood tests**

Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

### **3. HOW TO TAKE MILLINETTE**

Always take Millinette exactly as your doctor has told you. You should check with your doctor 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 you take the last pill of your present strip (or the day after the last **active** pill, if your present pill strip also contains dummy pills), but no later than on the day after the usual tablet-free or dummy pill interval with your previous pill.

#### *Changing to Millinette from progestogen-only preparations (progestogen-only pills, injection, implant)*

You may change from progestogen-only pills (POPs) on any day. Stop taking the POP and start taking Millinette the next day at the same time point. When changing from injections, Millinette should be started when the next injection is due to be given. When changing from an implant, Millinette should be started on the day the implant is removed. In all these cases you should also use a barrier method for the first 7 days of taking the pills.

#### **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 an 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 one pill is 12 hours late or less**

Your contraceptive protection should not be affected if you take the late pill at once, and keep taking your next pills at the usual time. This may mean taking two pills in one day.

#### **If you are more than 12 hours late in taking a pill, or have missed more than one pill**

If you are more than 12 hours late in taking a pill, or you have missed more than one pill, your contraceptive protection may be lower so you must use extra protection. The more pills you have missed, the more risk there is that your contraceptive

protection is reduced. In this case follow the instructions for daily practice:

#### *What to do if you miss the pill during the first week?*

You must take the last missed tablet as soon as you remember, even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You must also use a barrier method of contraception, e.g. a condom, for the next 7 days. If intercourse has taken place during the preceding 7 days the possibility of pregnancy must be considered. The more missed tablets and the closer to the tablet-free interval this happens, the greater the risk of pregnancy.

#### *What to do if you miss the pill during the second week?*

You must take the last missed tablet as soon as you remember even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. Provided that the tablets have been taken in a correct manner during the 7 days preceding the missed tablet, it is not necessary to take further contraceptive measures. However, if this is not the case, or if more than 1 tablet has been missed, you should use another contraceptive method for 7 days.

#### *What to do if you miss the pill during the third week?*

The risk of contraceptive failure is higher because of the approaching tablet-free interval. Reduced contraceptive protection may, however, be prevented by following one of the following two alternatives. It is not necessary to take further contraceptive precautions, provided that all tablets have been taken correctly during the 7 days preceding the first missed tablet.

However, if you have not taken Millinette correctly during the 7 days preceding the first missed tablet, you should follow the first of the two alternatives and additionally use a barrier method (such as a condom) for the next 7 days.

1. Take the last missed tablet as soon as you remember, even if it means that you have to take 2 tablets at the same time. You should continue taking the tablets at the usual time of the day. Start your next pack immediately after taking the last tablet in the current pack, i.e. without a tablet-free interval between the packs. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or breakthrough bleeding, on the days you are taking tablets.
2. Stop taking tablets from the current pack. You should then have 7 pill-free days, including those when you forgot to take you tablets, before starting your next pack.

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.

#### **If you stop taking 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 want to shift your period to another day of the week**

If you take Millinette correctly, you will always have your monthly period on the same day of the month. If you want to shift your period to another day of the week, rather than the one you are used to with the present pill intake, you may shorten (but never lengthen) the forthcoming pill-free interval by as many days as you like. For example, if your monthly period usually starts on Friday and you want it to start on Tuesday (i.e. three days earlier), you should start the next pack of Millinette three days earlier. The shorter the pill-free interval, the greater the possibility that you will not have a withdrawal bleeding, and that you may have breakthrough bleeding or spotting during the second pack.

### **4. POSSIBLE SIDE EFFECTS**

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

The following serious adverse events have been reported in women using combined oral contraceptives, see section 2 under "The pill and thrombosis" and "The pill and cancer".

- Venous thromboembolism (a blood clot in vessels);
- Arterial thrombotic disorders (obstruction of an artery);
- Cervical cancer (cancer of the neck of the womb).

**Reasons for stopping Millinette immediately if you experience any of the following conditions whilst taking Millinette, take no further tablets and tell your doctor straight away. In the meantime use another non-hormonal method of contraception such as a condom.**

- Migraine for the first time, or if existing migraine occurs more often or worse than before;
- Unusually bad headache or if you have headaches more often than before;
- Sudden changes to your eyesight or

- difficulties in seeing or speaking;
- Unusual pains or swelling in your leg, sharp pains in your chest or sudden shortness of breath, crushing pains or feelings of heaviness in your chest, persistent coughing or coughing blood;
- Numbness in an arm or leg;
- Your skin becomes yellow (jaundice);
- A large increase in your blood pressure;
- The levels of lipids (fats) in your blood change;
- Pregnancy;
- Definite worsening of conditions which had got worse during a previous pregnancy or while taking the pill in the past;
- Severe abdominal pain.

These side effects have been reported in women using the pill, which can occur in the first few months after starting Millinette, but they usually stop once your body has adjusted to the pill.

**The most commonly reported** undesirable effects (more than 1 in 10 women) are: irregular bleeding, nausea, weight gain, tender breast and headache.

**Common** (equal or more than 1 in 100 women, but less than 10 in 100): Mood changes, including depression, excitability, acne, none, reduced or painful bleeding, breast enlargement and secretion, changes in vaginal secretions, abdominal pain, fluid retention, changes in the sexual desire (increased or decreased), nervousness, eye irritation, dizziness, visual disturbances, migraine, increase or decrease in body weight.

**Uncommon** (equal or more than 1 in 1,000 women, but less than one in 100) **and rare** (equal or more than 1 in 10,000 women, but less than one in 1,000): Allergic reactions, vomiting, brown patches on your face and body (chloasma or melasma), loss of hair, hirsutism, rash, a rash with tender red lumps on the legs and arms (erythema nodosum), high blood pressure, breast cancer, cervical cancer, blood clot, enhanced levels of blood fat, decrease in blood folate level, impaired hearing (otosclerosis), abdominal cramps or bloating, inflammation of the pancreas, liver tumours, chorea (a movement disease), systemic lupus erythematosus (SLE, a disease of the connective tissue), changes in appetite (increase or decrease), irritation of the eye due to contact lenses.

**Very rare** (more than 1 in 10,000 women): Burst of systemic lupus erythematosus (SLE, a disease of the connective tissue), burst of inherited disease called porphyria, burst of chorea (a movement disease), urticaria, angioedema, inflammation of the optic nerve (may lead to partial or complete loss of vision), blood clot in the blood-vessels of the eye, aggravation of varicose veins, inflammation of the walls of the bowel (ischemic colitis), gallbladder disease (including gallstones), fever and rash of the face, arms and legs (erythema multiforme), a blood disorder called haemolytic uraemic syndrome (a disorder where blood clots cause the kidneys to fail).

**Unknown frequency:** Liver disorders.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE MILLINETTE**

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

Do not use after the expiry date stated on the package after Exp. The expiry date refers to the last date of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. FURTHER INFORMATION**

#### **What Millinette contains**

The active substances are: 20 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 (E170), Sucrose.

#### **What Millinette looks like and contents of the pack**

Pale 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 x 21 tablets; 3 x 21 tablets, 6x 21 tablets, 13 x 21 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder:**

Medimpex France SA, 1-3 rue Caumartin, 75009 Paris, France

#### **Distributed by:**

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