

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Madeline®?

Madeline® contains the active ingredients desogestrel and ethinylestradiol. Madeline® is used to prevent pregnancy. It is a combined oral contraceptive, commonly known as a "birth control pill" or "the Pill".

For more information, see section [1. Why am I using Madeline®?](#) in the full CMI.

2. What should I know before I use Madeline®?

Do not use if you have ever had an allergic reaction to Madeline® or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see section [2. What should I know before I use Madeline®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Madeline® and affect how it works.

A list of these medicines is in section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Madeline®?

Take one tablet daily at about the same time every day. **Take your first tablet from the blue area on the blister pack corresponding to the day of the week. Follow the direction of the arrows on the blister pack until all the tablets have been taken. Follow the instructions provided and use Madeline® until your doctor tells you to stop.**

More instructions can be found in section [4. How do I use Madeline®?](#) in the full CMI.

5. What should I know while using Madeline®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Madeline®.• If you are going to be immobilized, have surgery, tell the surgeon or anesthetist beforehand that you are using Madeline®.• If you are about to have any blood tests, tell your doctor that you are taking this medicine.• Stop taking Madeline® and see your doctor immediately or go to the Emergency Department at your nearest hospital if you notice any sign of a blood clot or any of the other signs detailed in section 5. What should I know while using Madeline®?• Consult your doctor immediately if you become pregnant, breastfeeding or develop high blood pressure, or unexpected bleeding/vomit, or have severe diarrhoea, or if you plan to air travel for greater than 4 hours.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or change the dosage without checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking Madeline® or do not take a tablet every day.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see section [5. What should I know while using Madeline®?](#) in the full CMI.

6. Are there any side effects?

- If you notice possible signs or are concerned about increased risk of blood clots, stop taking Madeline® and consult your doctor immediately.
- Breast cancer has been diagnosed slightly more often in women who take the Pill, than in women of the same age who do not take the Pill.
- In women who use the Pill for a long time, the chance of getting cervical cancer may be slightly higher.
- In rare cases liver tumors have been reported in women who take the Pill.

For more information, including what to do if you have any side effects, see section [6. Are there any side effects?](#) in the full CMI.

Madeline®

Active ingredients: *desogestrel and ethinylestradiol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Madeline®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Madeline®.**

Where to find information in this leaflet:

- [1. Why am I using Madeline®?](#)
- [2. What should I know before I use Madeline®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Madeline®?](#)
- [5. What should I know while using Madeline®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Madeline®?

Madeline® contains the active ingredient desogestrel and ethinylestradiol. It is a combined oral contraceptive, commonly known as a "birth control pill" or "the Pill".

Madeline® is used to prevent pregnancy.

While taking Madeline® you may also experience the following benefits:

- more regular periods, lighter bleeding
- a decrease in the occurrence of anaemia (iron deficiency)
- a decrease in period pain.

There is also evidence that some medical conditions such as benign breast disease, ovarian cysts, pelvic inflammatory disease (pelvic infections), ectopic pregnancy (pregnancy in which the embryo implants outside of the womb) and cancer of the endometrium (lining of the womb) and ovaries may be less common in women using combined oral contraceptives containing 50 micrograms of ethinylestradiol (high-dose Pills). This may also be the case for low-dose Pills but so far this has only been confirmed for endometrial and ovarian cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

When taken correctly, this medicine prevents pregnancy in several ways:

- it inhibits the egg release by stopping it maturing.
- it changes the cervical mucus consistency making it difficult for the sperm to reach the egg.

- changing the lining of the uterus making it less suitable for implantation.

There is no evidence that this medicine is addictive.

2. What should I know before I use Madeline®?

Warnings

When you must not take it

Do not use the combined Pill if you have or have had any of the conditions listed below. If any of these conditions apply to you, tell your doctor before starting to use this medicine. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- a disorder affecting the blood circulation; in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack) or other parts of the body (see also the section later in this leaflet called 'The Pill and Thrombosis')
- a stroke (caused by a clot in or a rupture of a blood vessel in the brain)
- a condition that may be the first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke)
- a serious risk factor or several risk factors for developing a blood clot
- very high blood pressure
- a very high level of fat in the blood (cholesterol or triglycerides)
- if you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see also the section later in this leaflet called 'The Pill and Thrombosis')
- if you know that you have Activated Protein C resistance, (including Factor V Leiden), antithrombin-III, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant), and hyperhomocysteinaemia.
- a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of the body
- diabetes mellitus with blood vessel damage
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- jaundice (yellowing of the skin) or severe liver disease
- a cancer that may grow under the influence of sex hormones (e.g. of the breast or of the genital organs)
- a benign or malignant liver tumour
- any unexplained vaginal bleeding
- you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using this medicine, stop taking it at once and tell your doctor.

In the meantime, use non-hormonal contraceptive measures. See also 'General Notes' in the next section.

Do not use this medicine if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir and medicinal products including glecaprevir and pibrentasvir (see section 3. What if I am taking other medicines?).

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, desogestrel, ethinylestradiol or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

General notes

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

If you are concerned about contracting a sexually transmitted infection (STI), ask your partner to wear a condom when having sexual intercourse with you.

This medicine will not protect you from HIV (AIDS) or any other sexually transmitted infections. To help protect yourself from STIs, you need to use a barrier contraceptive such as a condom, but even barrier contraceptives may not protect you against human papilloma virus (HPV).

Before you start to take it

You should have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine check.

Tell your doctor if:

- you smoke. The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke. When using the Pill you should stop smoking, especially if you are older than about 35 years of age.
- you are overweight.

- you or anyone in your immediate family has had blood clots in the legs (thrombosis), a heart attack, a stroke, breast cancer or high cholesterol.

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - diabetes
 - high blood pressure
 - heart valve disorder or a certain heart rhythm disorder
 - anyone in your immediate family has had a thrombosis, a heart attack or a stroke
 - you or someone in your immediate family has or has had high levels of cholesterol or triglycerides (fatty substances) in the blood
 - anyone in your immediate family has had breast cancer
 - inflammation of your veins (superficial phlebitis)
 - varicose veins
 - migraine
 - epilepsy
 - liver disease
 - gall bladder disease
 - Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
 - systemic lupus erythematosus (SLE, a disease affecting the skin, joints and kidneys)
 - haemolytic uraemic syndrome (HUS, a disorder of blood coagulation causing failure of the kidneys)
 - sickle cell disease
 - a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea); hereditary and acquired angioedema (you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, potentially difficulty breathing). Products containing estrogens may cause or worsen hereditary and acquired angioedema.
 - chloasma (yellow brownish pigmentation patches on the skin, particularly of the face). If so, avoid too much exposure to the sun or ultraviolet radiation.
 - you need an operation or if your ability to move around is limited for a long period of time. This includes travelling by plane for greater than 4 hours.
 - if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using this medicine (see also the section in this leaflet called 'The Pill and Thrombosis').
 - lactose intolerant.

If any of the above conditions appear for the first time, or recur or worsen while taking this medicine, you should contact your doctor.

3. You are currently breastfeeding or you plan to breastfeed. This medicine is generally not recommended whilst breastfeeding.
4. You are planning to have surgery or an anaesthetic.
5. You are currently receiving or are planning to receive dental treatment.
6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not take Madeline® if you are pregnant or think you might be pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed if you are taking Madeline®.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and herbal products may interact with desogestrel and/or ethinylestradiol. These include:

- medicines for epilepsy (such as phenytoin, primidone, phenobarbital, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine)
- medicines for tuberculosis (e.g. rifampicin and rifabutin)
- medicines for HIV infections (ritonavir, nelfinavir, nevirapine, efavirenz)
- medicines for Hepatitis C virus infection (e.g. boceprevir, telaprevir)
- certain antibiotics (e.g. penicillin, and tetracyclines)
- antifungals (e.g. griseofulvin)
- ciclosporin, a medicine used for suppressing the immune system (i.e. during and after organ transplants)
- medicines for high blood pressure in the blood vessels of the lungs (bosentan)
- herbal medicines containing St. John's wort primarily for the treatment of depressive moods.

If you are taking any of these you may need a different dose or you may need to take different medicines.

You may also need to use an additional barrier method of contraception (such as a condom or a diaphragm) while you are taking any of these medicines and for some time after stopping them. Your doctor will be able to advise how long you will need to use additional barrier contraceptive methods.

Do not use the Pill if you have Hepatitis C and are taking the combination drug regimen

ombitasvir/paritaprevir/ritonavir, with or without dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). The Pill can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen. (See section 2. What should I know before I use Madeline®? 'When you must not take it').

If you are taking other Hepatitis C drug combinations (such as glecaprevir/pibrentasvir) you may experience increased levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood.

Other medicines not listed above may also interact with desogestrel and ethinylestradiol.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Madeline®.

4. How do I use Madeline®?

How much to take

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

The pack contains 28 tablets: 21 white tablets with active substances and 7 green placebo tablets that contain inactive substances.

Take one tablet daily.

Swallow each tablet whole with a glass of water.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

If you do not understand the directions, ask your doctor or pharmacist for help.

When to take Madeline®

On the blister, each tablet is marked with the day of the week on which it is to be taken.

Take one tablet daily in the order directed on the blister, at about the same time every day. This will help you remember when to take it. It does not matter if you take this medicine before or after food.

You must take this medicine every day even if you do not have sex very often.

A period should begin during the 7 days that you use the inactive tablets (the withdrawal bleed). Usually, it will start on day 2-3 after the last white active tablet.

How to start taking Madeline®

Start with a tablet from the blue zone marked with that day of week.

When no hormonal contraception has been used in the past month:

Start on the first day of your period (i.e. the first day of menstrual bleeding). Take a tablet from the blue zone marked with that day of the week. For example, if your period starts on a Wednesday, then take a tablet marked 'Wednesday'. Then follow the days in order.

If your period starts on a Thursday or Friday, make sure you also use an additional barrier method of contraception (e.g. condom) for the first 7 days of white active tablet taking, as the Thursday and Friday tablets in the blue zone are green placebo (inactive) tablets.

Changing from another combined oral contraceptive, vaginal ring or transdermal patch:

Start the day after taking the last active tablet in your previous Pill pack (or at the latest on the day following the last placebo tablet or tablet free interval of your previous Pill pack), taking a tablet from the blue zone marked with that day of the week.

Ask your doctor or pharmacist if you are not sure which the active tablets were in your previous Pill pack. Your previous Pill pack may have had different colour tablets to those of this medicine.

If a vaginal ring or transdermal patch has been used, start on the day of removal (but at the latest when the next application would have been due), taking a tablet from the blue zone marked with that day of the week.

Changing from a progestogen-only pill (minipill):

You may change any day, taking a tablet from the blue zone marked with that day of the week, but make sure you also use an additional barrier method of contraception (e.g. condom) for the first 7 days of white active tablet taking.

Changing from a progestogen-only implant or progesterone-releasing intrauterine system (IUS):

Change on the day of its removal, taking a tablet from the blue zone marked with that day of the week, and make sure you also use an additional barrier method of contraception (e.g. condom) for the first 7 days of white active tablet taking.

Changing from a progestogen-only injectable:

Change when the next injection would be due, taking a tablet from the blue zone marked with that day of the week, and make sure you also use an additional barrier method of contraception (e.g. condom) for the first 7 days of white active tablet taking.

After having a baby, miscarriage or abortion:

Your doctor will advise you. Please note that there is an increased risk of thrombosis (venous thrombosis embolism, VTE) during the postpartum period and this risk should be considered when restarting this medicine.

How long to take Madeline® for

Daily tablet taking should be continuous. One tablet is taken daily for 28 consecutive days in the order directed on the blister.

Start a new blister pack on the day after the last green placebo (inactive) tablet of the previous pack.

If you do not understand the instructions, ask your doctor or pharmacist for help.

If you forget to take Madeline®

Madeline® should be taken regularly, at the same time each day. If you miss your dose, see the instructions below:

Missed green placebo (inactive) tablets

Missed green placebo (inactive) tablets should be discarded to avoid accidentally extending the placebo tablet phase. Take the next tablet at the usual time. You are still protected against pregnancy because the green placebo (inactive) tablets do not contain any active ingredients.

Missed white active tablets

For this medicine to be most effective, white active tablets need to be taken every day without interruption for 7 days.

If you missed a white active tablet and take the missed tablet within 12 hours, you will be protected against pregnancy and should continue taking the tablets as normal.

If you missed a white active tablet (or several white active tablets - in which case also speak to your doctor for advice) and are more than 12 hours late, take the last missed white active tablet immediately, even if it means taking two tablets in one day. Make sure you also use an additional barrier method of contraception (e.g. condom) for the next 7 days and complete the pack as normal.

However, if these next 7 days include the taking of green placebo (inactive) tablets, the white active tablets of the next pack should be started as soon as the white active tablets from the current pack are finished.

If you missed one or more of the first 7 white active tablets and sexual intercourse has taken place, there is a possibility you may be pregnant. See your doctor for advice.

Ask your doctor or pharmacist to answer any questions you may have.

If you use too much Madeline®

If you think that you have used too much Madeline®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Madeline®?

Things you must do

Tell your doctor that you are taking Madeline® if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to be immobilised, have surgery or an anaesthetic or are going into hospital (consult your doctor at least 4 weeks in advance)

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a pap smear test. Your doctor will advise how often you need a pap smear test. A pap smear test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who take the Pill, the risk may be higher.

The excess risk of thrombosis is highest during the first year a woman takes a combined oral contraceptive. Your doctor may tell you to stop taking the Pill several weeks before surgery, or at the time of immobilisation, and when you can start taking the Pill again. If you notice possible signs of a thrombosis (see section 6. Are there any side effects?), stop taking the Pill and consult your doctor immediately.

Consult your doctor if you develop high blood pressure while taking this medicine – you may be told to stop taking it.

If you vomit within 3-4 hours or have severe diarrhoea after taking a white active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

This medicine will not protect you from HIV-AIDS or any other Sexually Transmitted Diseases (STDs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

To protect yourself from STDs, you will need to use an extra barrier method of contraception (e.g. condom).

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the

Pill may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method.

Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Things you must not do

- Give your medicine to anyone else even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor. You may become pregnant if you are not using any other contraceptive and you stop taking this medicine, or do not take a tablet every day.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Madeline® affects you.

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> nausea, vomiting, abdominal pain or diarrhoea increase in body weight or fluid retention headache or migraine decreased sexual drive, increased sexual drive depressed mood or mood changes breast pain, breast tenderness or breast enlargement rash, hives contact lens intolerance decrease in body weight breast secretion vaginal secretion male-pattern hair growth or loss acne erythema nodosum, erythema multiforme (these are skin conditions) angioedema, particularly in patients who already have a (family) history of angioedema 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> jaundice (yellowing of the eyes or skin). <p>See 'Thrombosis and the Pill'. Possible signs of a blood clot, heart attack or a stroke can include:</p> <ul style="list-style-type: none"> an unusual cough severe pain in the chest which may reach the left arm breathlessness any unusual, severe or prolonged headache or migraine attack partial or complete loss of vision, or double vision slurring or speech disability sudden changes to your hearing, sense of smell or taste dizziness or fainting weakness or numbness in any part of your body severe pain in your stomach severe pain or swelling in either of your legs. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

When to contact your doctor

Regular check-ups

When you are using the Pill, your doctor will tell you to return for regular check-ups. You should have a check-up at least once a year.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see section 2. What should I know before I use Madeline®? 'When you must not take it' and 'Before you start to take it'); do not forget about the items related to your immediate family
- you feel a lump in your breast
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also Section 3. What if I am taking other medicines?)
- you are going to use other medicines (see also Section 3. What if I am taking other medicines?)
- you are going to be immobilised or are to have surgery (consult your doctor at least 4 weeks in advance)
- you have unusual, heavy vaginal bleeding
- you forgot tablets in the first week of the pack and had intercourse in the seven days before
- you have severe diarrhoea
- you miss your period twice in a row or suspect you are pregnant. Do not start the next pack until told to by your doctor.

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction or a stroke such as:

- an unusual cough
- severe pain in the chest which may reach the left arm - this discomfort may include the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting, anxiety
- breathlessness or rapid breathing
- any unusual, sudden, severe or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- confusion, slurring or speech disability
- sudden changes to your hearing, sense of smell or taste
- dizziness or fainting
- fast or irregular heartbeat
- weakness or numbness in any part of your body
- severe pain in your stomach
- severe pain or swelling in either of your legs
- pain or tenderness in the leg which may be felt only when standing or walking
- warmth, red or discoloured skin on the leg
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden trouble walking, loss of balance or coordination

The situations and symptoms mentioned above are described and explained in more detail in section 'Before you take this medicine'.

Thrombosis and the Pill

Thrombosis is the formation of a blood clot that may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis (DVT)). If a blood clot breaks away from the veins where it has formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest after you started using the Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more. Thrombosis can also occur during pregnancy.

The risk of getting a blood clot in the deep veins of the legs for women using Pills with desogestrel (in Madeline®) may be slightly higher than for women using Pills with levonorgestrel, norgestimate or norethisterone. The absolute numbers remain very small. If 10,000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10,000 women use a Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10,000 women get pregnant, approximately 6 would get a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

If you develop high blood pressure while using the Pill, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example when you have your leg or legs in plaster or splints). In women who use the Pill, the risk may be yet higher. Tell your doctor you are using the Pill well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking the Pill several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking the Pill again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately.

Cancer and the Pill

Regularly examine your breasts.

The information given below was obtained from studies of women who used combined oral hormonal

contraceptives, such as the combined pill, and from an additional study that included both oral and non-oral hormonal contraceptive-users.

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill.

In the additional study that included both oral and non-oral hormonal contraceptive-users, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who have never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women-years.

It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

Tell your doctor immediately if you have severe pain in your stomach.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Chronic infection with Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer. HPV is a sexually transmitted infection. In women who use combined oral contraceptives for a long time the chance of getting cervical cancer may be slightly higher. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

Allergic reactions

If you think you are having an allergic reaction to this medicine, do not take any more and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Madeline® contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• desogestrel• ethinylestradiol
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• maize starch• povidone• colloidal anhydrous silica• hypromellose• triacetin• polysorbate 80• titanium dioxide• d-alpha-tocopherol (white active tablets only)• silicon dioxide (white active tablets only)• stearic acid (white active tablets only)• magnesium stearate (green placebo tablets only)• indigo carmine aluminium lake (green placebo tablets only)• iron oxide yellow (green placebo tablets only).
Potential allergens	lactose monohydrate

This medicine contains lactose and d-alpha-tocopherol.

Do not take this medicine if you are allergic to any of these ingredients.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

What Madeline® looks like

MADELINE® desogestrel 150 micrograms and ethinylestradiol 30 micrograms tablet blister pack (AUST R 202833)

21 active tablets: round, biconvex, white, film-coated tablet with "MI" debossed on one side and "7" debossed on the other.

7 placebo tablets: round, biconvex, plain, green, film-coated tablet with no markings.

Who distributes Madeline®

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 2121

www.arrotex.com.au

This leaflet was prepared in September 2023.