

Madeline[®]

Contains: 21 white active tablets, each containing 150 mcg of desogestrel and 30 mcg of ethinyloestradiol; 7 green placebo (inactive) tablets

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about desogestrel and ethinyloestradiol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Read this information carefully before you start taking this medicine.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Madeline. It contains the active ingredients desogestrel and ethinyloestradiol.

It is a combined oral contraceptive, commonly known as a "birth control pill" or "the Pill".

It is used to prevent pregnancy. 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 pelvic inflammatory disease, ovarian cysts, ectopic pregnancy and disorders of the uterus (womb), ovaries and breast may be less common in women using combined oral contraceptives.

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 two 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.

There is no evidence that this medicine is addictive.

Before you take this medicine

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)
- if you know that you have Activated Protein C resistance, antithrombin-III, protein C or protein S deficiencies

- 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 take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, desogestrel, ethinyloestradiol 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
 - 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)
 - chloasma (yellow brownish pigmentation patches on the skin, particularly of the face). If so, avoid too much exposure to the sun or ultraviolet radiation.
- 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.

Taking Other Medicines

Some medicines may interact with desogestrel and/or ethinyloestradiol. These include:

- medicines for epilepsy (such as phenytoin, primidone, barbiturates, carbamazepine, oxcarbamazepine, topiramate, felbamate)
- medicines for tuberculosis (e.g. rifampicin and rifabutin)
- medicines for HIV infections (ritonavir)
- certain antibiotics (e.g. penicillin, and tetracyclines)
- antifungals (e.g. griseofulvin)
- cyclosporin, a medicine used for suppressing the immune system (i.e. during and after organ transplants)
- 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.

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

Your doctor has more information on medicines that you need to be careful with or avoid while taking this medicine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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

How much to take

Take one tablet daily.

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

How to take it

Swallow each tablet whole with a glass of water.

When to take it

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 this medicine

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.

How long to take it 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 it

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 take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine 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 Possible 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

ERROR PARADo not:

- Give this 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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
- 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)

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

- jaundice (yellowing of the eyes or skin).

See 'Thrombosis and the Pill'.

Possible signs of a blood clot, heart attack or a stroke can include:

- 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.

Other side effects not listed above may occur in some patients.

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 also '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 are going to use other medicines (see also '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.

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. They can also happen 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. 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.

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.

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.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

June 2016.

What Madeline looks like

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, green, film-coated tablet with no markings.

Ingredients

Each white active tablet contains 150 micrograms of desogestrel and 30 micrograms of ethinyloestradiol as the active ingredients. It also contains the following inactive ingredients:

- lactose, maize starch, povidone, d-alpha-tocopherol, silicon dioxide, colloidal anhydrous silica, stearic acid, hypromellose, glycerol triacetate, polysorbate 80 and titanium dioxide.

Each green placebo tablet contains the following inactive ingredients:

- lactose, maize starch, povidone, colloidal anhydrous silica, magnesium stearate, hypromellose, glycerol triacetate, polysorbate 80, titanium dioxide, indigo carmine aluminium lake and iron oxide yellow.

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

Australian Registration Numbers

MADELINE® desogestrel 150 micrograms and ethinyloestradiol 30 micrograms tablet blister pack:
AUST R 202833.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

MADELINE is a registered trademark of Apotex Pty Ltd.

This leaflet was last updated in: