

Micronelle® 20 ED Tablets

Each blister pack contains: 21 pink (active) tablets each containing 20 micrograms ethinylloestradiol and 100 micrograms levonorgestrel; 7 white 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 Micronelle 20 ED. 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.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

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 Micronelle 20 ED. It contains the active ingredients levonorgestrel and ethinylloestradiol.

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 periods
- a decrease in anaemia (iron deficiency)
- a decrease in period pain.

This medicine must only be used after a female's first period has occurred and should not be used after menopause.

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 three ways:

- inhibiting ovulation (egg release)
- changing the cervical mucus consistency, making it more 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.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had a blood clot in:**
 - the blood vessels of the legs (deep vein thrombosis)
 - the lungs (pulmonary embolism)
 - the heart (heart attack)
 - the brain (stroke)
 - other parts of the body.
- **You are concerned about an increased risk of blood clots.**

Blood clots are rare. Very occasionally blood clots may cause serious permanent disabilities, or may even be fatal.

You are more at risk of having a blood clot when you take the Pill. But the risk of having a blood clot when taking the Pill is less than the risk during pregnancy.

You are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke.

You should stop smoking when taking the Pill, especially if you are older than 35 years of age.

- **You have, or have had any of the following:**

- angina (chest pain)
- mini-stroke (also known as TIA or transient ischaemic attack)
- migraine, accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body
- diabetes mellitus with blood vessel damage
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- severe liver disease and your liver function has not returned to normal
- benign or malignant liver tumour
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- unexplained vaginal bleeding.
- **You are pregnant or think you might be pregnant.**

You are hypersensitive to, or have had an allergic reaction to, levonorgestrel and/or 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you smoke
- 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 disorders or certain heart rhythm disorders
 - inflammation of your veins (superficial phlebitis)
 - varicose veins
 - migraine
 - epilepsy
 - high cholesterol or triglycerides
 - liver disease
 - kidney disease
 - gall bladder disease
 - Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
 - systemic lupus erythematosus (SLE - a disease affecting the skin all over the body)
 - 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 (yellowish-brown pigmentation patches on the skin, particularly of the face) - if so, avoid exposure to the sun or ultraviolet radiation
- hereditary angio-oedema - you should see your doctor immediately if you experience symptoms of angio-oedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

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

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
4. You are currently breastfeeding or you plan to breast-feed. This medicine is generally not recommended whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. 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.

Some medicines may interact with Micronelle 20 ED. These include:

- medicines used to treat tuberculosis, such as rifampicin and rifabutin

- antibiotics (for e.g. penicillins, tetracyclines, macrolides such as erythromycin and clarithromycin)
- medicines used to treat fungal infections, such as fluconazole and griseofulvin
- medicines used to treat HIV, such as ritonavir and nevirapine
- medicines used to treat epilepsy, such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- cyclosporin, an immunosuppressant medicine
- verapamil, a medicine used for high blood pressure, chest pain and irregular heartbeats.
- herbal medicines containing St John's Wort.
- grapefruit juice

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 condoms 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 you about how long you will need to use additional barrier contraceptive methods.

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

Your doctor and pharmacist have 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.

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 the tablet whole with 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.

How to start this medicine

Start with a pink (active) tablet from the green 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 pink (active) tablet from the green 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.

You must also use an additional barrier method of contraception (e.g. condom) for the first 7 days of tablet taking.

Changing from another combined oral contraceptive:

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 (inactive) tablet or tablet free interval of your previous Pill pack), taking a pink tablet(active) from the green zone marked with that day of the week.

Ask your doctor or pharmacist if you are not sure which were the active/inactive tablets in your previous Pill pack.

Your previous Pill pack may have had different colour tablets to those of this medicine.

Changing from a vaginal ring:

If a vaginal ring has been used, start on the day of removal taking a pink tablet (active) from the green zone marked with that day of the week.

Changing from a progestogen-only pill (minipill):

You may change any day, taking a pink tablet(active) , but make sure you also use an additional barrier method of contraception (e.g. condom) for the first 7 days of tablet taking.

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

Change on the day of its removal, taking a pink tablet(active) from the green 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 tablet-taking.

Changing from a progestogen-only injectable:

Change when the next injection would be due, taking a pink tablet(active) from the green 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 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 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 white placebo (inactive) tablets

Missed white 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 white placebo (inactive) tablets do not contain any active ingredients.

Missed pink (active) tablets

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

If you missed taking a pink (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 pink (active) tablet and are more than 12 hours late, follow the advice below:

- Week 1 - Take the pink (active) tablet you missed as soon as you remember (even if this means taking 2 pink (active) tablets at the same time) and complete the pack as normal. You should also use an extra barrier method of contraception (e.g. condom) for 7 days. If you had sex in the previous 7 days you should speak to your doctor due to the possibility of pregnancy.
- Week 2 - Take the pink (active) tablet you missed as soon as you remember (even if this means taking 2 pink (active) tablets at the same time) and complete the pack as normal. If you have also missed an additional pink (active) tablet in the previous 7 days, you should also use an extra barrier method of contraception (e.g. condom) for 7 days.
- Week 3 - Take the pink (active) tablet you missed as soon as you remember (even if this means taking 2 pink (active) tablets at the same time) and continue taking the pink (active) tablets

until they have all been taken. When the final pink (active) tablet has been taken, discard the 7 white placebo (inactive) tablets and start a new pack right away. If you have missed an additional pink (active) tablet in the previous 7 days, you should also use an extra barrier method of contraception (e.g. condom) for 7 days. You are unlikely to have a withdrawal bleed until the end of the pink (active) tablets of the second pack, but you may experience spotting or breakthrough bleeding on tablet-taking days.

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.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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 breast-feed
- 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 pink (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

Do not:

- Give this medicine to anyone else.
- Take this 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 you do not take a tablet every day.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

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
- stomach pain
- changes in weight
- headache, including migraines
- mood changes, including depression
- acne
- breast tenderness or pain
- abnormal growth of hair on the face and body.
- hair loss

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. You may need urgent medical attention or hospitalisation.

- pain in the chest, arm or below the breastbone
- discomfort radiating to the back
- breathlessness and/or difficulty breathing
- swelling, pain or tenderness of one leg
- sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- severe, sudden stomach pains
- a fainting attack or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with your speech, understanding or eyesight.

The side effects listed above are possible signs of a thrombosis.

Other very serious but rare side effects not listed above include the following:

- jaundice (yellowing skin or yellowing eyes)
- coughing up blood
- breast lumps
- unexplained vaginal bleeding.

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

Other side effects not listed above may also occur in some people.

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).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in Pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or after having a break from the Pill for 4 weeks or more.

Therefore, you should keep the possibility of an increased risk of blood clots in mind, particularly where there is a history of thrombosis.

If you notice possible signs of a blood clot, stop taking this medicine and consult your doctor immediately.

Cancer and the Pill

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 diagnosed gradually disappears during 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.

It is important that you check your breasts regularly and to contact your doctor if you feel any lump.

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

Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women who have been taking the Pill for a long time. 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 tablets in its original packaging until it is time to take it.

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

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

Do not store this 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

What Micronelle 20 ED looks like

Active tablet: Plain, round, pink tablets.

Placebo (inactive) tablet: Plain, round, white tablets.

This medicine comes in a box containing either 1, 3 or 4 blister packs. Each blister pack contains 21 pink (active) tablets and 7 white placebo (inactive) tablets.

* Not all pack sizes may be available.

Ingredients

Each pink (active) tablet contains 20 micrograms ethinyloestradiol and

100 micrograms levonorgestrel as the active ingredients.

It also contains the following inactive ingredients:

- lactose
- povidone
- crospovidone
- magnesium stearate
- OPADRY II complete film coating system 85F34610 Pink (ARTG ID 108065).

Each white placebo (inactive) tablet contains the following inactive ingredients:

- anhydrous lactose
- povidone
- magnesium stearate
- OPADRY II complete film coating system 85F18422 White (ARTG ID 11376).

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

Australian Registration Number

Micronelle 20 ED tablets (blister pack): AUST R 211154.

Sponsor

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