

Micronelle® 30 ED Tablets

Each blister pack contains: 21 yellow (active) tablets each containing 30 micrograms ethinylestradiol and 150 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 30 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 30 ED. It contains the active ingredients levonorgestrel and ethinylestradiol.

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.

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy (where the foetus is carried outside of your womb), lumpy breasts, acne and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill.

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 of having a blood clot 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:

- any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions
- a confirmed blood test showing:
 - increased levels of homocysteine
 - antiphospholipid antibodies (APLAs) e.g. anticardiolipin-antibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage)
- major surgery after which you have not been able to move around for a period
- 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
- high risk of blood clots due to conditions such as diabetes mellitus with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood
- 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.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).

You are pregnant or think you might be pregnant.

Do not give this medicine to a child.

This medicine is not intended for use in females whose periods have not yet started.

You are taking any antiviral medicines which contain ombitasvir, paritaprevir, dasabuvir and/or any combinations of these.

These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus (HCV)).

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 or anyone in your immediate family has had blood clots in the legs (deep vein thrombosis), in the lungs (pulmonary embolism), a heart attack, a stroke, breast cancer or high cholesterol.

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

You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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
- cancer

- hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood
- high level of fats in your blood
- are overweight
- high cholesterol or triglycerides
- liver disease
- kidney disease
- gall bladder disease
- any hereditary or acquired conditions that may make it more likely for you to get blood clots
- epilepsy
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- 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 angioedema - you should see your doctor immediately if you experience symptoms of angioedema, 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.

You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant.

You are currently breastfeeding or you plan to breast-feed.

This medicine is generally not recommended whilst breastfeeding.

You are planning to have surgery or an anaesthetic.

You are currently receiving or are planning to receive dental treatment.

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 30 ED. These include:

- medicines used to treat tuberculosis, such as rifampicin and rifabutin
- antibiotics (for e.g., penicillins, tetracyclines, and 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
- some medicines used to treat HCV, such as boceprevir, telaprevir, ombitasvir, paritaprevir, dasabuvir or any combination of these
- medicines used to treat epilepsy, such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- cyclosporin, an immunosuppressant medicine
- etoricoxib, a medicine used to treat painful joint disease
- melatonin, a hormone used as a sleep aid
- midazolam, a medicine used as a sedative
- theophylline, a medicine used to treat respiratory disease
- tizanidine, a medicine used as a muscle relaxant
- some medicines used to treat high blood pressure, chest pain or irregular heartbeats such as diltiazem and verapamil.
- 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. You must take this medicine every day regardless of how often you have sex.

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. It does not matter if you take it before or after food.

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.

How to start this medicine

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

Depending on the day of the week, this may be a yellow (active) tablet or a white placebo (inactive) tablet.

Follow the direction of the arrows on the blister pack until all the tablets have been taken.

A period should begin 2 to 3 days after starting to take the white inactive tablets (last row) and may not have finished before the next pack is started.

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

If you are starting this medicine after a natural cycle, start on the first day of your period (i.e. the first day of menstrual bleeding). Take a tablet from the red 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 or a cap or diaphragm with spermicide) for the first 14 days of tablet taking.

Changing from another combined oral contraceptive:

Start the day after taking the last active tablet in your previous Pill pack, taking a yellow tablet (active) from the red 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 yellow tablet (active) from the red zone marked with that day of the week.

Changing from a progestogen-only pill (minipill):

You may change any day, taking yellow tablet (active) a tablet from the red 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 14 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 yellow tablet (active) from the red 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 14 days of tablet-taking.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.

Changing from a progestogen-only injectable:

Change when the next injection would be due, taking a yellow tablet (active) from the red 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 14 days of tablet-taking.

You must also use additional barrier contraceptive precautions (e.g. condoms

or a diaphragm) for the first 14 days of tablet-taking when having intercourse.

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.

How to stop taking this medicine

You can stop taking this medicine at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking this medicine and not stop until your doctor advises this. Ask your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from sex, or use a barrier method of contraception, a cap (or diaphragm) plus spermicide, or a condom. Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

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 yellow (active) tablets

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

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

- Week 1 - Take the yellow (active) tablet you missed as soon as you remember (even if this means taking 2 yellow (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 yellow (active) tablet you missed as soon as you remember (even if this means taking 2 yellow (active) tablets at the same time) and complete the pack as normal. If you have also missed an additional yellow (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 yellow (active) tablet you missed as soon as you remember (even if this means taking 2 yellow (active) tablets at the same time) and continue taking the yellow (active) tablets until they have all been taken. When the final yellow (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 yellow (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 yellow (active) tablets of the second pack, but you may experience spotting or breakthrough bleeding on tablet-taking days.

There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.

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.

Symptoms that may occur are nausea, vomiting and withdrawal bleeding. Withdrawal bleeding may even occur in girls before their first menarche (first period), if they have accidentally taken the medicinal product.

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.

Stop taking this medicine and see your doctor immediately if you notice the following signs:

- one-sided swelling of the leg and/ or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood

- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing
- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting
- extreme weakness and anxiety.

Have regular check-ups with your doctor.

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.

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking this medicine.

The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take this medicine, the risk may be higher. The excess risk of thrombosis is highest during the first year a woman takes a combined oral contraceptive.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if this medicine has not been discontinued in advance. If you notice possible signs of a thrombosis (see Possible side effects), stop taking the medicine and consult your doctor immediately.

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors.

Consult your doctor if you plan to air travel for greater than 4 hours.

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 yellow (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.

If you have missed a period, but you have taken all your tablets, it is unlikely that you are pregnant, as long as:

- you have taken the yellow (active) tablets at the right time
- you have not been taking a medicine(s) that may interfere with this medicine
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take this medicine as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant, even if you have taken this medicine correctly. Stop taking this medicine and seek advice from your doctor. You must use a nonhormonal method of contraception, (such as condoms or a diaphragm) until your doctor rules out pregnancy.

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

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.

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
- pain or 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 blood clot (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 30 ED looks like

Active tablet: Plain, round, yellow tablets.

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

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

* Not all pack sizes may be available.

Ingredients

Each yellow (active) tablet contains 30 micrograms ethinylestradiol and 150 micrograms levonorgestrel as the active ingredients.

It also contains the following inactive ingredients:

- lactose monohydrate
- povidone
- crospovidone
- magnesium stearate
- OPADRY II complete film coating system 85F32450 Yellow (ARTG ID 108067).

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

- 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 30 ED tablets (blister pack):
AUST R 211155.

Sponsor

Apotex Pty Ltd
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This leaflet was last updated in:
February 2018