

Consumer Medicine Information

This leaflet provides important information about using Rosie. **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 Rosie.**

Where to find information in this leaflet:

1. Why am I using Rosie?
2. What should I know before I use Rosie?
3. What if I am taking other medicines?
4. How do I use Rosie?
5. What should I know while using Rosie?
6. Are there any side effects?
7. Product details

1. Why am I using Rosie?

Rosie contains the active ingredient ingredients drospirenone and ethinylestradiol.

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

Rosie is used to prevent pregnancy. It is also used to treat moderate acne and symptoms of premenstrual dysphoric disorder (PMDD) in women seeking oral contraception.

You may also experience the following benefits:

- more regular and lighter periods
 - potentially resulting in a decrease in anaemia (iron deficiency);

- a decrease in period pain;
- improvement in symptoms like bloating, swelling or weight gain related to fluid retention.

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

When taken correctly, it prevents you from becoming pregnant in several ways, including:

- inhibiting the egg release by stopping it maturing;
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg.

2. What should I know before I use Rosie?

Warnings

Do not use Rosie if:

- you are allergic to drospirenone or ethinylestradiol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath;
 - wheezing or difficulty breathing;
 - swelling of the face, lips, tongue or other parts of the body;
 - rash, itching or hives on the skin.

- you are taking antiviral medicines which contain ombitasvir, paritaprevir or dasabuvir, 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).

- **you have, or have had, a blood clot in:**

- the blood vessels of the legs (deep vein thrombosis - DVT);
- the lungs (pulmonary embolism - PE);
- the heart (heart attack);
- the brain (stroke);
- other parts of the body.

- **you have or 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 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; or antiphospholipid antibodies (APLAs) (eg. 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 of time;
- angina (chest pain);
- mini stroke (also known as TIA or transient ischaemic attack);
- severe kidney insufficiency or an acute failure of your kidney;
- migraine, where you have also had problems with seeing, speaking or had weakness or numbness in any part of your body;
- high risk of blood clots due to conditions such as diabetes 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;
- cancer that may grow under the influence of sex hormones (eg. of the breast or the genital organs);
- benign or malignant liver tumour;
- unexplained vaginal bleeding.

If any of these conditions appear for the first time while using Rosie, 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).

- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- smoke.
- have had blood clots in the legs (DVT), or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol – or if anyone in your immediate family has had any of these.
- are overweight;
- have or have had any other medical conditions like:
 - liver cancer or a liver disease and your liver is not working normally;
 - 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);
 - breast cancer;
 - diabetes;
 - high blood pressure;
 - heart valve disorders or certain heart rhythm disorders;
 - migraine;
 - an increased potassium blood level (eg. due to problems with your kidney/s) and also use diuretics or other drugs that may increase the potassium in your blood;
 - cancer;
 - hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood;
 - kidney disease. If you have kidney's that are not working well, your doctor will do a blood test to check your potassium levels during the first cycle.
 - haemolytic uraemic syndrome (HUS– a disorder of blood coagulation causing failure of the kidneys);
 - any hereditary or acquired conditions that may make it more likely for you to get blood clots;

- high cholesterol or triglycerides;
 - 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);
 - sickle cell disease;
 - a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (eg. 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.
- take any medicines for any other condition.

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?

How Rosie is different from other contraceptive pills

Rosie has 24 active (hormone) tablets and 4 inactive tablets, rather than the traditional 21 active tablets and 7 inactive tablets.

This means that with Rosie, you take the active (hormone) tablets for three more days. This helps your hormone levels to stay even.

When the Pill is taken by women under close observation in clinical

trials, it is more than 99% effective in preventing pregnancy.

However, in real life the Pill is around 92% effective. This is because pills might be missed, or taken with medicines that may interfere with their effectiveness, or may not be absorbed due to vomiting and diarrhoea.

Like all oral contraceptives, Rosie is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

Pregnancy and breastfeeding

Do not use Rosie if you are pregnant or think you might be pregnant.

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

Rosie is generally not recommended if you are breastfeeding.

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 may interfere with Rosie and affect how it works. These include:

- medicines used to treat tuberculosis, such as rifampicin, rifabutin;
- macrolide antibiotics (eg. clarithromycin, erythromycin);
- medicines used to treat fungal infections, such as griseofulvin, ketoconazole;
- medicines used to treat HIV, such as ritonavir or nevirapine;

- some medicines used to treat Hepatitis C virus (HCV), such as boceprevir, telaprevir;
- medicines used to treat epilepsy, such as phenytoin, primidone, barbiturates (eg. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine;
- ciclosporin, an immunosuppressant medicine;
- medicines used to treat high blood pressure, chest pain and/or irregular heartbeats, such as diltiazem, verapamil;
- etoricoxib, an anti-inflammatory medicine used to treat pain;
- tizanidine, melatonin or midazolam which are medicines that relax the body;
- theophylline, a medicine that helps with breathing;
- herbal medicines containing St John's Wort;
- grapefruit juice.

Some medicines can:

- have an influence the amount of Rosie in your blood levels;
- make Rosie less effective in preventing pregnancy;
- cause unexpected bleeding.

You might have an increase in potassium in the blood if you are taking Rosie with medicines that may increase potassium levels in the blood. These include:

- medicines used to treat high blood pressure, such as ACE inhibitors, angiotensin-II-receptor antagonists and diuretics. In a study of women taking drospirenone together with an ACE inhibitor, no significant differences were observed in the potassium levels when compared to the placebo;
- certain anti-inflammatory medicines, such as indomethacin;
- aldosterone antagonists, such as spironolactone and eplerenone.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines and for some time after stopping them.

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

4. How do I use Rosie?

How much to use

- Take one tablet daily at about the same time each day. You must take Rosie every day regardless of how often you have sex. This will also help you remember when to take it.
- Swallow the tablet whole with a full glass of water. It does not matter if you take it before or after food.

How to take Rosie

- **Do not confuse the tablets.**
- Each blister strip is marked with the day of the week.
- Take your first tablet from the teal area on the blister strip corresponding to the relevant day of the week.
- Follow the direction of the arrows on the blister strip until all the tablets have been taken.
- A period should begin 2-3 days after starting to take the white inactive tablets and may not have finished before the next blister strip is started.
- Always start a new blister strip on the same day of the week as your previous blister strip.
- Follow the instructions provided and use Rosie until your doctor tells you to stop.

When to take Rosie

Taking Rosie for the first time

- If you are starting Rosie after a natural cycle, and you have not used a hormonal contraceptive in the past month start on the first day of your period, ie. on the first day of your menstrual bleeding.
- You may also start on days 2-5 of your period, but in that case make sure you also use additional barrier contraceptive precautions (eg. condom) for the first 7 days of tablet-taking.
- Your doctor will advise you when to start if you:
 - are taking Rosie after having a baby;
 - have had a miscarriage or an abortion.

Changing from a combined oral contraceptive

- Start taking Rosie on the day after taking the last active tablet in your previous Pill pack.
- Bleeding may not occur until the end of the first blister strip of Rosie.
- You can also switch to Rosie after taking one or more inactive tablets in your previous Pill pack, but no later than the day after taking the last inactive tablet.
- If you are not sure which were the active/inactive tablets in your previous Pill pack, ask your doctor or pharmacist. Your previous Pill pack may have different colour tablets to those of Rosie.

Changing from a progestogen-only pill ('minipill')

- Stop taking the minipill on any day and start taking Rosie at the same time the day after you took your last minipill.
- You must also use additional barrier contraceptive precautions (eg. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Changing from a progestogen only injection, implant or intrauterine system (IUS)

- Start taking Rosie when your next injection is due, or on the day that your implant or IUS is removed.
- You must also use additional barrier contraceptive precautions (eg. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Changing from a vaginal ring

- Start on the day of removal of the ring but at the latest when the next application would have been due.

Stopping Rosie

- You can stop taking Rosie 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 Rosie 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.

If you want to delay a period

- Continue taking the pink active tablets in the current blister.
- Skip the white placebo tablets in the last row of the same blister.
- Start a new blister by taking the pink active tablet from the teal area corresponding to the relevant day of the week.
- To ensure that you take your tablets on the corresponding day of the week as marked on the blister strip, you may have some extra tablets left over in your current blister which you can discard.

You can continue to delay your period by skipping the white placebo tablet in the second/next blister. The delay can be extended

until the last pink active tablet in the third blister is taken.

If you wish for your period to begin at any time during the extension, stop taking the pink active tablets and start taking the white placebo tablets instead.

You should get your period approximately 2-3 days after you start taking the white placebo tablet. After taking the last white placebo tablet, start a new blister by taking the pink active tablet from the teal area corresponding to the relevant day of the week.

During the extension, you may have some breakthrough bleeding or spotting on active tablet-taking days.

If you forget to take Rosie

Rosie should be used regularly at the same time each day.

If you are late taking a tablet but still take it within 24 hours, contraception is maintained. If you are more than 24 hours late, this is called a missed pill. Follow these detailed instructions:

- For Rosie to be most effective, the pink active tablets need to be taken uninterrupted for 7 days.
- **If you have been taking the pink active tablets for 7 uninterrupted days and miss a pink active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day.** You will not need to use additional barrier contraceptive precautions.
- The chance of pregnancy after missing a pink active tablet depends on when you missed the tablet. There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a blister strip.
- If after taking your missed tablet you have less than 7 days of

pink active tablets left in a row, you should finish the active tablets in your blister strip but skip the white inactive tablets and start a new blister strip. This is the best way to maintain contraceptive protection.

However, you may not have a period until the end of the pink active tablets of the second blister strip. You may have spotting or breakthrough bleeding on tablet-taking days.

- If you have been taking the pink active tablets for less than 7 days and miss a pink active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day. In addition, you must also use additional barrier contraceptive precautions (eg. condoms or a diaphragm) for the next 7 days.
- **If you have had sexual intercourse during that time, there is a possibility of pregnancy and you may need emergency contraception.**
- **If you forget to take more than one pink active tablet, seek advice from your doctor or pharmacist about what to do.**
- If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.
- **If you miss a white inactive tablet, you do not need to take them later because they do not contain any active ingredients.** However, it is important that you discard the missed white tablet(s) to make sure that the number of days between taking active tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time.

Please see the diagram at the end of this leaflet for “Summary of

advice if you missed a pink active tablet more than 24 hours ago”.

If you use too much Rosie

If you think that you have used too much Rosie, 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.

If you take several pink active tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

5. What should I know while using Rosie?

Things you should do

Have regular check ups with your doctor

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

Call your doctor straight away if you have:

- 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;
- high blood pressure.

Rosie contains lactose (milk sugar). If you have an intolerance to some sugars, contact your doctor before you start to take Rosie.

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 products 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 very unlikely that you are pregnant, as long as:

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

If this is so, continue to take Rosie 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 the Pill correctly. Stop taking Rosie and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms or a diaphragm) until your doctor rules out pregnancy.

If you choose to delay your period while taking Rosie, your regular bleeding is not expected to occur during the extension period when the intake of the pink active tablet is uninterrupted. Therefore, the absence of regular bleeding cannot be used as a sign of an unexpected pregnancy and, as such, unexpected pregnancy may be difficult to recognise. Although pregnancy is

unlikely if Rosie is taken as directed, if for any reason you think you might be pregnant, contact your doctor and do a pregnancy test. This may be of particular importance if you are also using other medications, since some medications are known to be harmful to the foetus.

Rosie will not protect you from HIV-AIDS or any other Sexually Transmitted Infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis. **To protect yourself from STIs, you will need to use additional barrier contraceptives (eg. condoms).**

Remind any doctor, dentist or pharmacist you visit that you are using Rosie.

Things you should not do

- Do not take Rosie to treat any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else.
- 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 Rosie, or do not take a tablet every day.

Cancer and the Pill

Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in 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.

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.

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.

Thrombosis (formation of a blood clot in a blood vessel)

See your doctor immediately, if you notice possible signs of a thrombosis.

Blood clots may block blood vessels in your body. This type of blood clot is also called thrombosis.

Blood clots sometimes occur in the deep veins of the legs (DVT). If a blood clot breaks away from the veins where it has formed, it may reach and block the blood vessels of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking an oral contraceptive.

They can also happen during pregnancy. The risk of having blood clots is higher in oral contraceptive users than in non-users, but not as high as during pregnancy.

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

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

To prevent pregnancy, you must also use additional barrier contraceptive precautions if you stop taking Rosie (eg. condoms or a diaphragm).

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 Rosie, the risk may be higher.

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 Rosie (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 (eg. treatment for blood clots) if Rosie has not been discontinued in advance.

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.

If you are concerned about an increased risk of blood clots while on Rosie, speak to your doctor.

Driving or using machines

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

No effects on ability to drive and use machines have been observed in users of oral hormone contraceptives.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C.

Follow the instructions on 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.

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

Serious side effects

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.

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 Rosie contains

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

What Rosie looks like

Rosie tablets are as follows (AUST R 407771):

- active tablets are pink, round, biconvex film-coated tablets, plain on one side and marked with "DR1" on the other side.
- inactive/placebo tablets are white to off-white, round, biconvex film-coated tablets, plain on both sides.

Each blister strip contains 24 pink active tablets followed by 4 white inactive/placebo tablets (AUST R 407771).

Who distributes Rosie

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 726 369

This leaflet was prepared in August 2023.

*Summary of advice if you
missed a tablet more than 12
hours ago*