

# ROSALEE

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I using Rosalee?

Rosalee contains the active ingredients drospirenone and ethinylestradiol. Rosalee is a combined oral contraceptive used to prevent pregnancy. For more information, see Section [1. Why am I using Rosalee?](#) in the full CMI.

### 2. What should I know before I use Rosalee?

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

**Talk to your doctor if you have any other medical conditions, especially if they increase your risk of blood clots, if you have or have had blood clots, certain cancers or migraines. Tell your doctor if you take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Rosalee and affect how it works. The main types of medicines that affect how well Rosalee works include certain antibiotics, antifungal medicines, HIV treatments, hepatitis C virus treatments, epilepsy medicines, medicines for high blood pressure and the heart.

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

### 4. How do I use Rosalee?

- **Swallow whole one tablet daily at around the same time each day.**
- 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 at the end of this leaflet.

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

### 5. What should I know while using Rosalee?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Rosalee</li><li>• <b>Use additional barrier contraceptives (e.g. condoms) to protect yourself from STIs.</b></li><li>• Tell your doctor if you are going to have surgery or if you plan to travel by air for more than 4 hours</li><li>• <b>Stop taking Rosalee and call your doctor immediately if you notice signs of a possible blood clot e.g. chest pains, breathlessness or difficulty breathing, swelling, pain or tenderness in one leg, sudden dizziness, loss of balance, trouble speaking or seeing.</b></li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• 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 Rosalee, or do not take a tablet every day.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

Less serious side effects include nausea, diarrhoea, vomiting, gut inflammation, sore throat, headache (including migraines), dizziness, mood changes, nervousness, reproductive system disorders (e.g. breast pain, unscheduled vaginal bleeding), acne, infections. Serious side effects include jaundice (yellowing skin or eyes); signs of a blood clot (e.g. breathlessness, sudden weakness/pins and needles, sudden stomach pains, fainting, unusual headaches or migraines that are worse than usual, sudden problems speaking, sudden trouble walking, pain in chest, arms or below breast bone); coughing up blood; unexplained vaginal bleeding; breast lumps. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ROSALEE

Active ingredient(s): *drospirenone and ethinylestradiol*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I using Rosalee?

**Rosalee contains the active ingredients drospirenone and ethinylestradiol.** Rosalee is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

**Rosalee is used to prevent pregnancy.**

You may also experience the following benefits:

- improvement in symptoms like bloating, swelling or weight gain related to fluid retention
- more regular and lighter periods – potentially resulting in 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 and cancer of the uterus (womb) and 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.

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.

## 2. What should I know before I use Rosalee?

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

### Warnings

**Do not use Rosalee if:**

- you are allergic to drospirenone and 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.
- you are taking antiviral medicines which contain glecaprevir, pibrentasvir, sofosbuvir, velpatasvir, voxilaprevir, ombitasvir, paritaprevir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat 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. 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
- you have, or have had:
  - 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 miscarriages
  - 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 (e.g. of the breast or the genital organs)
- a benign or malignant liver tumour
- unexplained vaginal bleeding.
- have gall bladder disease
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over the body)
- have haemolytic uraemic syndrome (HUS– a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have 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)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- have 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 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).

**Do not give this medicine to a child**

**Check with your doctor if you:**

- smoke
- you or anyone in your immediate family has had blood clots in the legs (DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol
- are overweight
- have, or have had any of the following medical conditions:
  - diabetes
  - high blood pressure
  - heart valve disorders or certain heart rhythm disorders
  - migraine
  - an increased potassium blood level (e.g. 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
  - have any hereditary or acquired conditions that may make it more likely for you to get blood clots
  - have high cholesterol or triglycerides
  - have liver disease
  - have kidney disease
  - have high potassium in your blood
  - 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)

**If any of the above conditions appear for the first time, recur or worsen while taking Rosalee, you should tell your doctor.**

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

### Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant. **Do not take this medicine if you are pregnant or think you might be pregnant.**
- **Talk to your doctor if you are breastfeeding or intend to breastfeed.** Rosalee 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 and Rosalee may interfere with each other: These include:

Medicine class	Examples
Antibiotics	rifampicin, rifabutin, macrolide antibiotics (e.g. clarithromycin, erythromycin)
Antifungal medicines	griseofulvin, ketoconazole
Medicines used to treat HIV	ritonavir or nevirapine

Medicine class	Examples
<b>Medicines used to treat Hepatitis C Virus (HCV)</b>	boceprevir, telaprevir, glecaprevir, pibrentasvir, ombitasvir, paritaprevir, or dasabuvir
<b>Medicines used to treat epilepsy</b>	phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
<b>Immunosuppressants</b>	cyclosporin
<b>Medicines used to treat high blood pressure, chest pain or irregular heartbeats</b>	diltiazem, verapamil, ACE inhibitors (e.g. lisinopril, perindopril), angiotensin II receptor antagonists (e.g. candesartan, irbesartan), diuretics (e.g. hydrochlorothiazide, furosemide), aldosterone antagonists (e.g. spironolactone, eplerenone)
<b>Anti-inflammatory medicines</b>	Etoricoxib, indomethacin
<b>Other medicines</b>	Tizanidine Melatonin Midazolam Theophylline St John's Wort Grapefruit juice

These medicines may be affected by Rosalee or may affect how well it works. They can:

- have an influence on the blood levels of Rosalee
- make it less effective in preventing pregnancy
- cause unexpected bleeding.

Your doctor may need to alter the dose of these medicines, or prescribe a different medicine.

**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.** Your doctor will be able to tell you how long you will need to use additional contraceptive methods.

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

## 4. How do I use Rosalee?

### How much to take

- Take one tablet daily at about the same time every day. You must take Rosalee 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.

- 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.

### How to take Rosalee

- Each blister pack is marked with the day of the week.
- Take your first yellow (active) tablet from the green area on the blister pack corresponding to the day of the week.
- Follow the direction of the arrows on the blister pack until all the tablets have been taken.
- A period should begin 2-3 days after starting to take the white placebo tablets and may not have finished before the next pack is started.
- Always start a new blister pack on the same day of the week as your previous pack.

### Taking Rosalee for the first time

- If you are starting Rosalee after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. 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 (e.g. condom) for the first 7 days of tablet-taking.
- Your doctor will advise you when to start if you:
  - are taking Rosalee after having a baby
  - have had a miscarriage or an abortion.

### Switching from another contraceptive

Type of contraceptive	How do I change over to Rosalee?	Will I need additional contraception?
<b>Combined oral contraceptive</b>	Start taking Rosalee on the day after taking the last active tablet in your previous pill pack. Bleeding may not occur until the end of the first pack of Rosalee.  You can also switch to Rosalee after taking one or more inactive tablets in your previous pack. But no later than the day after taking the last inactive tablet	No

Type of contraceptive	How do I change over to Rosalee?	Will I need additional contraception?
Vaginal ring	Start Rosalee on the day of removal of the vaginal ring or at the latest when the next application would have been due	No
Progesterone only pill (minipill)	Stop taking the minipill on any day and start taking Rosalee at the same time the day after you took your last minipill	You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse
Progestogen-only injection, implant or intrauterine system (IUS)	Start taking Rosalee when your next injection is due, or on the day that your implant or IUS is removed	

## Stopping Rosalee

You can stop taking Rosalee 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 Rosalee 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 forget to use Rosalee

For Rosalee to be most effective, yellow active tablets need to be taken uninterrupted for 7 days.

If you miss a tablet and take the missed tablet within 12 hours of missing it, you should still be protected against pregnancy. If you are more than 12 hours late follow these detailed instructions:

- **If you have been taking the yellow active tablets for 7 uninterrupted days and miss a yellow 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 yellow 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 pack.**

- If after taking your missed tablet you have less than 7 days of yellow active tablets left in a row, you should finish the active tablets in your pack but skip the white placebo tablets and start a new pack. This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the yellow active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.
- **If you have been taking the yellow active tablets for less than 7 days and miss a yellow 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 must also use additional barrier contraceptive precautions (e.g. 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 yellow 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 placebo 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 placebo 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 yellow active tablet more than 12 hours ago”.

## If you use too much Rosalee

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

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), 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 yellow 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 ROSALEE?

### Things you should do

- Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.
- Rosalee 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 (e.g. condoms).**
- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
- **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 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.
- If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Rosalee
- **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 Rosalee, 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 (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 Rosalee has not been discontinued in advance.
- **Consult your doctor if you plan to air travel for greater than 4 hours.** 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 develop high blood pressure while taking Rosalee** – you may be told to stop taking it.
- If you become pregnant while taking this medicine, tell your doctor immediately.

### Call your doctor straight away if you notice:

- 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.

### Things you should not do

- Do not take Rosalee 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 Rosalee, or do not take a tablet every day.

### Bleeding and Missed Periods

- **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 yellow active tablets at the right time
  - you have not been taking medicine(s) that may interfere with Rosalee
  - you have not vomited or had severe diarrhoea during this cycle.
- If this is so, continue to take Rosalee 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 Rosalee 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.

### Driving or using machines

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

### Looking after your medicine

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

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C.

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

Less serious side effects	What to do
<p><b>Gastrointestinal system-related:</b></p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Diarrhoea</li> <li>• Vomiting</li> <li>• inflammation of the stomach and intestines</li> <li>• sore throat and discomfort when swallowing</li> </ul> <p><b>Nervous system-related:</b></p> <ul style="list-style-type: none"> <li>• headache, including migraines</li> <li>• dizziness</li> </ul> <p><b>Mood-related:</b></p> <ul style="list-style-type: none"> <li>• mood changes, including depression</li> <li>• nervousness</li> </ul> <p><b>Reproductive system-related:</b></p> <ul style="list-style-type: none"> <li>• menstrual disorders</li> <li>• breast pain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• abnormal vaginal discharge</li> </ul> <p><b>Skin-related</b></p> <ul style="list-style-type: none"> <li>• acne</li> </ul> <p><b>Infections</b></p> <ul style="list-style-type: none"> <li>• inflammation of the bladder due to urinary tract infection</li> <li>• vaginal yeast infection</li> <li>• sinus infection</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Blood clot-related:</b></p> <ul style="list-style-type: none"> <li>• pain in the chest, arm or below the breastbone</li> <li>• pain or discomfort that goes to your back</li> <li>• breathlessness and/or difficulty breathing</li> <li>• swelling, pain or tenderness of one leg</li> <li>• sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination</li> <li>• severe, sudden stomach pains</li> <li>• a fainting attack, or you collapse</li> <li>• unusual headaches or migraines that are worse than usual</li> <li>• sudden problems with your speech, understanding or eyesight</li> </ul> <p><b>Liver-related</b></p> <ul style="list-style-type: none"> <li>• jaundice (yellowing skin or yellowing eyes)</li> </ul> <p><b>Bleeding-related</b></p> <ul style="list-style-type: none"> <li>• coughing up blood</li> </ul> <p><b>Reproductive system-related</b></p> <ul style="list-style-type: none"> <li>• breast lumps</li> <li>• unexplained vaginal bleeding</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

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

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

### Blood clots and the Pill

Blood clots are rare. Very occasionally blood clots may cause serious permanent disability and may even be fatal.

Blood clots can form, travel and block different blood vessels in the body. They can occur in the deep veins of the legs (causing deep vein thrombosis), the clot can travel and cause a blockage in the lungs (called pulmonary embolism). Blood clots can occur in the blood vessels of

the heart (causing a heart attack) or the brain (causing a stroke).

All combined oral contraceptive pills, including Rosalee will increase the risk of having a blood clot. However, blood clots can form whether or not you are taking the pill, including in pregnancy. The risk of having a blood clot when taking Rosalee is less than the risk of having a blood clot during pregnancy.

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

**Stop taking Rosalee and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice signs of a possible blood clot.**

To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).

#### 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 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.
- **It is important that you check your breasts regularly and contact your doctor if you feel any lumps.**
- 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.

#### 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](http://www.tga.gov.au/reporting-problems) or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. 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 Rosalee contains

<b>Active ingredients (main ingredients in the yellow tablets)</b>	<ul style="list-style-type: none"><li>• 3 mg drospirenone</li><li>• 30 microgram ethinylestradiol</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<p><b>Yellow tablet</b></p> <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• maize starch</li><li>• pregelatinised maize starch</li><li>• magnesium stearate</li><li>• OPADRY complete film coating system 03F82726 Yellow (containing hypromellose, titanium dioxide, macrogol 6000, purified talc and iron oxide yellow).</li></ul> <p><b>White placebo tablet</b></p> <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• maize starch</li><li>• pregelatinised maize starch</li><li>• magnesium stearate</li><li>• OPADRY complete film coating system 03B28796 White (containing hypromellose, titanium dioxide and macrogol 400).</li></ul>
<b>Potential allergens</b>	lactose monohydrate

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

#### What Rosalee looks like

Each active tablet is yellow coloured, round, biconvex, film coated tablets, debossed with 'DR2' on one side and plain on the other side.

Each placebo tablet is white to off-white coloured, round, biconvex, film coated tablet, plain on both sides.

Rosalee comes in a box containing either 1 or 3 blister packs. (AUST R 407772)

Each blister pack contains 21 yellow active tablets and 7 placebo tablets.

#### Who distributes Rosalee

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel: 1800 726 369

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**SUMMARY OF ADVICE IF YOU MISSED A YELLOW ACTIVE TABLET MORE THAN 12 HOURS AGO**

<b>Before missing your tablet, did you take the yellow active tablets for the previous 7 days?</b>	<b>No</b>	Did you have sex in the 7 days before missing the tablet?	→	<b>No</b>	Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 yellow active tablets left in the pack, finish the active tablets and go straight to the yellow active tablets of the next pack. This means you skip the white inactive tablets.
				<b>Yes</b>	See your Doctor or Pharmacist for advice.
	<b>Yes</b>	Does your pack still have 7 active yellow tablets in a row to follow?	→	<b>No</b>	Take the tablet you missed AND complete taking the yellow active tablets. Skip the white placebo tablets. Start your next pack with the yellow active tablets.
				<b>Yes</b>	Take the tablet you missed AND complete the pack as normal.