

Botanitech® ROSELLA

Dried Cannabis

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.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Botanitech ROSELLA?

Botanitech ROSELLA contains the active ingredients delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Botanitech ROSELLA is not approved for any specific indication and should only be used to treat specific conditions or symptoms authorised by your doctor.

For more information, see Section [1. Why am I using Botanitech ROSELLA?](#) in the full CMI.

2. What should I know before I use Botanitech ROSELLA?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Botanitech ROSELLA and affect how it works.

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 Botanitech ROSELLA?

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained within this leaflet.
- If you do not understand the instruction on the pharmacist dispensing label, ask your doctor or pharmacist for help.
- A titration period is required to reach optimal dose. The volume, number and timing of doses will vary between patients. Your doctor will provide you with a treatment schedule based on your needs. Always use Botanitech ROSELLA exactly as your doctor has told you.
- Botanitech ROSELLA can be taken before or after food.
- Only a doctor can start you on treatment with Botanitech ROSELLA. Your doctor will assess you from time to time to see if you should continue taking Botanitech ROSELLA.

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

5. What should I know while using Botanitech ROSELLA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Botanitech ROSELLA.• You must tell your doctor if you have or have had any allergies to cannabis or cannabis-based medicines.• You must tell your doctor if you have or have had any problem with your liver, kidneys, heart, gut, substance use disorder (abuse, dependence), or any other medical condition.• Tell your doctor if you have or have had any psychotic or concurrent disorder.• Tell your doctor if you are under 18 years of age.• Tell your doctor if you are pregnant or planning to become pregnant. Tell your doctor if you become pregnant while taking Botanitech ROSELLA.• Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket, or health food shop.• Take Botanitech ROSELLA as your doctor has prescribed.• If you are about to start any new medicine, tell your doctor and pharmacist that you are taking Botanitech ROSELLA.• Tell your doctor if your symptoms do not improve.• If you need to have any medical tests while you are taking Botanitech ROSELLA, tell your doctor.
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Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly (if relevant). • Do not take Botanitech ROSELLA if you have an allergy to cannabis or cannabis-based medications. • Do not take Botanitech ROSELLA after the use-by (expiry) date printed on the packaging or if the packaging shows signs of tampering. • Do not take Botanitech ROSELLA if you are pregnant, planning to become pregnant, or breastfeeding. • Do not take this medicine to treat any other complaint unless your doctor says it is safe. • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Do not drive or operate machinery while taking Botanitech ROSELLA.
Drinking alcohol	<ul style="list-style-type: none"> • Take special care if you drink alcohol while taking this medicine. • Taking Botanitech ROSELLA and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).
Looking after your medicine	<ul style="list-style-type: none"> • Keep your Botanitech ROSELLA in its packaging until it is time to take it. • If you leave this medicine out of its packaging, it may not keep well. • Store it in a cool dry place away from moisture, heat, or sunlight. • Do not store Botanitech ROSELLA or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. • Keep Botanitech ROSELLA where children cannot see it or reach it.

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

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. You are more likely to get side effects when you start your treatment. They are usually mild and wear off within a few hours.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- daytime drowsiness
- fatigue
- dry eyes
- increased appetite
- nausea
- dizziness
- dry mouth
- headache
- difficulty concentrating
- memory impairment
- blurred vision
- constipation or diarrhoea
- euphoria

Tell your doctor immediately or go to the Emergency Department at your nearest hospital if any of the following happen:

- thoughts of suicide
- rapid heartbeat
- chest pain
- convulsion
- hallucinations
- psychosis
- you develop signs of allergy such as swelling of the face, lips, mouth, tongue, throat, or other part of the body; shortness of breath or difficulty breathing; rash, itching or redness on the skin.

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.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly on 1800 654 327 or via medical@botanitech.com.au

Botanitech[®] ROSELLA

Active ingredient(s): delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Botanitech ROSELLA. **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 Botanitech ROSELLA.**

Where to find information in this leaflet:

[1. Why am I using Botanitech ROSELLA?](#)

[2. What should I know before I use Botanitech ROSELLA?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use Botanitech ROSELLA?](#)

[5. What should I know while using Botanitech ROSELLA?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using Botanitech ROSELLA?

Botanitech ROSELLA contains the active ingredients delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

Botanitech ROSELLA is not approved for any specific indication and should only be used to treat specific conditions or symptoms prescribed by your doctor.

Botanitech ROSELLA may be used to:

- Relieve chronic non-cancer pain
- Relieve cancer related pain
- Improve sleep (insomnia)
- Decrease inflammation
- Reduce tremors
- Provide relief from nausea
- Reduce spasticity from neurological conditions
- Stimulate appetite in anorexia or wasting conditions associated with chronic illness.

Your doctor may prescribe Botanitech ROSELLA for another purpose.

Ask your doctor if you have any questions about why Botanitech ROSELLA has been prescribed for you.

Botanitech ROSELLA is an alternative therapeutic option when medicines and lifestyle treatments have not been beneficial. The therapeutic benefit of Botanitech ROSELLA may vary between individuals. This medicine is only available with a doctor's prescription.

2. What should I know before I use Botanitech ROSELLA?

Warnings

Do not use Botanitech ROSELLA if:

- you are allergic to cannabis, cannabis-based medications, or any of the ingredients listed at the end of this leaflet.
- You are pregnant, planning to become pregnant, or breastfeeding. THC can pass into your breastmilk if you are breastfeeding. It may affect your baby.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as:
- allergies to any other medicines
- any problem with your liver
- any problems with your kidney
- any problems with your heart
- gastrointestinal obstruction
- any previous psychotic or concurrent disorder
- any other medical conditions
- take any medicines for any other condition
- substance use disorder (abuse, dependence) to alcohol, opioids, benzodiazepines, or illicit stimulants.

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.

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

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Botanitech ROSELLA.

If you see a different doctor or go into hospital, let them know all the medicines you are taking.

Some medicines may interfere with Botanitech ROSELLA and affect how it works.

Avoid taking Botanitech ROSELLA with alcohol and/or other CNS depressants/sedatives including prescription medications, e.g., benzodiazepines. Using Botanitech ROSELLA at the same time as alcohol and/or other sedative drugs may cause more severe levels of impairment and adverse effects.

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

4. How do I use Botanitech ROSELLA?

How much to take/use

- Follow all directions given to you by your doctor.
- They may differ to the instructions in this leaflet.
- If you do not understand the instruction on the label, ask your doctor or pharmacist for help.
- A titration period is required to reach optimal dose. The number and timing of doses will vary between individuals. Your doctor will provide you with a treatment schedule based on your needs. Always use Botanitech ROSELLA exactly as your doctor has told you.
- Only a doctor can start you on treatment with Botanitech ROSELLA. Your doctor will assess you from time to time to see if you should continue taking Botanitech ROSELLA.
- Your doctor may increase your dosage until a dose is reached which works best for you.
- Note that higher doses of Botanitech ROSELLA are associated with an increased risk of experiencing side effects.
- Follow the instructions provided and use Botanitech ROSELLA until your doctor tells you to stop.

When to take / use Botanitech ROSELLA

- Botanitech ROSELLA should be used as directed by your doctor.
- Botanitech ROSELLA can be taken before or after food.

How to use Botanitech ROSELLA

- This product should be administered using a medical device vaporizer, as recommended by your doctor or pharmacist.
- Your dose of Botanitech ROSELLA is individualized, and the rate and speed of dose adjustment is dependent on each individual response. It is recommended to start low and titrate the dose slowly. The optimal dose is the lowest dose that achieves the highest benefit.
- Follow the instructions provided and use Botanitech ROSELLA until your doctor tells you to stop.
- If you have any further questions on the use of Botanitech ROSELLA, ask your doctor or pharmacist.

If you forget to use Botanitech ROSELLA

Botanitech ROSELLA should be used regularly at the same time each day. If you have trouble remembering when to use your medicine, talk to your doctor or pharmacist.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Botanitech ROSELLA

If you think that you have used too much Botanitech ROSELLA, 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.

5. What should I know while using Botanitech ROSELLA?

Things you should do

- Take Botanitech ROSELLA as your doctor has prescribed.
- If you are about to start any new medicine, remind your doctor and pharmacist that you are taking Botanitech ROSELLA.
- Take special care if you drink alcohol while using Botanitech ROSELLA. Using Botanitech ROSELLA and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).

Call your doctor straight away if you:

- Are pregnant or become pregnant while taking Botanitech ROSELLA.
- Need to have medical tests while you are taking Botanitech ROSELLA. It may affect the results of some tests.
- Tell your doctor if your symptoms do not improve.

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

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor. If you stop taking it suddenly or change the dose, your condition may worsen, or you may have unwanted side effects.
- Do not use Botanitech ROSELLA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Travelling overseas with Botanitech ROSELLA

- Check that it is legal for you to take Botanitech ROSELLA into any countries you are travelling to and countries you are travelling through. Botanitech ROSELLA is a Controlled Drug in Australia, and its legal status will vary between countries.

Driving or using machines

Do not drive or use machinery while taking Botanitech ROSELLA.

Botanitech ROSELLA may cause dizziness or drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of Botanitech ROSELLA, or the latter may increase the effects of alcohol (such as loss of balance or ability to respond quickly).

Looking after your medicine

- Keep your Botanitech ROSELLA in its packaging until it is time to take it.
- If you leave Botanitech ROSELLA out of its packaging, it may not keep well.

Follow the instructions provided on the label 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 windowsills.

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

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
<ul style="list-style-type: none"> • daytime drowsiness • dizziness • fatigue • dry mouth • dry eyes • headache • increased appetite • difficulty concentrating • nausea • memory impairment • blurred vision • constipation or diarrhoea • euphoria 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy-related:</p> <ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in breathing • Shortness of breath or difficulty in breathing • Skin reaction which may include rash, itching, redness, blistering or peeling of the skin <p>Cardiovascular:</p> <ul style="list-style-type: none"> • rapid heartbeat • chest pain • low blood pressure/feeling faint <p>Brain/Nervous system:</p> <ul style="list-style-type: none"> • convulsions • numbness • burning sensation • vomiting • loss of coordination balance • disorientation • confusion, depression • agitation • hallucinations • psychosis • thoughts of suicide <p>General:</p> <ul style="list-style-type: none"> • upper respiratory infection • strong abdominal pain 	<p>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.</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.

Reporting side effects

After you have received medical advice for any side-effects you experience, you can report side effects on **1800 654 327** or via medical@botanitech.com.au.

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 Botanitech ROSELLA contains

Active ingredient (Main Ingredient)	delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD) Contains 23% w/w THC and not more than 1% w/w CBD
Other ingredients (Inactive Ingredients)	None

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

What Botanitech ROSELLA looks like

Botanitech ROSELLA is a whole cannabis dried flower presented in a plastic jar.

Each jar contains *Cannabis sativa* flower, dry weight 10 g minimum, containing THC 2.3 g and not more than CBD 0.1 g.

Pack sizes of 10 g (1 jar) and 30 g (3 x 10 g jars).

Who distributes Botanitech ROSELLA

Botanitech ROSELLA is supplied in Australia by the product Sponsor:

Cannoperations Pty Ltd
(a Cann Group Limited company)

Telephone: 1800 654 327

Email: medical@botanitech.com.au

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