

AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

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 AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

Australian Natural Rocky Oral Solution contains the active ingredient delta-9-tetrahydrocannabinol (THC) at a strength of 30mg/mL. Australian Natural Rocky Oral Solution is not approved for any specific indication and should only be used to treat conditions or symptoms advised by your doctor.

Your doctor might recommend its use to reduce nausea, vomiting, chronic non-cancer pain, cancer-related pain, spasticity from neurological conditions and muscle spasms, improve sleep and appetite, and manage seizures, depression and/or anxiety. Your doctor might prescribe Australian Natural Rocky Oral Solution for another purpose.

For more information, see [Section 1. Why am I using Australian Natural Rocky Oral Solution?](#) in the full CMI.

2. WHAT SHOULD I KNOW BEFORE I USE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

Do not use if you have ever had an allergic reaction to cannabis 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 Australian Natural Rocky Oral Solution?](#) in the full CMI.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with Australian Natural Rocky Oral Solution and affect how it works. Conversely, Australian Natural Rocky Oral Solution may change the way certain pharmaceutical medicines work.

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 AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

Use the amount of Australian Natural Rocky Oral Solution directed by your doctor. Follow your doctor's instructions and use Australian Natural Rocky Oral Solution until your doctor tells you to stop.

AUSTRALIAN NATURAL ROCKY ORAL SOLUTION (/rɒki/)

Active ingredient: delta-9- tetrahydrocannabinol (THC) 30mg/mL.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Australian Natural Rocky Oral Solution. **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 Australian Natural Rocky Oral Solution.**

WHERE TO FIND INFORMATION IN THIS LEAFLET:

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

1. WHY AM I USING AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

Australian Natural Rocky Oral Solution contains the active ingredient whole dried Cannabis flower cured and trimmed from a hybrid cultivar of the cannabis plant. The trichomes (glands) on the Cannabis flower are abundant with phytocannabinoid compounds. When taken internally, phytocannabinoids interact with the body's receptors to produce psychoactive effects (changes to a person's mental state, such as behavior, mood, thoughts or perception) and therapeutic effects. Australian Natural Rocky Oral Solution is not approved for any specific indication and should only be used to treat conditions or symptoms advised by your doctor.

Your doctor might recommend its use to reduce nausea, vomiting, chronic non-cancer pain, cancer-related pain, spasticity from neurological conditions and muscle spasms, improve sleep and appetite, and manage seizures, depression and/or anxiety. Your doctor might prescribe Australian Natural Rocky Oral Solution for another purpose.

This medicine is only available with a doctor's prescription. This medicine is only available through the Special Access Scheme (SAS), through the Authorised Prescriber Scheme (APS), or through a registered clinical trial.

Possession without authority is illegal.

2. WHAT SHOULD I KNOW BEFORE I USE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

WARNINGS

DO NOT USE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION IF:

- you are allergic to any cannabis product, 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 under 18-years-old.
- you have pre-existing heart problems, such as narrowing of the arteries (ischaemic or coronary heart disease), irregular heartbeat, poorly controlled high blood pressure, or have had previous heart attack or heart failure.
- you have serious liver or kidney problems.

More instructions can be found in [Section 4. How do I use Australian Natural Rocky Oral Solution?](#) in the full CMI.

5. WHAT SHOULD I KNOW WHILE USING AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

Things you should do

- Remind any health care practitioner you visit that you are using Australian Natural Rocky Oral Solution.
- You should use Australian Natural Rocky Oral Solution under medical supervision.
- Talk to your healthcare provider if you do not feel better, or if you feel worse.

Things you should not do

- Do not change your dosage without first checking with your doctor.

Driving or using machines

- Do not drive or operate heavy or dangerous machines while being treated on this product.

Drinking alcohol

- Alcohol may increase the effects of Australian Natural Rocky Oral Solution and you should avoid taking it while taking this medicine. Alcohol taken in combination with Australian Natural Rocky Oral Solution can impair your cognitive abilities, coordination, reaction time and motor skills.

Looking after your medicine

- Store below 25°C.

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

6. ARE THERE ANY SIDE EFFECTS?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). Common, but usually mild side effects known from medicinal cannabis treatment (both cannabidiol (CBD) and delta-9- tetrahydrocannabinol (THC)) include fatigue and sedation, dizziness, nausea, dry mouth, and increase or decrease in appetite. Serious side effects of THC (and products high in THC) include convulsions, feeling 'high' or intoxicated, depression, confusion, hallucinations, paranoid delusions, psychosis (severe mental condition where a person loses contact with reality, and is unable to think and judge clearly), cognitive distortion (having thoughts that are not perceived accurately), and allergy symptoms.

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.

CHECK WITH YOUR DOCTOR IF YOU:

- have or have had any other medical conditions, especially the following:
 - kidney problems.
 - liver problems.
 - serious mental disorders, such as schizophrenia or another psychotic disorder.
 - panic attacks.
 - lung problems.
 - heart problems.
 - epilepsy or recurrent seizures.
 - you have a history of dependence or addictive behaviour associated with prescription or non- prescription products.
 - you are 65-years-old or older.
- 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 before starting this product if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Cannabinoids can pass into breastmilk and may affect foetal development.

Do not take this product whilst pregnant or breastfeeding until you and your doctor have discussed the risks and benefits involved.

USE IN CHILDREN

Australian Natural Rocky Oral Solution is not recommended for use in children or adolescents less than 18-years of age.

MEDICAL SUPERVISION OF TREATMENT WITH AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

Australian Natural Rocky Oral Solution treatment should be initiated and supervised by a qualified healthcare provider experienced in the treatment of the symptom or disorder for which it is prescribed.

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 Australian Natural Rocky Oral Solution and affect how it works.

Tell your doctor if you are using medicines for:

- Cold or allergy (medicines that make you drowsy, such as antihistamines)
- Pain (medicines known as opioids, such as oxycodone, hydrocodone, codeine, and morphine)
- Muscle-related conditions, such as muscle spasms, overactive bladder, movement disorders (Parkinson's disease), and asthma (medicines known as anticholinergics, e.g. tolterodine, oxybutynin, darifenacin, solifenacin, benztropine mesilate, trihexyphenidyl, ipratropium bromide, tiotropium bromide)
- Sleeping problems (sleeping pills, sedatives/hypnotics or antihistamines, e.g. benzodiazepine, zopiclone, zolpidem)
- Epilepsy, seizures, or nerve pain (e.g. carbamazepine, phenytoin, and phenobarbital)
- Attention Deficit Hyperactivity Disorder (ADHD) or narcolepsy (medicines such as

- amphetamines that may increase your heart rate and blood pressure)
- Bacterial or fungal infections (e.g. rifampicin, clarithromycin, ketoconazole, itraconazole, amphotericin B)
- Suppression of the immune system (e.g. cyclosporine)
- Anticoagulant Therapy (medicines known as coumarins, e.g. warfarin)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Australian Natural Rocky Oral Solution.

4. HOW DO I USE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

HOW MUCH TO USE

- Use the amount of Australian Natural Rocky Oral Solution directed by your doctor.
- The amount of Australian Natural Rocky Oral Solution your doctor tells you to use each day will depend on your condition, whether you are taking any other medicines, as well as how you respond to and tolerate the product.
- Your doctor may recommend that you start with a low dose of Australian Natural Rocky Oral Solution and then slowly increase the dose to the lowest amount needed to improve your symptoms.
- Follow the instructions provided and use Australian Natural Rocky Oral Solution until your doctor tells you to stop.

WHEN TO TAKE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

- Australian Natural Rocky Oral Solution can be taken with or without food.
- Taking Australian Natural Rocky Oral Solution under the similar conditions each day may help achieve a more consistent effect.

HOW TO TAKE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

- This product should be administered as directed by your doctor.
- Effects from Australian Natural Rocky Oral Solution may begin within approximately 60-180 minutes after you take a dose and may last for between 6-8 hours, depending on the dose taken, how long you have been taking this medicine, the amount and type of food you had when taking this medicine, and your individual response

IF YOU FORGET TO USE AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

Australian Natural Rocky Oral Solution should be used regularly at the same time each day.

If you miss your dose at the usual time, take it as soon as you remember, then go back to taking this product as you would normally.

If you have missed a dose by more than 4 hours, 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 AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

If you think that you have used too much Australian Natural Rocky Oral Solution, 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 AUSTRALIAN NATURAL ROCKY ORAL SOLUTION?

THINGS YOU SHOULD DO

- You should use Australian Natural Rocky Oral Solution under medical supervision to help determine if the product is working or if you are having any side effects from the treatment.
- Talk to your healthcare provider if you do not feel better, or if you feel worse
- Remind any doctor, dentist or pharmacist you visit that you are using Australian Natural Rocky Oral Solution.

THINGS YOU SHOULD NOT DO

- Do not change your dosage without first checking with your doctor.

TRAVELLING WITH AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

- Before travelling to another state within Australia or to an international country (this includes your final destination and any in transit countries), consult with your doctor, country consulates, The Department of Foreign Affairs and Trade, insurance company and/or pharmacist to confirm if it is legal for you to travel with this product.

DRIVING OR USING MACHINES

Do not drive or operate heavy or dangerous machines while being treated on this product. Talk to your doctor on when to resume these activities after completing treatment.

DRINKING ALCOHOL

Tell your doctor if you drink alcohol.

Alcohol may increase the effects of Australian Natural Rocky Oral Solution and you should avoid taking it while taking this medicine. Alcohol taken in combination with Australian Natural Rocky Oral Solution can impair your cognitive abilities, coordination, reaction time and motor skills.

LOOKING AFTER YOUR MEDICINE

- Store below 25°C.
- 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; 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.

SIDE EFFECTS

Side effects	What to do
Changes to mental status: • Poor short-term memory • Lack of concentration • Confusion • Abnormal thoughts • Poor coordination and balance • Dizziness	Speak to your doctor if you have any of these less serious side effects and they worry you.
Personality or behavioural changes: • Anxiety • Loss of inhibition • Quiet and reflective mood, or other unusual changes in mood • Changes in appetite • Spontaneous laughter • Sleepiness/ feeling tired	
Eye-related: • Bloodshot eyes • Altered visual perception	
Ear-related: • Altered hearing perception	
General body-related: • Phlegm and cough • Dry mouth • Malaise (feeling unwell) or a general feeling of discomfort • Nausea • Muscle weakness	

SERIOUS SIDE EFFECTS

Serious side effects	What to do
Changes to mental status or personality: • Depression or thoughts of suicide • Paranoia • Seeing or hearing things that are not there • Irrational thinking • Hallucinations • Addiction/dependence	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.
Heart-related: • Rapid or irregular heartbeat • Signs of low blood pressure, such as light-headedness, dizziness or fainting	
Nervous system-related: • Seizures or convulsions (if you do not have epilepsy)	
Allergic reaction-related: • Shortness of breath • Wheezing or difficulty breathing • Swelling of the face, lips, tongue or other parts of the body • Rash, hives or swelling on the skin	

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 AUSTRALIAN NATURAL ROCKY ORAL SOLUTION CONTAINS

Active ingredient (main ingredient)	The active substance is delta-9- tetrahydrocannabinol (THC). Each mL of oral solution contains 30 mg of delta-9- tetrahydrocannabinol (THC). Each bottle contains 50 mL of oil solution which has a total of 1500 mg of delta-9- tetrahydrocannabinol (THC).
Other ingredients (inactive ingredients)	N/A

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

WHAT AUSTRALIAN NATURAL ROCKY ORAL SOLUTION LOOKS LIKE

Australian Natural Rocky Oral Solution is a clear dark coloured liquid in a 50 mL amber bottle which has a child-resistant cap & tamper proof seal. Together with a 1 mL syringe and a bottle adaptor for using these syringes. The syringe is graduated to 0.1 mL increments.

WHO DISTRIBUTES AUSTRALIAN NATURAL ROCKY ORAL SOLUTION

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This leaflet was prepared in April 2022.