

KIKUYA Arroyo

Consumer Medicine Information (CMI) summary

Active ingredient:

Total THC [THC+THCA (as THC)] 200mg/g (20% w/w)
 Total CBD [CBD+CBDA (as CBD)] <10mg/g (<1% w/w)

Please read this leaflet carefully before you start taking KIKUYA Arroyo.

This leaflet answers some common questions about KIKUYA Arroyo. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking KIKUYA Arroyo against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

WHERE TO FIND INFORMATION IN THIS LEAFLET:

1. What is KIKUYA Arroyo used for?
2. Before you use KIKUYA Arroyo
3. How to take KIKUYA Arroyo
4. While you are taking KIKUYA Arroyo
5. In case of overdose
6. Side Effects
7. After taking KIKUYA Arroyo
7. Product details

1. WHAT IS KIKUYA ARROYO USED FOR?

KIKUYA Arroyo contains active ingredients from whole dried cannabis flower cured and trimmed from a *Sativa* Dominant 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 effects that have a therapeutic role. KIKUYA Arroyo 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 anxiety. Your doctor might prescribe KIKUYA Arroyo for another purpose. This medicine is only available with a doctor's prescription. Possession without authority is illegal.

Ask your doctor if you have any questions about why KIKUYA Arroyo has been prescribed for you.

2. BEFORE YOU USE KIKUYA ARROYO

WARNINGS

Do not use KIKUYA Arroyo 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 or anyone directly related to you has any mental health problems such as schizophrenia, psychosis, or other significant psychiatric disorder
- You are under 18 years of age
- You are breast-feeding
- Do not use during pregnancy, unless advised to by your doctor
- Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking KIKUYA Arroyo, talk to your doctor.

Before you start to use it

Tell your doctor if:

- You are pregnant or plan to become pregnant.
- You have epilepsy or regular fits (seizures).
- You have serious liver or kidney problems.
- 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 are elderly, especially if you have problems doing activities such as making hot food and drinks.
- You have previously abused any drug or substance.

If you have not told your doctor about any of the above, tell them before you start taking KIKUYA Arroyo.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines 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 KIKUYA Arroyo.

Some medicines may interfere with KIKUYA Arroyo. 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 or sedatives/hypnotics, 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).
- Thinning of your blood (medicines known as coumarins, e.g., warfarin).

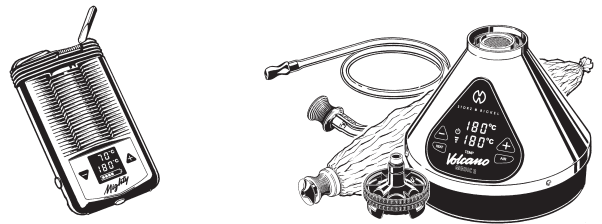
These medicines may be affected by KIKUYA Arroyo or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking KIKUYA Arroyo.

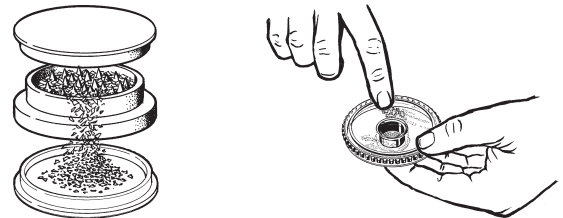
3. HOW TO TAKE KIKUYA ARROYO

- Take the amount of KIKUYA Arroyo as directed by your doctor.
- The amount of KIKUYA Arroyo your doctor tells you to take 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 KIKUYA Arroyo and then slowly increase the dose to the lowest amount needed to improve your symptoms.
- Inhale prescribed KIKUYA Arroya dose with a vaporiser only.
- Follow the instructions provided and take KIKUYA Arroyo until your doctor tells you to stop.

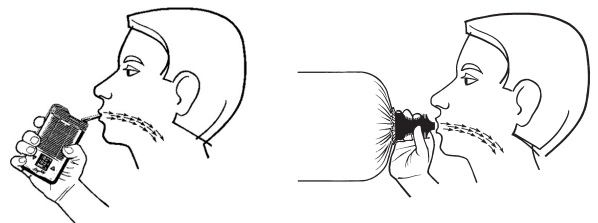
Using a medicinal cannabis vaporiser with KIKUYA Arroyo



1. Grind the KIKUYA Arroyo flower and fill the prescribed amount in the Dosing Capsule.



2. Insert the Dosing Capsule in the vaporiser.
3. Turn on the vaporiser and set target temperature with "+" and "-" buttons.
4. When the required temperature is reached, inhale slowly and evenly for several seconds. Inhale only half of the air you can normally manage. Hold your breath for a few seconds and exhale slowly. Consciously concentrate on your inhalation.



5. After inhalation, turn off the vaporiser and remove the dosing capsule. Dispose of the used flower in the compost or residual waste.
6. Read the vaporiser instruction manual for more information.

If you are known with respiratory tract or lung conditions, vaporisers might not be appropriate for you.

How much to take

The number of inhalations you need each day depends on you as an individual. Each person needs a different number of inhalations to give them the best relief from their

symptoms, with the least unwanted effects. When you first start taking KIKUYA Arroyo, you need to keep track of the number of inhalations/puffs until you find the best number for you. Stop increasing your number of inhalations when you find the best number of inhalations for you. This may only take a few days, or it may take up to 2 weeks. Aim to use this number of inhalations each day.

- Start with 1 inhalation, wait 15 minutes;
- Notice the effect you get;
- Increase by 1 inhalation every 30 minutes if needed, until symptom relief and as tolerated;
- Maximum of FOUR breathes in one setting (you might need less).

When to take it

KIKUYA Arroyo can be taken with or without food.

Taking KIKUYA Arroyo under similar conditions (e.g., before or after food/meals) each day may help achieve a more consistent effect.

How long to take it

Continue to use this medicine for as long as your doctor tells you to. If you have any further questions on the use of this product, ask your doctor or pharmacist. Seek advice from the prescriber before stopping the medicine. If you stop taking KIKUYA Arroyo, you may experience increased dreaming, sleep disturbances, appetite changes, and mood changes. You may also experience irritability, stomach upset, headache and lack of appetite. These effects do not tend to last more than a few days. You may also expect that the symptoms treated by KIKUYA Arroyo to return at their initial intensity. Consult with doctor for the best management approach if you decide to stop taking KIKUYA Arroyo.

If you forget to take it

KIKUYA Arroyo should be taken 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.

4. WHILE YOU ARE TAKING KIKUYA ARROYO

Things you must do

- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking KIKUYA Arroyo.
- Take special care if you drink alcohol while using KIKUYA Arroyo. Taking KIKUYA Arroyo and alcohol together may increase their effects (such as loss of balance or ability to respond quickly). If you drink alcohol with KIKUYA Arroyo, see what effect it has on you.
- Talk to your doctor before taking this medicine if you are pregnant or plan to become pregnant.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do

- Do not give KIKUYA Arroyo to anyone else, this medicine is for you. Even if they have the same condition as you, do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Do not use KIKUYA Arroyo while breast-feeding / do not use KIKUYA Arroyo during pregnancy, unless advised to by your doctor.
- Avoid smoking. Minimise exposure to harmful combustion compounds produced by smoking. Always use a vapouriser instead for cannabinoid inhalation.

Things to be careful of

- Taking KIKUYA Arroyo with food and drink.
- Take special care if you drink alcohol while taking KIKUYA Arroyo. Taking KIKUYA Arroyo and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).
- You can take KIKUYA Arroyo with or without food.

Driving and using machines in New Zealand

- You must not drive or use machinery when you first start to take KIKUYA Arroyo and until you are established on a stable daily dose.
- KIKUYA Arroyo may cause you to feel sleepy or dizzy, which may impair your judgment and performance of skilled tasks.
- Once you are more used to taking KIKUYA Arroyo and your dose is stable, you should still not drive or use machinery if KIKUYA Arroyo causes effects such as sleepiness or dizziness that could impair your ability to perform these tasks. If you are not sure, do not drive or operate machines.

Travelling overseas with KIKUYA Arroyo

- Check that it is legal for you to take this medicine into any countries you are travelling to, including countries you are travelling through before you reach your final destination.
- KIKUYA Arroyo's legal status will vary between countries.
- Driving while taking KIKUYA Arroyo might be illegal in some countries.

5. IN CASE OF OVERDOSE

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much KIKUYA Arroyo.

Do this even if there are no signs of discomfort or poisoning.

If you accidentally take more of this medicine than you normally do you may:

- See or hear things that are not there (hallucinations).
- Feel dizzy, sleepy, or confused.
- Feel your heart rate change.

If you get any of the above and they get serious, please tell your doctor or pharmacist.

6. SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking KIKUYA Arroyo.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Side effects	What to do
Changes to mental status: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• Anxiety• Loss of inhibition• Quiet and reflective mood, or other unusual changes in mood• Changes in appetite• Spontaneous laughter• Sleepiness/feeling tired	
Eye-related: <ul style="list-style-type: none">• Bloodshot eyes• Altered visual perception	
Ear-related: <ul style="list-style-type: none">• Altered hearing perception	
General body-related: <ul style="list-style-type: none">• Phlegm and cough• Dry mouth• Malaise (feeling unwell) or a general feeling of discomfort• Nausea• Muscle weakness	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects	What to do
Changes to mental status or personality: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• Rapid or irregular heartbeat• Signs of low blood pressure, such as light-headedness, dizziness or fainting	
Nervous system-related: <ul style="list-style-type: none">• Seizures or convulsions (if you do not have epilepsy)	
Allergic reaction-related: <ul style="list-style-type: none">• 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	

Other adverse effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

REPORTING SIDE EFFECTS

After you have received medical advice for any side effects you experience, you can report side effects to your doctor, pharmacist, NUBU Pharmaceuticals and/or the New Zealand Pharmacovigilance Centre by visiting www.otago.ac.nz/carm. 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. AFTER TAKING KIKUYA ARROYO

Storage

- Store below 25°C
- Follow the instructions on the bottle 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, near a sink, in the car or on windowsills.

Medicines should not be kept indefinitely. Keep it where young children cannot reach it.

Disposal

Return to a pharmacy any unused medicine, and any medicine past its expiry date as shown on the dispensing label or on the packaging.

8. PRODUCT DESCRIPTION

Active ingredient (main ingredient)	Each bottle has 10g whole dried <i>Cannabis Sativa</i> dominant flower, which contains 2000 mg of delta-9-tetrahydrocannabinol (20% THC), <100 mg of cannabidiol (<1% CBD) and other minor cannabinoids.
Other ingredients	N/A

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

WHAT KIKUYA ARROYO LOOKS LIKE

Trimmed dried *Cannabis Sativa* dominant flower. Available in a white polyethylene terephthalate (PET) jar with a child-resistant cap and tamper proof seal.

WHO DISTRIBUTES KIKUYA ARROYO

KIKUYA Arroyo is supplied in New Zealand by:

NUBU Pharmaceuticals 0800 46 33 22
Auckland, New Zealand info@nubupharma.com
Material Number: NUBU037v3 Prepared by NUBU Pharmaceuticals, May 2022