

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S6

### ELIXIR 1:1 OIL SPRAY (Oromucosal spray)

Tetrahydrocannabinol 9.70 mg/ml

Cannabidiol 9.66 mg/ml

Sugar free

No sweetener added

### Read all of this leaflet carefully before you start taking ELIXIR 1:1 OIL SPRAY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ELIXIR 1:1 OIL SPRAY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### WHAT IS IN THIS LEAFLET?

1. What ELIXIR 1:1 OIL SPRAY is and what it is used for?
2. What you need to know before you take ELIXIR 1:1 OIL SPRAY?
3. How to take ELIXIR 1:1 OIL SPRAY
4. Possible side effects
5. How to store ELIXIR 1:1 OIL SPRAY
6. Contents of the pack and other information

### 1. WHAT ELIXIR 1:1 OIL SPRAY IS AND WHAT IT IS USED FOR?

ELIXIR 1:1 OIL SPRAY is a mouth spray which contains cannabis extracts called cannabinoids.

ELIXIR 1:1 OIL SPRAY may have a role in a number of medical conditions. These include chemotherapy-induced nausea and vomiting associated with cancer, refractory paediatric epilepsy called Dravets syndrome, palliative care, cancer pain, neuropathic pain, spasticity from neurological conditions (multiple sclerosis), appetite loss associated with chronic illness, post-traumatic stress disorder (PTSD), chronic pain (not of cancer origin), fibromyalgia, migraines and anxiety

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ELIXIR CBD OIL SPRAY?

#### DO NOT TAKE ELIXIR 1:1 OIL SPRAY IF:

- you are sensitive (allergic) to any extracts or to any the active ingredients or to any of the other ingredients that this product contains or if you develop sensitivity while using it.
- You are pregnant, planning to become pregnant, or if you are breastfeeding.
- have serious liver, kidney, heart or lung disease.
- have a personal or family history of serious mental disorders such as schizophrenia, psychosis, depression, or bipolar disorder.
- have a history of alcohol or drug abuse or substance dependence.

#### WARNINGS AND PRECAUTIONS:

Tell your doctor or health care provider before being given ELIXIR 1:1 OIL SPRAY

- If you are pregnant or plan to become pregnant.
- If you are under 18 years of age.
- If you have epilepsy or regular fits (seizures).
- If you have kidney problems.
- If you have moderate to severe liver problems.
- If you have a serious heart problem such as angina, a previous heart attack, poorly controlled high blood pressure or a problem with your heart rate or heartbeat.
- If you are elderly, especially if you have problems doing everyday activities such as making hot food and drinks.
- If you have previously abused any drug or substance.

#### OTHER MEDICINES AND ELIXIR 1:1 OIL SPRAY

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This is because ELIXIR 1:1 OIL SPRAY may affect the way some other medicines work. Also, some other medicines can affect the way ELIXIR 1:1 OIL SPRAY works.

In particular, tell your doctor or pharmacist if you are using medicines for:

- anxiety or sleeping problems (sedatives/hypnotics like benzodiazepine, for example diazepam or triazolam; other

sedatives, for example zopiclone, zolpidem, buspirone, St John's Wort (a herbal preparation))

- muscle spasms (such as baclofen)
- bacterial infections (antibiotics such as rifampicin, clarithromycin)
- epilepsy or nerve pain (such as phenytoin, phenobarbital, carbamazepine)
- high cholesterol (known as statins; for example, atorvastatin or simvastatin)
- fungal infections (such as itraconazole, fluconazole and ketoconazole)
- HIV infection (for example ritonavir)
- thinning your blood (known as coumarins; for example, warfarin)
- heart problems (known as betablockers, for example bisoprolol, propranolol)
- corticosteroids used for inflammation (such as hydrocortisone, beclomethasone, prednisolone)
- Some hormone medicines used for contraception or some types of cancer (such as ethinyloestradiol, levonorgestrel or dydrogesterone)

#### ELIXIR 1:1 OIL SPRAY WITH FOOD AND DRINK AND ALCOHOL

In general, alcoholic beverages should be avoided whilst using ELIXIR 1:1 OIL SPRAY especially at the beginning of treatment or when changing dose. If you do drink alcohol while using ELIXIR 1:1 OIL SPRAY, be aware that using ELIXIR 1:1 OIL SPRAY and alcohol together may increase their effects (such as loss of balance or ability to respond quickly) which could increase the risk of falls and other accidents.

- You can use ELIXIR 1:1 OIL SPRAY with or without food, however it is advised not to take it on empty stomach.
- Do not drink grapefruit juice while you are taking medicinal cannabis.
- Eating a light meal is recommended 30 minutes after taking the product.

#### PREGNANCY AND BREASTFEEDING AND FERTILITY

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

- Do not use ELIXIR 1:1 OIL SPRAY during pregnancy, unless advised to by your doctor. ELIXIR 1:1 OIL SPRAY may affect the way hormonal birth control methods, such as the "pill" or contraceptive implants, work. This means you should use an additional type of contraception. Whether male or

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female you must use a reliable barrier contraceptive method such as a condom, diaphragm or cap while using this medicine. Keep doing this for at least 3 months after your treatment has stopped.

- Do not use ELIXIR 1:1 OIL SPRAY while breast-feeding.

### DRIVING AND USING MACHINES

It is not always possible to predict to what ELIXIR 1:1 OIL SPRAY may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ELIXIR 1:1 OIL SPRAY affects them.

You must not drive or use machinery when you first start to take ELIXIR 1:1 OIL SPRAY and until you are established on a stable daily dose.

- ELIXIR 1:1 OIL SPRAY may cause you to feel sleepy or dizzy, which may impair your judgment and performance of skilled tasks. It has also rarely been reported to cause a brief loss of consciousness.
- Once you are more used to taking ELIXIR 1:1 OIL SPRAY and your dose is stable, you should still not drive or use machinery if ELIXIR 1:1 OIL SPRAY 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.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.

### FOREIGN TRAVEL WITH ELIXIR 1:1 OIL SPRAY

Before going abroad, check that it is legal for you to take this medicine. This includes any countries you are travelling through.

- ELIXIR 1:1 OIL SPRAY is a controlled drug and its legal status will vary between countries.
- Driving while taking ELIXIR 1:1 OIL SPRAY might be illegal in some countries.

ELIXIR 1:1 OIL SPRAY contains Medium-chain triglycerides (MCT) oil.

### 3. HOW TO TAKE ELIXIR 1:1 OIL SPRAY

Do not share medicines prescribed for you with any other person.

#### RECOMMENDED DOSE

Your doctor will work out the correct dose of ELIXIR 1:1 OIL SPRAY for you and how often it must be taken.

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Only use ELIXIR 1:1 OIL SPRAY in your mouth – on the inside of your cheek or under your tongue.

- You can take ELIXIR 1:1 OIL SPRAY with or without food. However, taking ELIXIR 1:1 OIL SPRAY with food can affect the amount your body takes in. You should try, as far as possible, to take ELIXIR 1:1 OIL SPRAY the same way in relation to food each time, so you get the same effect each time.

Your doctor will tell you how long your treatment ELIXIR 1:1 OIL SPRAY will last.

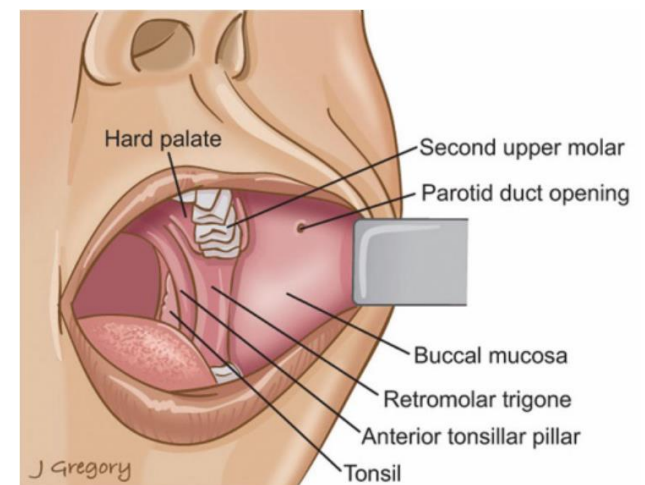
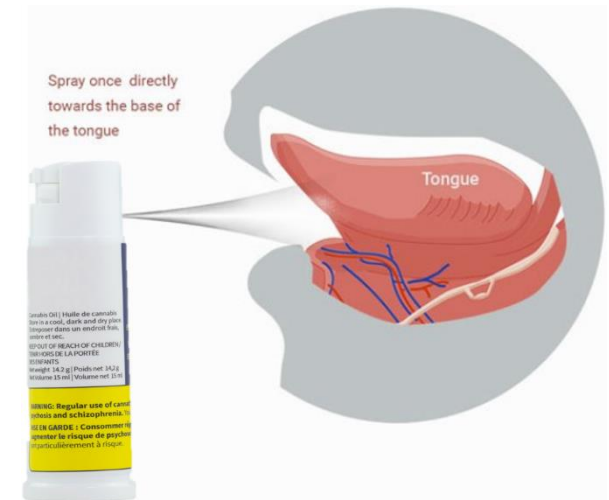
If you have the impression that the effect of ELIXIR 1:1 OIL SPRAY is too strong or too weak, tell your doctor or pharmacist.

#### USING YOUR SPRAY

1. Only use ELIXIR 1:1 OIL SPRAY in your mouth – on the inside of your cheek.
2. Hold the spray between your thumb and second finger. Put your first finger on the nozzle.
3. Hold it upright and point into your mouth. Point the nozzle towards the inside of your cheek. Alternate the sites where you spray each time.
4. Press the nozzle down firmly. Do not take more sprays as directed by your doctor, even if you feel that you only got a small amount of spray.
5. If you need to apply more than two sprays at a time, wait one minute before administering the next two sprays.
6. Replace the protective cap.

If you get spray in your eyes by accident, wash them with water as soon as possible.

- Do not breathe in the spray.
- Do not spray near children or pets.



Picture of area to spray

### IF YOU TAKE MORE ELIXIR 1:1 OIL SPRAY THAN YOU SHOULD

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

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- See or hear things that are not there (hallucinations).
- Feel dizzy, sleepy or confused.
- Feel your heart rate change.
- Please tell your doctor or pharmacist if you used more ELIXIR 1:1 OIL SPRAY than you should.

### IF YOU FORGET TO TAKE ELIXIR 1:1 OIL SPRAY

If you forget a dose, use a spray as soon as you remember.

Do not use 2 sprays at the same time to make up for a missed spray.

### IF YOU STOP USING ELIXIR 1:1 OIL SPRAY

If for any reason you decide to stop using ELIXIR 1:1 OIL SPRAY, tell your doctor or pharmacist. If you stop using your medicine suddenly your sleep, appetite or feelings might be affected for a short time. Your muscle stiffness usually comes back gradually if you stop using ELIXIR 1:1 OIL SPRAY.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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## 4. POSSIBLE SIDE EFFECTS

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ELIXIR 1:1 OIL SPRAY can have side effects.

Not all side effects reported for ELIXIR 1:1 OIL SPRAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ELIXIR 1:1 OIL SPRAY, please consult your health care provider for advice.

If any of the following happens, stop taking / using ELIXIR 1:1 OIL SPRAY and tell your doctor immediately or go to the casualty department at your nearest hospital as you will need to be monitored until the symptoms stop:

- seeing or hearing things that are not there (hallucinations).
- believing ideas that are not true.
- feeling that other people are against you.
- thoughts of suicide.
- feeling depressed or confused.
- feeling over-excited or losing touch with reality

These are all very serious side effects. If you have them, you may have had a serious reaction to ELIXIR 1:1 OIL SPRAY. You may need urgent medical attention or hospitalisation.

The following side effects are more likely when you start your treatment. In most cases side effects are quite mild and they generally wear off within a few days.

Tell your doctor if you notice any of the following:

**Very common (affecting more than 1 in 10 people)**

- Feeling dizzy or tired.

**Common (affecting less than 1 in 10 people)**

- Problems with your memory or having trouble concentrating.
- Feeling sleepy or giddy.
- Blurred vision.
- Difficulty speaking.
- Eating more or less than usual.
- Changed sense of taste or a dry mouth.
- Constipation or diarrhoea.
- Feeling or being sick.
- Mouth problems, including burning, pain or mouth ulcers.
- Lack of energy or feeling weak or generally unwell.
- Feeling abnormal or drunk.
- Loss of balance or falling over.

**Uncommon (affecting less than 1 in 100 people)**

- Fainting.
- Changes in pulse rate, heart rate or blood pressure.
- Sore throat or throat irritation.
- Tummy pain.
- Mouth or teeth changing colour.
- Irritation where ELIXIR 1:1 OIL SPRAY is sprayed.
- Red and swollen mouth or peeling inside it. Do not keep spraying onto these areas.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### REPORTING OF SIDE EFFECTS

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ELIXIR 1:1 OIL SPRAY.

You should also report side effects to the Holder of Certificate of

You should also report side effects to the [info@africann.net](mailto:info@africann.net)

The contact details for our national reporting system are:

Email: [safety@africann.net](mailto:safety@africann.net)

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## 5. HOW TO STORE ELIXIR 1:1 OIL SPRAY.

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Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Do not use after the expiry date stated on the label.

Do not use ELIXIR 1:1 OIL SPRAY if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

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### What ELIXIR 1:1 OIL SPRAY contains

- The active substances are the cannabis extracts. (from hybrid Cannabis), delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).
- The other ingredient (excipient) is Medium-chain triglycerides (MCT) oil

### What ELIXIR 1:1 OIL SPRAY looks like and contents of the pack

ELIXIR 1:1 OIL SPRAY is a yellow-brown oil packaged in a 15 ml plastic spray bottle.

### Holder of Certificate of Registration

To be allocated

### Registration number

To be allocated

### Access to the corresponding Professional Information

[info@africann.net](mailto:info@africann.net)