

SOMÁI 20:<1 THC Oil

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 and is not yet approved on the Australian Register of Therapeutic Goods. Please report side effects. See the [full CMI](#) for further details.

WARNING: SOMÁI 20:<1 THC Oil is an unapproved medicine that contains controlled substances. Possession without authority is illegal.

1. WHY AM I USING SOMÁI 20:<1 THC OIL?

SOMÁI 20:<1 THC Oil contains the active ingredient tetrahydrocannabinol (THC). It also contains a very small amount of cannabidiol (CBD). Each 1mL of SOMÁI 20:<1 THC Oil contains 20mg THC and <1mg CBD.

Your doctor can indicate the desired symptom or condition for which this medication has been prescribed to you. For more information, see Section [1. Why am I using SOMÁI 20:<1 THC Oil?](#) in the full CMI.

2. WHAT SHOULD I KNOW BEFORE I USE SOMÁI 20:<1 THC OIL?

Do not use if you have ever had an allergic reaction to THC, CBD, any other known cannabinoid 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 SOMÁI 20:<1 THC Oil?](#) in the full CMI.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with SOMÁI 20:<1 THC Oil 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 SOMÁI 20:<1 THC OIL?

- There is no scientifically defined dose of medical cannabis for any specific medical condition. Use SOMÁI 20:<1 THC Oil exactly as prescribed by your doctor.
- Your doctor will assess you and give you a dosing plan to follow.

More instructions can be found in Section [4. How do I use SOMÁI 20:<1 THC Oil?](#) in the full CMI.

5. WHAT SHOULD I KNOW WHILE USING SOMÁI 20:<1 THC OIL?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SOMÁI 20:<1 THC Oil.• Follow the dosing instructions provided by your doctor, because THC can produce dependence, presenting the potential for abuse.• Check with the country or countries that you intend to visit or crossing for information on whether you may take your medicine, because SOMÁI 20:<1 THC Oil contains controlled substances. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine suddenly.• 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 being treated with SOMÁI 20:<1 THC Oil.• Be aware that in most Australian states and territories, driving with detectable levels of THC in your body is illegal, even though it may not impair your driving. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• You should avoid drinking alcohol while using SOMÁI 20:<1 THC Oil. |
| Looking after your medicine | <ul style="list-style-type: none">• Store below 25°C. Store in the original package in order to protect from light and moisture.• Keep it where children cannot reach it. |

For more information, see Section [5. What should I know while using SOMÁI 20:<1 THC Oil?](#) in the full CMI.

6. ARE THERE ANY SIDE EFFECTS?

Call your doctor straight away, or go straight to the nearest hospital if you notice any of these serious side effects, such as: signs of an allergic reaction, paranoia, hallucinations, fast or irregular heartbeat, low blood pressure if associated with lightheadedness, dizziness or fainting, seizures, depression or thoughts of suicide. Less serious side effects can occur and you should speak to your doctor if any of them worry you.

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.

SOMAI 20:<1 THC Oil

Active ingredient(s): *Tetrahydrocannabinol (THC)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOMAI 20:<1 THC Oil. 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 SOMAI 20:<1 THC Oil.

Where to find information in this leaflet:

1. Why am I using SOMAI 20:<1 THC Oil?
2. What should I know before I use SOMAI 20:<1 THC Oil?
3. What if I am taking other medicines?
4. How do I use SOMAI 20:<1 THC Oil?
5. What should I know while using SOMAI 20:<1 THC Oil?
6. Are there any side effects?
7. Product details

1. WHY AM I USING SOMAI 20:<1 THC OIL?

SOMAI 20:<1 THC Oil contains the active ingredient tetrahydrocannabinol (THC). It also contains a very small amount of cannabidiol (CBD). Each 1mL of SOMAI 20:<1 THC Oil contains 20mg THC and <1mg CBD.

SOMAI 20:<1 THC Oil contains ingredients called cannabinoids, which have been extracted from cannabis plants. Cannabinoids, such as THC and CBD, interact with the body's endocannabinoid system to produce various effects. The therapeutic benefits of medicinal cannabis may vary depending on a patient's biology and the product selected. SOMAI 20:<1 THC Oil is high in THC.

SOMAI 20:<1 THC Oil are not approved for treatment of any specific conditions or symptoms. Your doctor can indicate the desired symptom or condition for which this medication has been prescribed to you.

To date, the Therapeutic Goods Administration (TGA) has approved medicinal cannabis SAS applications for indications including, but not limited to, the following:

- chemotherapy-induced nausea and vomiting
- refractory paediatric epilepsy
- symptom relief in palliative care, including non-cancer related palliation
- cancer pain
- neuropathic pain, including that related to multiple sclerosis
- spasticity from neurological conditions, such as multiple sclerosis
- anorexia and wasting associated with chronic illness
- Parkinson's Disease
- mental health disorders

Your doctor may also prescribe this medication for conditions or symptoms which have not been mentioned. Ask your doctor if you have any questions about why SOMAI 20:<1 THC Oil has been prescribed for you.

2. WHAT SHOULD I KNOW BEFORE I USE SOMAI 20:<1 THC OIL?

Warnings

Do not use SOMAI 20:<1 THC Oil if:

- you are allergic to THC, CBD, any other known cannabinoid, 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 a close family member directly related to you has any mental health conditions including psychosis, schizophrenia, or other significant psychiatric disorder
- you have severe and unstable cardio-pulmonary disease (angina, peripheral vascular disease, cerebrovascular disease and arrhythmias) or risk factors for heart disease
- you have severe kidney or liver conditions
- you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant

Check with your doctor if you:

- have mild or moderate kidney or liver conditions because your doctor may consider that you need to be monitored while using this medicine
- have a history of drug dependence, including nicotine and heavy users of alcohol
- have a history of epilepsy or recurrent seizures due the THC content of this medicine
- take any medicines for any other condition. See additional information under *Section 3. What if I am taking other medicines?*
- are an elderly patient (more than 65 years of age) because you may be more sensitive to the neurological, psychoactive, and postural hypotensive effects of cannabinoids
- are a younger patient (under 18 years of age) due to the potentially adverse effects of cannabis on the developing brain

The use of SOMAI 20:<1 THC Oil may involve additional health risks beyond those described above, some of which are not known or fully understood. There may be additional contraindications/precautions that are unknown due to limited medical and scientific information.

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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant you cannot take this medicine.

Fertility

Cannabis preparations should not be used by anyone planning to have a child. Cannabinoids may impact fertility (whether male or female) and can affect the gestational development of the fetus.

Check with your doctor if you are planning to have a baby.

It is advisable to always use a highly effective contraceptive method. Women using hormonal contraceptives should add a barrier non-hormonal contraceptive method during treatment with **SOMAÍ 20:<1 THC Oil**.

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 interact with SOMAÍ 20:<1 THC Oil and affect how it works, increasing or reducing its effects. SOMAÍ 20:<1 THC Oil may also interact with some medicines and affect how they work.

There is limited evidence about how medicinal cannabis reacts with other approved medications. Most interactions are associated with drugs that slow down the nervous system, causing drowsiness, such as sedatives, benzodiazepines and hypnotics. The list below does not include all possible drug interactions. The doctor or pharmacist should evaluate all possible drug interactions on a case-by-case basis.

- The association with antispastic medications, used in muscle-related diseases, can reduce muscle strength and increase the risk of falls, so precautions must be taken
- Medicines used for sleep problems (sleeping pills or sedatives/hypnotics such as: benzodiazepines, zopiclone, zolpidem)
- Medications used for pain (opioids, such as oxycodone, hydrocodone, codeine and morphine)
- Medicines used to treat epilepsy, seizures or neuropathic pain (for example, carbamazepine, phenytoin, primidone, phenobarbital, clobazam)
- Medicines used to treat bacterial (e.g. antibiotics such as rifampicin, rifabutin, clarithromycin and erythromycin) or fungal (e.g. antifungals such as itraconazole, fluconazole, ketoconazole and miconazole, amphotericin B) infections
- Medicines used to thin the blood (anticoagulants such as warfarin, apixaban, rivaroxaban)
- Medicines used for heart disease or hypertension (such as amiodarone, diltiazem and verapamil)
- Medicines used to control HIV/AIDS infection (HIV protease inhibitors) in particular ritonavir

- Medicines used to treat diabetes (troglitazone)
- St John's Wort
- Anti-depressants (fluoxetine, fluvoxamine)
- Stomach acid inhibitors (omeprazole)
- Medicines that are strongly bound to proteins (e.g. cyclosporine)
- Any drug or complementary medicine metabolised by cytochrome P450

If you stop taking any of these medications, it may cause an increase in the bioavailability of THC, and there may be a need to adjust the dose titration to be administered.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SOMAÍ 20:<1 THC Oil.

If at any time you suspect that a combination of medicines is working in an unexpected way, or has any unwanted or unpleasant effects, consult your doctor immediately.

4. HOW DO I USE SOMAÍ 20:<1 THC OIL?

How much to take

Treatment must be initiated and supervised by a doctor.

There is no scientifically defined dose of medical cannabis for any specific medical condition. There are no set dosage schedules for medical cannabis; dose titration is necessary and requires an individualized approach to adjust the ideal dosage needed for each patient and the final dosage depends on the person and the condition being treated.

Your doctor will work with you to decide the dose of **SOMAÍ 20:<1 THC Oil** that best suits you and your symptoms and minimizes any side effects. It is highly recommended to begin at the lowest possible dose and increase slowly over time.

Follow the instructions provided by your doctor. Check with your doctor or pharmacist if you are not sure.

When to take SOMAÍ 20:<1 THC Oil

Once your ideal dosage of **SOMAÍ 20:<1 THC Oil** is found for your condition, continue to take that dose as needed.

You should try, as far as possible, to take **SOMAÍ 20:<1 THC Oil** consistently either with or without food, and according to your daily routine, so you get the same effect each time. Follow the instructions provided and use this medicine until your doctor tells you to stop.

How to use SOMAÍ 20:<1 THC Oil

SOMAÍ 20:<1 THC Oil is for oral use.

Instructions on measuring the dose using the dosing syringe:

- 1 – Unscrew the bottle cap.
- 2 - Insert the tip of the syringe into the bottle adaptor and press down until it is snug.
- 3 – Invert the bottle so that the top of the bottle with the attached syringe is facing downward.

4 – Draw up the prescribed dosage in milliliters (mL) into the syringe by pulling back the plunger so that the measurement line aligns with the medication dose.

The syringe can be filled with oil several times, according to needs.

5 – Turn the bottle upright and remove the syringe by pulling up on the barrel.

6 - Administer the oil directly through the syringe into the mouth by depressing the plunger into the barrel. Swallow the dose, avoiding choking.

7 - After administration, clean the syringe. To do this, disassemble the syringe completely. Both pieces, plunger and barrel, must be carefully rinsed with water and dried.

If you forget to use SOMAÍ 20:<1 THC Oil

SOMAÍ 20:<1 THC Oil should be used regularly at the same time each day.

If you miss your dose at the usual time, 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 SOMAÍ 20:<1 THC Oil

If you think that you have used too much SOMAÍ 20:<1 THC Oil, 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 SOMAÍ 20:<1 THC OIL?

Things you should do

Talk to your doctor if your condition worsens or does not improve.

- THC can produce physical and psychological dependence, presenting the potential for abuse, although in the case of medical treatment with low doses of cannabis this is very unlikely to occur. You should follow the dosing instructions provided by your doctor.

Call your doctor straight away if you:

- feel unwell or experience any side effects that worry you while using your SOMAÍ 20:<1 THC Oil. See additional information under Section 6. *Are there any side effects?*
- stop taking SOMAÍ 20:<1 THC Oil suddenly

Remind any doctor, dentist or pharmacist you visit that you are using SOMAÍ 20:<1 THC Oil.

Things you should not do

- Do not stop using this medicine suddenly. If this happens, the following symptoms may occur, especially within the first 7 days: anger or aggression, irritability, anxiety, nightmares, strange dreams, insomnia, sleep disturbances, desire to consume, headache, restlessness, decreased appetite or loss weight loss, depressed mood, chills, stomach pain, tremors and sweating.
- Do not give SOMAÍ 20:<1 THC Oil to anyone else, even if they have the same condition as you.

Travelling overseas with SOMAÍ 20:<1 THC Oil

- As SOMAÍ 20:<1 THC Oil contains controlled substances, the legality of its use and transport may differ between countries. As such, you should check if the country or countries that you intend to visit or crossing for information on whether you may take your medicine.

Driving or using machines

Do not drive or operate machinery while being treated with SOMAÍ 20:<1 THC Oil.

THC can cause drowsiness or dizziness and affect cognitive abilities. Such effects may impact concentration, coordination, delay reaction time and thus impair motor skills. These effects can be further increased when taking other medications or drinking alcohol.

Talk to your doctor about driving, using machines, or when undertaking other activities that require balance such as cycling or other sports, because this medicine may affect your ability to do so safely.

Measurable concentrations of THC (the main psychoactive substance in cannabis) can be detected in urine many days after the last dose of SOMAÍ 20:<1 THC Oil. It may take up to 5 days for 80 to 90% of the dose to be excreted. Be aware that in most Australian states and territories, driving with detectable levels of THC in your body is illegal, even though it may not impair your driving.

Drinking alcohol

Tell your doctor if you drink alcohol.

You should avoid drinking alcohol while using SOMAÍ 20:<1 THC Oil.

Alcohol can increase the effects of SOMAÍ 20:<1 THC Oil that impair cognitive abilities, reaction time, coordination and motor skills. Cognitive impairment may be greatly increased when SOMAÍ 20:<1 THC Oil is consumed along with alcohol or other drugs which affect the activity of the nervous system (e.g. opioids, sleeping pills, other psychoactive drugs).

Looking after your medicine

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

Store below 25°C. Store in the original package in order to protect from light and moisture.

Keep it where children cannot reach it.

When to discard your medicine

After first opening, use within 120 days. Keep the bottle tightly closed.

Do not use this medicine if you notice any visible signs of deterioration.

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, which is stated on the pack. The expiry date refers to the last day of that month.

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.

Information on the side effects associated with medical cannabis use is limited. Patients generally tolerate it well. Often a low dosage provides sufficient relief so that side effects rarely occur. When these happen, they are usually the result of a high dosage or combined use with a substance, such as alcohol, which intensifies its effects.

The toxic and pharmacological effects of cannabinoids may overlap due to the small therapeutic window of THC, which is mainly responsible for possible side effects.

Medicinal cannabis side effects are commonly dose-dependent, so it's important to follow your doctor's dosing recommendations.

Long-term use may decrease one or more of the effects of cannabis (tolerance).

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">● Dizziness● Feeling sick or nauseous● Increased heart rate or palpitations● Changes in appetite● Dry mouth● Muscle weakness● Mood changes● General feeling of discomfort● Blurred vision● Anxiety● Confusion● Problems with memory, concentration, perception of reality, sense of time, ability to think and make decisions, reaction time and coordination● Problems with balance or falls | <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 |
|---|--|
| <ul style="list-style-type: none">● Signs of an allergic reaction such as swelling of the face, lips, tongue or other body part, severe fainting or dizziness, or rash/itching of the skin● Paranoia (feeling suspicious, angry or betrayed by other people)● Hallucinations (hearing voices or seeing things that aren't there)● Fast or irregular heartbeat● Low blood pressure if associated with lightheadedness, dizziness or fainting● Seizures (if you have no history of epilepsy)● Depression or thoughts of suicide | <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 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 SOMAÍ 20:<1 THC Oil contains

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|--|--|
| Active ingredients (main ingredient) | ● THC: 20mg/mL |
| Other ingredients (inactive ingredients) | ● CBD: <1mg/mL ● Medium-chain triglycerides oil |

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

What SOMAÍ 20:<1 THC Oil looks like

SOMAÍ 20:<1 THC Oil is a liquid solution for oral use supplied in an amber glass bottle with a polyethylene closure, dosing syringe and leaflet and is available in packs of 30mL.

Who distributes SOMAÍ 20:<1 THC Oil

Somaí Pharmaceuticals Pty Ltd
contact@somaipharma.com.au

This leaflet was prepared in December 2023.