

# Southern Sky<sup>®</sup>

BY ALFIE THERAPEUTICS

## CONSUMER MEDICINE INFORMATION (CMI)

### SOUTHERN SKY SATIVA 24%

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#### PRODUCT DETAILS

Southern Sky Sativa 24% THC Dried Medicinal Cannabis Flower is an sativa dominant strain, and each gram contains 24% w/w THC and 1% CBD.

Active ingredients:

- THC 24% w/w (delta-9-tetrahydrocannabinol)
- CBD 1% w/w (cannabidiol)

The medicine name is Southern Sky Sativa and is only available with a Doctor's prescription.

#### WHY AM I USING SOUTHERN SKY?

The Therapeutic Good Administration (TGA) has approved Special Access Scheme (SAS) applications for medicinal cannabis products including, but not limited to, the below:

- Chemotherapy induced nausea and vomiting (CINV)
- Anxiety
- Cancer pain
- Palliative care
- Neuropathic and chronic pain
- Refractory pediatric epilepsy
- Post Traumatic Stress Disorder (PTSD)
- Insomnia and sleep disorders
- Anorexia and wasting associated with chronic illness (e.g., Cancer)
- Spasticity from neurological conditions (e.g., Multiple Sclerosis)

Possession of medicinal cannabis products without authority is illegal and Southern Sky should only be used to treat specific conditions or symptoms as authorised by your Doctor.

#### WHAT SHOULD I KNOW BEFORE USING SOUTHERN SKY?

Do not use Southern Sky if:

- You have had an allergic reaction to medicinal cannabis products in the past
- You are allergic to THC (delta-9-tetrahydrocannabinol) or CBD (cannabidiol)
- The expiry date has passed
- The packaging is damaged or shows signs of tampering

Always check the ingredients to ensure you can use this medicine.

Tolerance or dependence on Southern Sky is unlikely but may occur in some persons.

Psychoactive side effects attributed to THC may occur in some persons.

Southern Sky is contraindicated for:

- Women who are pregnant or lactating
- Patients with liver or kidney dysfunction (consult with your Doctor)
- Patients with cardio-pulmonary disease (consult with your Doctor)
- Patients with family history of schizophrenia
- Patients with a diagnosed history of psychosis and/or active mood disorders
- Patients with a history of serious psychiatric disorders including but not limited to schizophrenia or psychosis, unless specifically prescribed by a qualified healthcare professional with a knowledge of your psychiatric history

There may be other contraindications not yet known due to limited scientific information.

#### WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with Southern Sky and its effectiveness.

Ensure you consult with your doctor or pharmacist if you are currently using or have recently used any other medications or if you have any known food intolerances. Southern Sky may interact with other drugs or some foods.

**If you have not yet informed your Doctor about any other medications or food allergies, tell them before you begin using Southern Sky.**

## **WHAT SHOULD I KNOW WHILE USING SOUTHERN SKY?**

### **STORAGE**

All medicines (including cannabis medicines) must be stored safely in a location that children and animals cannot reach. Light and heat can degrade cannabis products. Store all cannabis products in a cool dark place below 25°C. Do not transfer product material to a different container. Do not use product after the expiry date printed on the label.

### **SAFETY INFORMATION**

Southern Sky is a medicinal cannabis product that contains THC (delta-9-tetrahydrocannabinol), is psychoactive and may lead to temporary cognitive impairment. Patients are advised not to drive or operate any complex machinery for 24 hours after administering medicines containing THC.

Do not consume alcohol whilst taking Southern Sky.

Always consult with your doctor prior to administration of medicinal cannabis products. Remind any doctor, dentist or pharmacist you visit that you are using Southern Sky.

### **CHILDREN AND ADOLESCENTS**

Southern Sky should not be used by children or adolescents under the age of 18 years old unless prescribed under the supervision of a registered healthcare practitioner.

### **OVERDOSE**

In line with TGA recommendations of "start low, go slow" there may be a potential for patients to ingest more medicinal cannabis than is suitable for them, which may lead to discomfort. Adverse effects associated with ingesting too much medicinal cannabis are generally temporary and self-resolving upon cessation.

## **HOW DO I USE SOUTHERN SKY?**

### **DOSING AND ADMINISTRATION**

Southern Sky is designed for inhalation using a TGA-approved vaporiser and is available as a dried medicinal cannabis flower, taken as needed (PRN) or on a metered dosage as determined by your prescriber.

This medicine is always to be used as instructed by your doctor or pharmacist. Combustion (smoking or using smoking paraphernalia) is not to be used with Southern Sky due to risks, including the potential contribution to chronic obstructive pulmonary disease (COPD).

Unlike the combustion method, vaporisation heats the medicinal cannabis below its burning point, allowing for a rich cannabinoid filled vapour. Vaporisation is the most efficient administration method for medicinal cannabis as it provides rapid onset times. Ensure you use vaporisers in accordance with the accompanying manufacturer instructions.

### **TITRATION**

Titration is the process which involves gradually increasing a dose until the desired result is achieved. This is done through the TGA guided approach of "start low, go slow" whereby patients begin with a low dose and gradually slowly increase it until the optimal therapeutic benefit is achieved.

As dosing levels are highly individual, patients should work with their doctors to determine the optimal dosing schedule that allows for the maximum medical benefit to be achieved.

Perfecting the dosing and titration can be difficult with the medicinal cannabis flowers due to a number of factors including variance in cannabinoid profiles, depth of breath when inhaled and inconsistency in the amount of medicine administered.

To ensure reliable and repeatable dosing of medicinal cannabis, it is recommended that patients pay close attention to the conditions in which the medicinal cannabis is administered to allow for consistent replication.

Maintaining a consistent dosing schedule and adjusting dose timing is advised during the initial titration process. It is also advised that new patients of medicinal cannabis should wait up to 30 minutes between their initial dose before this next inhalation. .

## **SIDE EFFECTS**

Like all medicines, Southern Sky may produce unwanted side effects in some people. Side effects are more common when you start your treatment. They are usually mild and temporary, wearing off within a few hours. Rare side effects that warrant immediate cessation of Southern Sky are:

- Depression or suicidal thoughts
- Seizures or convulsions
- Difficulty breathing
- Paranoia

- Hallucinations (auditory/visual)
- Fainting, lightheadedness and dizziness associated with low blood-pressure

**Notify your Doctor immediately, or proceed to the nearest hospital, if you experience any of the above symptoms.**

More common side effects associated with taking medicinal cannabis products for the first time, or from increasing usual dosing, are mild and transient in nature and include:

- Headaches
- Blurred vision
- Dry mouth
- Nausea
- Increased heart rate or palpitations
- Occasional or brief paranoid thoughts
- Euphoria or other cognitive effects
- Confusion or problems concentrating
- Coughing or phlegm
- Drowsiness
- Anxiety

If any of the above side effects are experienced for a prolonged period of time (i.e., greater than 24 hours) or if severe, immediately stop taking Southern Sky and consult your doctor or pharmacist or seek immediate medical attention.

**This list does not serve as a complete list of potential adverse effects. If you experience any unexpected serious adverse effects not listed, stop using Southern Sky immediately and contact your Doctor or seek immediate medical attention. Reporting adverse effects assists us to provide more information on the safety of this product.**

## **SPONSOR INFORMATION**

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