

Southern Sky®

BY ALFIE THERAPEUTICS

CONSUMER MEDICINE INFORMATION (CMI)

SOUTHERN SKY SATIVA PASTILLES

PRODUCT DETAILS

Southern Sky Sativa Pastilles are a medicated pastille containing the active ingredients Delta-9-Tetrahydrocannabinol (THC), Cannabidiol (CBD) and Cannabigerol (CBG).

Active ingredients:

- THC 10mg (delta-9-tetrahydrocannabinol)
- CBD 10mg (cannabidiol)
- CBG 10mg (cannabigerol)

The medicine name is Southern Sky Sativa Pastilles 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 Sativa Pastilles should only be taken orally, chewing thoroughly until swallowed.

They can be taken with or without food however a fatty meal may improve absorption.

Always take Southern Sky Sativa Pastilles exactly as your doctor/nurse practitioner has prescribed.

You should check with your prescriber or pharmacist if you are not sure.

Continue to take Southern Sky Sativa Pastilles until your doctor/nurse practitioner tells you to stop.

Do not make up missed or skipped doses as this can increase the chances of unwanted side effects.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If there is still a long time to go before your next dose, take it as soon as you remember and then go back to take it as prescribed.

If you are not sure what to do, speak to your doctor/nurse practitioner or pharmacist.

Refer to your Doctor's instructions on how much and when to take the medicine.

The label should always be carefully read.

The Southern Sky Sativa Pastilles should only be taken orally, chewing thoroughly until swallowed.

Southern Sky Sativa Pastilles should be taken at a frequency that is per the advice of your Doctor or Medical Practitioner.

It can be taken with, or without food.

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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