



CONSUMER MEDICINE INFORMATION (CMI)

BALANCED GT HAZE VAPE

PRODUCT DETAILS

Alfie Therapeutics Balanced GT Haze is a distillate which contains the active ingredient Delta-9-Tetrahydrocannabinol (THC) in a 510-thread vaporisation cartridge.

Active ingredients:

- THC 340mg/g (delta-9-tetrahydrocannabinol)
- CBD 340mg/g (cannabidiol)
- CBG 225mg/g (cannabigerol)

The medicine name is Alfie Therapeutics Balanced GT Haze and is only available with a Doctor's prescription.

WHY AM I USING BALANCED GT HAZE?

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 Balanced GT Haze should only be used to treat specific conditions or symptoms as authorised by your Doctor.

WHAT SHOULD I KNOW BEFORE USING BALANCED GT HAZE?

Do not use Balanced GT Haze 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 Balanced GT Haze is unlikely but may occur in some persons.

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

Balanced GT Haze 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 Balanced GT Haze 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. Balanced GT Haze 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 Balanced GT Haze.

WHAT SHOULD I KNOW WHILE USING BALANCED GT HAZE?

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

Balanced GT Haze 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 Balanced GT Haze.

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

CHILDREN AND ADOLESCENTS

Balanced GT Haze 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 BALANCED GT HAZE?

DOSING AND ADMINISTRATION

Balanced GT Haze is a vapourisation cartridge (vape cart) containing a viscous substance called THC distillate inside a clear glass cartridge with a mouthpiece on one end and a 510-thread connection port on the other.

A 510-thread rechargeable vape device will need to be purchased separately to use this product.

Screw the cartridge containing the distillate onto the vape device.

Follow your doctor's instructions as to which vape device to purchase and how to use it. The recommended voltage range is 3.5 to 3.7V to prevent clogging of the mouthpiece

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 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, Balanced GT Haze 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 Balanced GT Haze 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 Balanced GT Haze 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 Balanced GT Haze 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

Alfie Therapeutics
Suite 1333
17 Gould Road
Herston, 4006 QLD

E: support@alfietherapeutics.com
W: www.alfietherapeutics.com

This leaflet was prepared in August 2024.