Alma Flawless Victory (Medicinal Cannabis)

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.

1. Why am I using Alma Flawless Victory?

Alma Flawless Victory contains the active ingredient tetrahydrocannabinol (THC). Alma Flawless Victory is not an approved medicine. It should only be used to treat specific conditions or symptoms authorised by your healthcare practitioner.

For more information, see Section 1. Why am I using Alma Flawless Victory? in the full CMI.

2. What should I know before I use Alma Flawless Victory?

Do not use if you have ever had an allergic reaction to cannabis 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 Alma Flawless Victory? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Alma Flawless Victory 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 Alma Flawless Victory?

Alma Flawless Victory should be administered only by using a TGA registered vaporiser device.

Use the amount of Alma Flawless Victory directed by your doctor. Follow your doctor's instructions and use Alma Flawless Victory until your doctor tells you to stop.

More instructions can be found in Section 4. How do I use Alma Flawless Victory? in the full CMI.

5. What should I know while using Alma Flawless Victory?

Things you should do	 Remind any doctor, nurse or pharmacist you visit that you are using Alma Flawless Victory. Talk to your healthcare provider if you do not feel better, or if you feel worse. You must tell your doctor if you have had any problem with your liver, kidneys, heart, gut, substance use disorder (abuse, dependence), or any other medical condition. Tell your doctor if you have had any psychotic or concurrent disorder. 	
Things you should not do	 You should not start taking any other medicines without first informing your doctor. You should not use this medicine if you are pregnant or plan to become pregnant or are breastfeeding. Do not stop taking this medicine suddenly 	
Driving or using machines	You should not drive, operate machinery or engage in any potentially hazardous activity under the influence of cannabis-based medicines containing THC.	
Drinking alcohol	Alcohol taken in combination with Alma Flawless Victory can impair your thinking abilities, coordination, reaction time and motor skills. You should not drink alcohol while taking this medication.	
Looking after your medicine	• Your medicine should be stored in its original labelled packaging, in a safe and secure place away from children, and away from heat and direct sunlight (i.e. stored in a cool, dry place, at or below 25°C).	

For more information, see Section 5. What should I know while using Alma Flawless Victory? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur they are usually minor and temporary. You are more likely to get side effects when you start your treatment. Do not be alarmed by these lists.

Common but usually mild side effects include fatigue and sedation, dizziness, nausea, dry mouth, increase in appetite.

Serious potential side effects that require medical attention include thoughts of suicide, rapid heartbeat, chest pain, convulsions, hallucinations, psychosis, allergy symptoms.

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.

Alma Flawless Victory

Active ingredient: Tetrahydrocannabinol, 26% (w/w) (2600 mg/10 g)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Alma Flawless Victory. 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 Alma Flawless Victory.

Where to find information in this leaflet:

- 1. Why am I using Alma Flawless Victory?
- <u>2. What should I know before I use Alma Flawless Victory?</u>
- 3. What if I am taking other medicines?
- 4. How do I use Alma Flawless Victory?
- <u>5. What should I know while using Alma Flawless Victory?</u>
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Alma Flawless Victory?

Alma Flawless Victory contains, dried, trimmed and cured, medicinal cannabis from the cannabis plant.

Alma Flawless Victory is a THC dominant medicinal cannabis flower with high concentrations of THC. Alma Flawless Victory is an Indica dominant subspecies of Cannabis Sativa L.

Active Ingredients

The plant material contains the active ingredient tetrahydrocannabinol (THC). Each gram of dried flower contains 26% (w/w) THC. Each 10g package contains 2600mg THC.

Legal Status

Medicinal Cannabis is a Controlled Drug. Possession without authority is illegal. Poison Schedule: Schedule 8

Alma Flawless Victory is not an approved medicine. It should only be used to treat specific conditions or symptoms authorised by your doctor.

Alma Flawless Victory is an alternative therapeutic option when standard of care treatments have not been beneficial. This medicine is only available with a doctors prescription and approval via the TGA special access scheme or authorised prescriber scheme.

The therapeutic benefit of Alma Flawless Victory may vary between individuals.

Ask your doctor if you have any questions about why Alma Flawless Victory has been prescribed for you.

2. What should I know before I use Alma Flawless Victory?

Warnings

Do not use Alma Flawless Victory if:

- you are allergic to cannabis plant material or, or any of the ingredients listed at the end of this leaflet.
- you are pregnant, planning to become pregnant or breastfeeding. THC may affect fetal development and can pass into your breastmilk. It may affect your baby. Always check the ingredients to make sure you can use this medicine.

Check with your doctor 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 heart beat.
- have a personal history of serious mental disorders, such as schizophrenia or psychosis, unless specifically prescribed by a qualified healthcare provider aware of your psychiatric disorder.
- have serious pre-existing lung problem (pulmonary disease), such as chronic obstructive pulmonary disease (COPD), asthma, emphysema, pneumonia or other lung infections
- have epilepsy or regular fits (seizures)
- have serious liver or kidney disease
- are less than 18 years of age
- have previously abused any drug or substance
- take any medicines for any other condition.

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 <u>6</u>. <u>Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. THC can cross the placenta and may harm your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

THC can pass into your breastmilk if you are breastfeeding. It may affect your baby.

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Alma Flawless Victory. If you see a different doctor or go into hospital, let them know all the medicines you are taking.

Some medicines may interfere with Alma Flawless Victory and affect how it works. Alma Flawless Victory may also affect how other medicines work,

These medicines include warfarin and other blood thinners, strong pain killers and other medicines used for anxiety, depression, epilepsy and sleep aids. This list is not exhaustive. If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Alma Flawless Victory.

Do not take Alma Flawless Victory with alcohol and/or other CNS depressants/sedatives including prescription medications, e.g., benzodiazepines. Using Alma Flawless Victory at the same time as alcohol and/or other sedative drugs may cause more severe levels of impairment and side effects.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Alma Flawless Victory.

4. How do I use Alma Flawless Victory?

How much to take / use

- Alma Flawless Victory can be taken on a regular dosage schedule or as needed (PRN) as determined by your healthcare provider.
- An adjustment period may be required to reach optimal dose
- The amount of Alma Flawless Victory you use each day will depend on your response and tolerability to the product
- Your doctor will provide you with a treatment schedule based on your needs
- Always use Alma Flawless Victory exactly as instructed by your healthcare provider or pharmacist. Check with your healthcare provider or pharmacist if you are not sure.
- During the use of Alma Flawless Victory, you should be under medical supervision to help you determine if the product is working or if you are having any side effects from the treatment.
- Effects from Alma Flawless Victory may begin within approximately 5-10 minutes after you take a dose and may last for about 2-4 hours, depending on the dose

- you took, how long you have been taking this medication and individual response
- Do not use more than the recommended dosage.

When to take / use Alma Flawless Victory

- Alma Flawless Victory should be used as directed by your doctor
- This product can be taken with or without food.

How to administer Alma Flawless Victory

- Alma Flawless Victory should be inhaled using a TGA approved vaporizer.
- Do not administer Alma Flawless Victory via combustion (smoking or smoking paraphernalia) as this may pose a risk to your health, including the potential to contribute to chronic obstructive pulmonary disease (COPD).

If you use too much Alma Flawless Victory

If you think that you have used too much Alma Flawless Victory, 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 Alma Flawless Victory?

Things you should do

- Take Alma Flawless Victory as your doctor has prescribed.
- Remind any doctor or pharmacist you visit that you are using Alma Flawless Victory.
- Tell your doctor if your symptoms do not improve.
- Take special care if you drink alcohol while using Alma Flawless Victory. Using Alma Flawless Victory and alcohol together may increase their effects (such as loss of balance or ability to respond quickly).

Remind any doctor, dentist or pharmacist you visit that you are using Alma Flawless Victory.

Call your doctor straight away if you:

- Are pregnant or become pregnant while taking Alma Flawless Victory.
- Need to have medical tests while you are taking Alma Flawless Victory. It may affect the results of some tests

Things you should not do

 Do not stop using this medicine suddenly without telling your doctor. If you stop taking it suddenly or

- change the dose, your condition may worsen, or you may have unwanted side effects.
- Do not use Alma Flawless Victory to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Alma Flawless Victory affects you.

Alma Flawless Victory may cause you to feel sleepy or dizzy and can also slow your thinking abilities. This can lead to decreased concentration and coordination, slowed reaction time, and impaired motor skills. These effects may be increased while taking other medicines.

Before driving you should check your state's driving laws.

In Australian states and territories, it is against the law to drive with THC in your body, even if you are not impaired. If you are stopped for a random drug test and THC is detected, you could face a fine or loss of your license.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

You should not drink alcohol while using Alma Flawless Victory since alcohol may increase the effects of Alma Flawless Victory that impair your thinking abilities, reaction time, coordination, and motor skills.

Looking after your medicine

- Store below 25°C, away from direct sunlight in a cool and dry place.
- Always keep your medication in its original packaging until it is time to take it
- Refer to the product label for expiry dates

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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.

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.

Less serious side effects

Less serious side effects	What to do
 Less serious side effects Daytime drowsiness Dizziness Fatigue Dry mouth Dry eyes Headache Increased appetite 	Speak to your doctor or your pharmacists if you have any of these less serious side effects and they worry you.
Difficulty concentrating	
 Nausea/vomiting 	
Memory impairment	
Blurred vision	
Constipation or diarrhoea	
• Euphoria	

Serious side effects

Serious side effects	What to do
 Allergy Related: swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in breathing Shortness of breath or difficulty in breathing Skin reaction which may include rash, itching, redness, blistering or peeling of the skin Cardiovascular: Rapid heartbeat Chest pain 	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.
Low blood pressure / feeling faint	
Brain / Nervous System:	
 Convulsions Numbness Burning sensation Loss of coordination / balance Disorientation Confusion Depression Agitation Hallucinations Psychosis Thoughts of suicide 	

General:

- Upper respiratory infection
- Strong abdominal pain

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 Alma Cannabis on 1800 491 791 or via info@cannabisalma.com or 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 Alma Flawless Victory contains

Active ingredient (main ingredient)	tetrahydrocannabinol (THC) Contains 26% w/w THC
Other ingredients (inactive ingredients)	minor cannabinoids, terpenes and flavonoids
Potential allergens	Cannabis Flower

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

What Alma Flawless Victory looks like

Alma Flawless Victory is a whole dried cannabis flower presented in a plastic jar. Each jar contains 10 grams of dried cannabis.

Who distributes Alma Flawless Victory

Company: Alma Cannabis Pty Ltd

Address: Suite 11 Eastside, 232 Robina Town Centre Drive

Robina, Qld 4226, Australia

Phone: 1800 491 791

Email: info@cannabisalma.com
Website: www.cannabisalma.com

Alma Flawless Victory is a **Schedule 8** medicine:

CONTROLLED DRUG Possession without Authority Illegal.

Alma Flawless Victory is not listed on the Australian Register of Therapeutic Goods (ARTG) and can only be accessed via a Special Access Scheme (A or B) or an Authorised Prescriber scheme or through a registered clinical trial.

This leaflet was prepared in August 2023