THC 23 Opal Flower

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using THC 23 Opal Flower?

THC 23 Opal Flower contains the active ingredients tetrahydrocannabinol (THC) and cannabidiol (CBD).

It is used to treat a variety of disorders including: nausea induced by cancer treatment; chronic pain; palliative care; epilepsy; multiple sclerosis, and loss of appetite.

For more information, see Section 1. Why am I using THC 23 Opal Flower? in the full CMI.

2. What should I know before I use THC 23 Opal Flower?

Do not use if you have ever had an allergic reaction to medicinal cannabis or recreational cannabis or any ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, have a history of mental disorders, have a history of alcohol or drug abuse, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use THC 23 Opal Flower? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with THC 23 Opal Flower and affect how it works.

More instructions can be found in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use THC 23 Opal Flower?

Your doctor will work with you to decide the dose that best suits you and your symptoms.

If it is your first time using cannabis ensure you are in a safe location.

Recommended route of administration is vaporisation via a vaporising unit.

More instructions can be found in Section 4. How do I use THC 23 Opal Flower? in the full CMI.

5. What should I know while using THC 23 Opal Flower?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using THC 23 Opal Flower. Call your doctor straight away if you suspect that you are experiencing any side effects, or feel your condition worsens or does not improve over the time suggested by your doctor
Things you should not do	Do not give THC 23 Opal Flower to anyone else, even if they have the same symptoms as you.
Driving or using machines	Do not drive or operate machinery while taking THC 23 Opal Flower.
Drinking alcohol	Your doctor can tell you when to avoid alcohol and about side effects that may occur.
Looking after your medicine	Store THC 23 Opal Flower at less than 25°C.

For more information, see Section 5. What should I know while using THC 23 Opal Flower? in the full CMI.

6. Are there any side effects?

Common side effects may include tiredness, drowsiness and a reduced mental state.

Serious side effects include reduced physical control, a severely impaired mental state or an allergic reaction.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects that you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

THC 23 Opal Flower

Active ingredients: 23% (w/w) tetrahydrocannabinol (THC)

and <0.1% (w/w) cannabidiol (CBD).

Consumer Medicine Information (CMI)

This leaflet provides important information about using THC 23 Opal Flower. You should also speak to your doctor if you would like further information or if you have any concerns or questions about using THC 23 Opal Flower.

Where to find information in this leaflet:

- 1. Why am I using THC 23 Opal Flower?
- 2. What should I know before I use THC 23 Opal Flower?
- 3. What if I am taking other medicines?
- 4. How do I use THC 23 Opal Flower?
- 5. What should I know while using THC 23 Opal Flower?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using THC 23 Opal Flower?

THC 23 Opal Flower is made from medicinal cannabis and contains the active ingredients tetrahydrocannabinol (THC) and cannabidiol (CBD).

Your doctor has been authorised to give you medicinal cannabis products to treat disorders which have not responded to more common treatments. THC 23 Opal Flower may be used to treat: nausea induced by cancer treatment; chronic pain; palliative care; epilepsy; multiple sclerosis, and loss of appetite.

THC 23 Opal Flower is an unapproved medicinal cannabis product and is only available after approval from the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) for your doctor to prescribe for you.

2. What should I know before I use THC 23 Opal Flower?

Warnings

Always check the ingredients to make sure you can use this medicine.

Do not use THC 23 Opal Flower if:

- you have ever had a negative reaction to medicinal cannabis or recreational cannabis or any of the ingredients listed at the end of this leaflet.
- have unstable cardiovascular disease
- have liver or kidney disease

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have a personal or family history of psychotic, mood or anxiety disorders
- have a history of alcohol or drug abuse

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>. 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other cannabis products including recreational cannabis.

Tell your doctor or pharmacist if you are taking any other medicines, including other cannabis products, or vitamins, supplements or any other medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect THC 23 Opal Flower.

4. How do I use THC 23 Opal Flower?

How much THC 23 Opal Flower to take / use

Your doctor will work with you to decide the dose that best suits you and your symptoms. Dosage may need to be changed by your doctor to determine where the benefits are maximised and unwanted effects are minimised. Always follow the instructions from your doctor and do not adjust the dosage amount based on how you feel.

When to take / use THC 23 Opal Flower

Your doctor will work with you to decide how often to take the medicine that best suits you and your symptoms. Always follow the instructions from your doctor and do not adjust when you take THC 23 Opal Flower based on how you feel.

How to measure and dispense THC 23 Opal Flower

Your doctor will work with you to decide how to measure and dispense THC 23 Opal.

Vaporisation is the recommended route of administration.

If it is your first time taking cannabis it is recommended that you are in a safe location.

If you forget to use THC 23 Opal Flower

THC 23 Opal Flower should be used at the times directed by your doctor. Ask your doctor what is an acceptable amount of time to drift from the directions

If you are unsure, or if it is almost time for your next dose, 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 THC 23 Opal Flower

If you think you have used too much THC 23 Opal Flower, 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 THC 23 Opal Flower?

Things you should do

Call your doctor straight away if you:

- Suspect that you are experiencing any side effects
- Feel your condition worsens or does not improve over the time suggested by your doctor
- Change any of your other medications or are about to start using any new medication

Remind any doctor, dentist or pharmacist you visit that you are using THC 23 Opal Flower.

Things you should not do

• Do not give THC 23 Opal Flower to anyone else, even if they have the same symptoms as you.

Driving or using machines

THC 23 Opal Flower may make you feel drowsy, sleepy or dizzy.

Do not drive or operate machinery while taking THC 23 Opal Flower.

Check with your doctor when it is safe to drive after stopping taking THC 23 Opal Flower.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor can tell you when alcohol should be avoided and the side effects that may occur.

Looking after your medicine

- Store THC 23 Opal Flower at less than 25°C.
- Store away from moisture, heat and sunlight
- Do not store in the bathroom or near a sink
- Do not store in the car or on window sills.

Keep it where young children cannot reach.

When to discard your medicine

Return any unused or expired Flower to a pharmacy for disposal. Do not use this product past its expiry date.

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
Broad or affecting different parts of the body: • feeling tired or drowsy	Speak to your doctor if you have any of
 dry mouth, throat irritation reduced concentration, memory and attention, and ability to think and make decisions altered bodily perceptions 	these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Broad or affecting different parts of the body: • feeling dizzy or lightheaded • disorientation, confusion, feelings of unreality • headache • paranoia, feeling nervous or anxious, panic-attack • hallucinations, seeing or hearing things that do not exist • loss of control of bodily movements, falling over • irregular or fast heartbeat Allergic reaction or breathing related: • itching, hypersensitivity like a rash or hives • nausea or vomiting • chest tightness, wheezing coughing or difficulty breathing	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.

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 THC 23 Opal Flower contains

Active ingredients (main ingredient)	23% w/w tetrahydrocannabinol (THC) and <0.1% w/w cannabidiol (CBD)
Other ingredients	Nil
Potential allergens	Nil

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

THC 23 Opal Flower does not contain added gluten, sugars, lactose, colourants, artificial preservatives or flavourings.

What THC 23 Opal Flower looks like

The medicine is dried whole cannabis flowers.

Who distributes THC 23 Opal Flower

Tasmanian Botanics Pty Ltd

PO Box 4

Brighton TAS 7030

Australia

Telephone +61 3 6109 0644

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