

Balanced 10:10 Oral Liquid

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Balanced 10:10 Oral Liquid?

Balanced 10:10 Oral Liquid 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 Balanced 10:10 Oral Liquid?](#) in the full CMI.

2. What should I know before I use Balanced 10:10 Oral Liquid?

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 Balanced 10:10 Oral Liquid?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Balanced 10:10 Oral Liquid 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 Balanced 10:10 Oral Liquid?

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

Measure and dispense this medicine using the oral syringe provided.

More instructions can be found in Section [4. How do I use Balanced 10:10 Oral Liquid?](#) in the full CMI.

5. What should I know while using Balanced 10:10 Oral Liquid?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Balanced 10:10 Oral Liquid.• 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 | <ul style="list-style-type: none">• Do not give Balanced 10:10 Oral Liquid to anyone else, even if they have the same symptoms as you.• Do not “vape” Balanced 10:10 Oral Liquid or attempt to inhale the product in any way. |
| Driving or using machines | <ul style="list-style-type: none">• Do not drive or operate machinery while taking Balanced 10:10 Oral Liquid. |
| Drinking alcohol | <ul style="list-style-type: none">• Your doctor can tell you when to avoid alcohol and about side effects that may occur. |
| Looking after your medicine | <ul style="list-style-type: none">• Store Balanced 10:10 Oral Liquid at less than 25°C. It is acceptable to refrigerate but do not freeze. |

For more information, see Section [5. What should I know while using Balanced 10:10 Oral Liquid?](#) 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 [6. Are there any side effects?](#) 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.

Balanced 10:10 Oral Liquid

Active ingredients: *Each 1 mL contains 10mg tetrahydrocannabinol (THC) and 10mg cannabidiol (CBD).*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Balanced 10:10 Oral Liquid. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about using Balanced 10:10 Oral Liquid.**

Where to find information in this leaflet:

- [1. Why am I using Balanced 10:10 Oral Liquid?](#)
- [2. What should I know before I use Balanced 10:10 Oral Liquid?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Balanced 10:10 Oral Liquid?](#)
- [5. What should I know while using Balanced 10:10 Oral Liquid?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Balanced 10:10 Oral Liquid?

Balanced 10:10 Oral Liquid 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. Balanced 10:10 Oral Liquid may be used to treat: nausea induced by cancer treatment; chronic pain; palliative care; epilepsy; multiple sclerosis, and loss of appetite.

Balanced 10:10 Oral Liquid 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 Balanced 10:10 Oral Liquid?

Warnings

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

Do not use Balanced 10:10 Oral Liquid 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 [6. 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 Balanced 10:10 Oral Liquid.

4. How do I use Balanced 10:10 Oral Liquid?

How much Balanced 10:10 Oral Liquid 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

Balanced 10:10 Oral Liquid

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 Balanced 10:10 Oral Liquid based on how you feel.

How to measure and dispense Balanced 10:10 Oral Liquid

- Remove the child resistant cap by pushing it down firmly and turning it anti-clockwise. A plastic bottle adaptor comes pre-installed in bottle neck.
- The **oral syringe** has two components: the **barrel**, which is clear; and the **plunger** which has line markings. Ensure the oral syringe is clean & dry and push the plunger all the way in to the barrel.
- Keep the bottle upright and insert syringe firmly into the bottle adaptor. Carefully turn the bottle upside down while holding the syringe in place.
- To measure the required dose, pull the plunger down slowly until the top edge of the barrel is level with the correct marking on the plunger. If any bubbles are seen in the syringe, push the plunger back up into the barrel until the air bubbles are expelled and pull the plunger down again to the correct marking.
- Turn the bottle upright and remove the syringe by gently twisting it out of the bottle adaptor.
- Dispense the medicine by emptying the contents of the syringe into your mouth, and then swallow the medicine. Always empty the syringe **slowly into your lower mouth or side of your mouth**. If you squirt fast or dispense back to your throat, you may choke.
- Immediately screw the child resistant cap onto the bottle. The bottle adaptor should not be removed.
- After use, separate the syringe barrel & plunger and clean both with a small amount of soapy water, and then rinse with water. Leave the oral syringe separated to dry until it is required for the next dose.

If you forget to use Balanced 10:10 Oral Liquid

Balanced 10:10 Oral Liquid 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 Balanced 10:10 Oral Liquid

If you think you have used too much Balanced 10:10 Oral Liquid, 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 Balanced 10:10 Oral Liquid?

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 Balanced 10:10 Oral Liquid.

Things you should not do

- Do not give Balanced 10:10 Oral Liquid to anyone else, even if they have the same symptoms as you.
- Do not “vape” Balanced 10:10 Oral Liquid or attempt to inhale the product in any way.

Driving or using machines

Balanced 10:10 Oral Liquid may make you feel drowsy, sleepy or dizzy.

Do not drive or operate machinery while taking Balanced 10:10 Oral Liquid.

Check with your doctor when it is safe to drive after stopping taking Balanced 10:10 Oral Liquid.

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 Balanced 10:10 Oral Liquid at less than 25°C. It is acceptable to refrigerate but do not freeze.
- 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 Oral Liquid to a pharmacy for disposal. The expiry is 60 days from the date of first use, or the expiry date shown on the bottle label, whichever is the earliest 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: <ul style="list-style-type: none">feeling tired or drowsydry mouth, throat irritationreduced concentration, memory and attention, and ability to think and make decisionsaltered bodily perceptions | Speak to your doctor if you have any of 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: <ul style="list-style-type: none">feeling dizzy or lightheadeddisorientation, confusion, feelings of unrealityheadacheparanoia, feeling nervous or anxious, panic-attackhallucinations, seeing or hearing things that do not existloss of control of bodily movements, falling overirregular or fast heartbeat Allergic reaction or breathing related: <ul style="list-style-type: none">itching, hypersensitivity like a rash or hivesnausea or vomitingchest tightness, wheezingcoughing 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 Balanced 10:10 Oral Liquid contains

| | |
|---|---|
| Active ingredients (main ingredient) | Each 1 mL contains 10mg tetrahydrocannabinol (THC) and 10mg cannabidiol (CBD) |
| Inactive ingredients (other ingredients) | Medium chain triglycerides |
| Potential allergens | Nil |

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

Balanced 10:10 Oral Liquid does not contain added gluten, sugars, lactose, colourants, artificial preservatives or flavourings.

What Balanced 10:10 Oral Liquid looks like

The medicine is a clear, golden brown coloured liquid supplied in an amber glass bottle with a white tamper-evident child-resistant cap. An oral syringe is supplied for dosing of the medicine.

Who distributes Balanced 10:10 Oral Liquid

Tasmanian Botanics Pty Ltd

PO Box 4

Brighton TAS 7030

Australia

Telephone +61 3 6109 0644

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