

## AUSTRALIAN NATURAL ELAN

### 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 AUSTRALIAN NATURAL ELAN?

Australian Natural Elan oral solution contains cannabidiol (CBD) at 100mg/mL. Australian Natural Elan is not approved for any specific indication and should only be used to treat conditions or symptoms advised by your doctor.

Your doctor might recommend its use to reduce chronic non-cancer pain, cancer-related pain, inflammation, tremors, nausea, spasticity from neurological conditions and muscle spasms, improve sleep, and manage seizures and anxiety. Your doctor might prescribe Australian Natural Elan for another purpose.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Australian Natural Elan against the benefits they expect it will have for you.

For more information, see [Section 1. Why am I using Australian Natural Elan?](#) in the full CMI.

#### 2. WHAT SHOULD I KNOW BEFORE I USE AUSTRALIAN NATURAL ELAN?

Do not use Australian Natural Elan if you have had an allergic reaction to cannabis or any of the ingredients listed at the end of this CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines or supplements, are pregnant or plan to become pregnant, or are breastfeeding.

For more information, see [Section 2. What should I know before I use Australian Natural Elan?](#) in the full CMI.

#### 3. WHAT IF I AM TAKING OTHER MEDICINES?

Some medicines may interfere with Australian Natural Elan and affect how it works. Australian Natural Elan may also affect how other medicines work.

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 AUSTRALIAN NATURAL ELAN?

- Use the amount of Australian Natural Elan directed by your doctor. Follow your doctor's instructions and use Australian Natural Elan until your doctor tells you to stop.

More instructions can be found in [Section 4. How do I use Australian Natural Elan?](#) in the full CMI.

## AUSTRALIAN NATURAL ELAN

(/eɪlən/) **Active ingredient: Cannabidiol (CBD)**

### Consumer Medicine Information (CMI)

This leaflet provides important information about using Australian Natural Elan. **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 Australian Natural Elan.**

#### WHERE TO FIND INFORMATION IN THIS LEAFLET:

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

#### 1. WHY AM I USING AUSTRALIAN NATURAL ELAN?

Australian Natural Elan oral solution contains the active ingredient Cannabidiol (CBD) at a strength of 100mg/mL. This product is formulated with medium chain triglyceride carrier oil as an excipient.

Australian Natural Elan is not approved for any specific indication and should only be used to treat conditions or symptoms advised by your doctor.

Your doctor might recommend its use to reduce chronic non-cancer pain, cancer-related pain, inflammation, tremors, nausea, spasticity from neurological conditions and muscle spasms, improve sleep, and manage seizures and anxiety. Your doctor might prescribe Australian Natural Elan for another purpose.

This medicine is only available with a doctor's prescription. This medicine is only available through the Special Access Scheme (SAS), through the Authorised Prescriber Scheme (APS), or through a registered clinical trial.

Possession without authority is illegal.

#### 2. WHAT SHOULD I KNOW BEFORE I USE AUSTRALIAN NATURAL ELAN?

##### WARNINGS

##### DO NOT USE AUSTRALIAN NATURAL ELAN IF:

- you are allergic to any cannabis product or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have serious liver or kidney problems.

##### CHECK WITH YOUR DOCTOR IF YOU:

- have or have had any other medical conditions, especially the following:
  - kidney problems
  - liver problems

#### 5. WHAT SHOULD I KNOW WHILE USING AUSTRALIAN NATURAL ELAN?

##### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Australian Natural Elan.
- You should use Australian Natural Elan under medical supervision.
- Talk to your healthcare provider if you do not feel better, or if you feel worse.

##### Things you should not do

- Do not change your dosage without first checking with your doctor.

##### Driving or using machines

- Do not drive or operate heavy or dangerous machines while being treated on this product.

##### Drinking alcohol

- Alcohol may increase the effects of Australian Natural Elan and you should avoid taking it while taking this medicine. Alcohol taken in combination with Australian Natural Elan may impair your cognitive abilities, coordination, reaction time and motor skills.

##### Looking after your medicine

- Store below 25°C & protect from light.

For more information, see [Section 5. What should I know while using Australian Natural Elan?](#) in the full CMI.

#### 6. ARE THERE ANY SIDE EFFECTS?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details).

Common, but usually mild side effects known from cannabidiol (CBD) include fatigue and sedation, dizziness and light-headedness, malaise, drowsiness, nausea or vomiting, dry mouth, changes in appetite, increased heart rate or irregular heartbeat, and constipation or diarrhoea.

Serious side effects may include high liver enzymes (in blood tests) and 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.

- serious mental disorders, such as schizophrenia or another psychotic disorder
- panic attacks
- lung problems
- heart problems
- epilepsy or recurrent seizures
- you are 65 years or older
- you are under 18 years old

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 before using Australian Natural Elan.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Cannabinoids can pass into breastmilk and may affect foetal development.

Do not take this product whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

#### USE IN CHILDREN

Australian Natural Elan must not be given to children under the age of 2 years, since there is no information on use in children below this age.

#### MEDICAL SUPERVISION OF TREATMENT WITH AUSTRALIAN NATURAL ELAN

Australian Natural Elan treatment should be initiated and supervised by a qualified healthcare provider experienced in the treatment of the symptom or disorder for which it is prescribed.

#### 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.

Cannabidiol is metabolised by Cytochrome P450 enzymes, primarily the CYP2 and CYP3 families. Australian Natural Elan may affect medicines that are metabolised through these enzyme pathways. Some medicines may interfere with Australian Natural Elan and affect how it works. Australian Natural Elan may also affect how other medicines work. **Tell your doctor if you are using medicines for\*:**

##### Tell your doctor if you are using medicines for:

- Cold or allergy (medicines that make you drowsy, such as antihistamines)
- Anxiety or depression (e.g. Fluvoxamine, fluoxetine, St. John's Wort (Hypericum perforatum))
- Pain (medicines known as opioids, such as oxycodone, hydrocodone, codeine, and morphine)
- Muscle-related conditions, such as muscle spasms, overactive bladder and movement disorders (e.g. Parkinson's disease)
- Asthma (e.g. theophylline)
- Sleeping problems (sleeping pills or sedatives/hypnotics, e.g. benzodiazepine, zopiclone, zolpidem)
- Epilepsy, seizures, or nerve pain (e.g. carbamazepine, clobazam, lorazepam, phenytoin, stiripentol and valproate)

- Bacterial or fungal infections (e.g. rifampicin, clarithromycin, ketoconazole, erythromycin, itraconazole, amphotericin B)
- Suppression of the immune system (e.g. cyclosporine)
- Thinning of your blood (e.g. warfarin)
- HIV/AIDS (e.g. efavirenz)
- Heartburn / Acid reflux (e.g. omeprazole)
- Tumours in the adrenal gland (e.g. mitotane)
- Reducing cholesterol/lipids (e.g. simvastatin)
- Undergoing surgery (e.g. propofol)

\* The above list is not exhaustive.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Australian Natural Elan.**

**4. HOW DO I USE AUSTRALIAN NATURAL ELAN?**

**HOW MUCH TO USE**

- Use the amount of Australian Natural Elan directed by your doctor.
- Australian Natural Elan is an oral solution (a liquid to be swallowed only).
- The amount of Australian Natural Elan your doctor tells you to use each day will depend on your condition, whether you are taking any other medicines, as well as how you respond to and tolerate the product.
- Your doctor may recommend that you start with a low dose of Australian Natural Elan and then slowly increase the dose to the lowest amount needed to improve your symptoms.
- Follow the instructions provided and use Australian Natural Elan until your doctor tells you to stop.

**WHEN TO TAKE AUSTRALIAN NATURAL ELAN**

- Australian Natural Elan can be taken with or without food.
- Taking Australian Natural Elan under similar conditions each day may help achieve a more consistent effect.

**HOW TO TAKE AUSTRALIAN NATURAL ELAN**

- This product should be administered as directed by your doctor.
- Effects from Australian Natural Elan may begin within approximately 60-180 minutes after you take a dose and may last for about 6-8 hours, depending on the dose taken, how long you have been taking this medicine, the amount and type of food you had when taking this medicine, and your individual response.

**IF YOU FORGET TO USE AUSTRALIAN NATURAL ELAN**

Australian Natural Elan should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, then go back to taking this product as you would normally.

**If you have missed a dose by more than 4 hours, 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 AUSTRALIAN NATURAL ELAN**

If you think that you have used too much Australian Natural Elan, 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 AUSTRALIAN NATURAL ELAN?**

**THINGS YOU SHOULD DO**

- You should use Australian Natural Elan under medical supervision to help determine if the product is working or if you are having any side effects from the treatment.
- Talk to your healthcare provider if you do not feel better, or if you feel worse.

Remind any doctor, dentist or pharmacist you visit that you are using Australian Natural Elan.

**THINGS YOU SHOULD NOT DO**

- Do not change your dosage without first checking with your doctor.

**TRAVELLING WITH AUSTRALIAN NATURAL ELAN**

- Before travelling to another state within Australia or to an international country (this includes your final destination and any in transit countries), consult with your doctor, country consulates, The Department of Foreign Affairs and Trade, insurance company and/or pharmacist to confirm if it is legal for you to travel with this product.

**DRIVING OR USING MACHINES**

- Talk to your doctor about driving, using machines or when children undertake activities such as cycling or other sports, because you may feel sleepy after taking this medicine.
- You should not drive, use machines or take part in activities that require you to be alert and have fine control, until you are certain that your ability to perform such activities is not affected. As Australian Natural Elan is a cannabis-based medicine, you should also consider any local state laws concerning driving.

**DRINKING ALCOHOL**

**Tell your doctor if you drink alcohol.**

- Alcohol may increase the effects of Australian Natural Elan and you should avoid taking it while taking this medicine. Alcohol taken in combination with Australian Natural Elan may impair your cognitive abilities, coordination, reaction time and motor skills.

**LOOKING AFTER YOUR MEDICINE**

- Follow the instructions in the carton on how to take care of your medicine properly.
- Store below 25°C.
- Store it in a cool dry place away from moisture, heat or light; 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.

**SIDE EFFECTS**

Side effects	What to do
<b>Very common:</b> <ul style="list-style-type: none"><li>• Feeling drowsy or sleepy</li><li>• Decrease in appetite</li><li>• Diarrhoea</li><li>• Fever</li><li>• Feeling tired</li><li>• Vomiting</li></ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.
<b>Common:</b> <ul style="list-style-type: none"><li>• Lack of energy</li><li>• Cold, sore throat</li><li>• Respiratory tract infections (pneumonia, bronchitis)</li><li>• Blood tests showing increases in levels of certain liver enzymes (which may be signs of liver damage)</li><li>• Shaking of the body or parts of it</li><li>• Feeling bad-tempered (irritable, aggressive)</li><li>• Difficulty in sleeping</li><li>• Cough</li><li>• Rash</li><li>• Increased appetite, weight loss</li><li>• Drooling</li><li>• Urinary tract infection</li><li>• Agitation</li><li>• Abnormal behaviour</li></ul>	

**SERIOUS SIDE EFFECTS**

Serious side effects	What to do
<b>Changes to mental status or personality:</b> <ul style="list-style-type: none"><li>• Depression or thoughts of suicide</li></ul>	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.
<b>Heart-related:</b> <ul style="list-style-type: none"><li>• Rapid or irregular heartbeat</li><li>• Signs of low blood pressure, such as light-headedness, dizziness or fainting</li></ul>	
<b>Nervous system-related:</b> <ul style="list-style-type: none"><li>• Seizures or convulsions (if you do not have epilepsy)</li></ul>	
<b>Liver-related:</b> <ul style="list-style-type: none"><li>• High liver enzymes (transaminases elevation) seen in blood tests, which can be a sign of liver injury</li></ul>	

<b>Allergic reaction-related:</b> <ul style="list-style-type: none"><li>• Shortness of breath</li><li>• Wheezing or difficulty breathing</li><li>• Swelling of the face, lips, tongue or other parts of the body</li><li>• Rash, hives or swelling on the skin.</li></ul>
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**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](http://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 AUSTRALIAN NATURAL ELAN CONTAINS**

<b>Active ingredient (main ingredient)</b>	The active substance is cannabidiol. Each mL of oral solution contains 100 mg of cannabidiol (CBD).
	Each bottle contains 100 mL of oil solution which has a total of 10000 mg of cannabidiol.
<b>Other ingredients (inactive ingredients)</b>	MCT oil

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

**WHAT AUSTRALIAN NATURAL ELAN LOOKS LIKE**

Australian Natural Elan is a clear colourless/clear yellowish to clear pink solution in a 100mL amber bottle which has a child-resistant cap & tamper proof seal. Together with a 1.5 mL syringe and a bottle adaptor for using these syringes. The syringe is graduated to 0.25 mL increments.

**WHO DISTRIBUTES AUSTRALIAN NATURAL ELAN**

Australian Natural Therapeutics Group Pty Ltd 1/14 Jonson St Byron Bay NSW 2481 Australia	Email: <a href="mailto:info@antg.com.au">info@antg.com.au</a> Ph: 1800 287 628  This leaflet was prepared in September 2023.
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