## **Dyspro Pastilles**

## **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 <u>full CMI</u> for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

Tustines (our den)	Dyspro CBD:CBG:CBN	Pastilles (60 Pack)	Controlled Drug schedule 8, category 3
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## 1. Why am I using Dyspro Pastilles?

Dyspro Pastilles are vegan and contain the active ingredients CBD 35mg cannabidiol; CBG 25mg Cannabigerol; CBN 15mg cannabinol; and PEA 100mg palmitoylethanolamide natural soyabean fatty acid.

Dyspro Pastilles is used for management of:

- Relief of chronic pain
- Management of anxiety and depression
- Alleviation of nausea, particularly in patients undergoing chemotherapy
- Assistance with sleep disorders

For more information, see Section 1. Why am I using Dyspro Pastilles? in the full CMI.

#### 2. What should I know before I use Dyspro Pastilles?

Do not use if you have ever had an allergic reaction to Dyspro Pastilles 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 Dyspro Pastilles? in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with Dyspro Pastilles 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 medicated EVE Pastilles?

- Dosage: Start with 1 pastille. Allow it to dissolve slowly in your mouth for maximum absorption.
- Timing: Use as needed, every 4-6h but do not exceed more than 4 pastilles within a 24-hour period unless otherwise directed by your healthcare provider.

More instructions can be found in Section 4. How do I use Dyspro Pastilles? in the full CMI.



## 5. What should I know while using medicated EVE Pastilles?

Things you should do	<ul> <li>Remind any doctor, nurse practitioner, dentist or pharmacist or other health professional you visit, that you are using Dyspro Pastilles.</li> <li>Check the effectiveness of your medicine and discuss with your healthcare team.</li> </ul>	
Things you should not do		
Driving or using machines	<ul> <li>Do not drive or operate heavy machinery while affected and until 12 hours after your last dose.</li> <li>May cause drowsiness, dizziness, or impaired coordination.</li> </ul>	
Drinking alcohol	<ul> <li>Avoid drinking alcohol while using the medicine.</li> <li>May cause drowsiness, dizziness, or impaired coordination.</li> </ul>	
Looking after your medicine	<ul> <li>Keep out of reach and sight of children.</li> <li>Store in original child resistant container.</li> <li>Store in a cool, dry place below 25°C.</li> <li>Store away from direct sunlight.</li> </ul>	

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI.

## 6. Are there any side effects?

Some individuals may experience rare side effects while using Dyspro Pastilles, which can include:

- Dry mouth
- Increased heart rate
- Tiredness
- Changes in appetite
- Paranoia or anxiety (especially with higher doses)

If you experience severe side effects or an allergic reaction, discontinue use and seek medical attention immediately. 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 you may get. You can report side effects to your doctor, or <a href="mailto:info@evehealthgroup.com.au">info@evehealthgroup.com.au</a> or directly at <a href="www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. [Include if applicable]

## **Dyspro Pastilles**

#### Each pastille contains active ingredient(s):

CBD 35mg cannabidiol CBG 25mg cannabigerol CBN 15mg cannabinol

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Dyspro Pastilles. 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 Dyspro Pastilles.

#### Where to find information in this leaflet:

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

### Why am I using Dyspro Pastilles?

Dyspro Pastilles contain medicinal cannabis extract active ingredients

CBD 35mg cannabidiol

CBG 25mg Cannabigerol

CBN 15mg cannabinol

#### Dyspro Pastilles is used to manage

- Relief of period and pelvic discomfort
- Neuromuscular inflammation
- Musculoskeletal discomfort
- Mild generalised anxiety
- Supporting sleep

#### What should I know before I use DYSPRO PASTILLES?

#### Warnings

#### Do not use Dyspro Pastilles if:

- you are allergic to cannabinoids, terpenes, MCT oil, pectin 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 heart disease and recent heart attack.
- You have a history of schizophrenia. Check with doctor.
- You have a history of bipolar disorder. Check with doctor.

#### Check with your doctor if you:

 have any other medical conditions including heart disease and recent heart attack, schizophrenia or bipolar disorder. • 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>. 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.

### 2. 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.

## Some medicines may interfere with Dyspro Pastilles and affect how it works.

[Include an explanation of the nature of the interaction where possible] e.g.

## Medicines that may <u>increase</u> the effect of Dyspro Pastilles include:

- 1. **Benzodiazepines** (e.g., Diazepam, Lorazepam, Alprazolam)
- Opioids (e.g., Morphine, Oxycodone, Hydrocodone)
- 3. **Antidepressants** (Certain SSRIs, SNRIs, and Tricyclics)
  - o Fluoxetine
  - Sertraline
  - Amitriptyline
- 4. Anticonvulsants (e.g., Gabapentin, Pregabalin)
- Antihistamines (e.g., Diphenhydramine, Hydroxyzine)
- 6. **Muscle Relaxants** (e.g., Cyclobenzaprine, Carisoprodol)
- Alcohol (both cannabis and alcohol are CNS depressants)
- 8. **Barbiturates** (e.g., Phenobarbital)
- 9. **Some HIV medications** (e.g., Ritonavir, which can boost other medications)

## Medicines that may <u>reduce</u> the effect of Dyspro Pastilles include:

- Certain Antiepileptics (e.g., Phenytoin, Carbamazepine)
- 2. **St. John's Wort** (a herbal supplement that can induce liver enzymes)
- 3. **Rifampin** (an antibiotic that induces liver enzymes)
- 4. **Naltrexone** (an opioid antagonist that may counteract effects)

- 5. **Corticosteroids** (the effects may be variable)
- 6. **Some antipsychotics** (e.g., Aripiprazole, which may have mixed effects)
- 7. **Certain Statins** (e.g., Atorvastatin, as the metabolism may be altered)

#### **Additional Considerations**

- Medications Metabolized by CYP450
   Enzymes: Cannabinoids can influence the activity of enzymes in the cytochrome P450 system.
   Drugs metabolized by these enzymes may have altered effects when taken with cannabis.
  - CYP3A4 Substrates: Certain statins, calcium channel blockers, and benzodiazepines.
  - CYP2C9 Substrates: Warfarin (may require close monitoring).

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

#### 3. How do I use Dyspro Pastilles?

### How much to take / use

- Dosage: Start with QUARTER or HALF or ONE pastille.
   Allow it to dissolve slowly in your mouth for maximum absorption.
- Timing: Take a dose as needed, every 4-6 hours but do not exceed more than 4 pastilles in 24 hours unless otherwise directed by your healthcare provider.
- Follow the instructions and use Dyspro Pastilles until your healthcare provider tells you to stop.
- Always read the pharmacy label.

#### When to take Dyspro Pastilles

 Dyspro Pastilles should be used as required every 4-6 hours. Do not take more than 4 pastilles in 24 hours.

#### If you forget to use Dyspro Pastilles

Dyspro Pastilles should be used regularly at the same time each day or week or month. If you miss your dose at the usual time, take your next dose at the usual time.

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 Dyspro Pastilles

If you think that you have used too much Dyspro Pastilles, and you need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your prescriber, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 4. What should I know while using EVE Pastilles?

#### Things you should do

- **Dosage:** Start with 1 pastille. Allow it to dissolve slowly in your mouth for maximum absorption.
- Timing: Use as needed, but do not exceed more than 4 pastilles within a 24-hour period unless otherwise directed by your healthcare provider.
- **Storage:** Store in a cool, dry place away from direct sunlight. Keep out of reach of children.

#### Call your prescriber straight away if you:

- Contact your healthcare provider if you experience any unusual symptoms or if your condition does not improve.
- If you have any adverse reactions, please report them to your healthcare provider or local health authority.

Remind any doctor, dentist or pharmacist you visit that you are using Dyspro Pastilles.

#### Things you should not do

- Do not share your medicine with other people.
- Avoid drinking alcohol while affected by Dyspro Pastilles.
- Avoid driving and operating machinery while affected by Dyspro Pastilles and for 12 hours after last dose.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Dyspro Pastilles affects you.

- Dyspro Pastilles may cause dizziness in some people.
- Avoid driving and operating machinery while affected by Dyspro Pastilles and for 12 hours after last dose.

#### **Drinking alcohol**

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

Alcohol may increase the effects of Dyspro Pastilles by badly affecting your physical coordination.

#### Looking after your medicine

- Keep out of reach and sight of children.
- Store in the original child resistant container.
- Store in a cool, dry place away from direct sunlight.
- Store below 25°C.

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

Keep it where young children cannot reach it.

#### When to discard your medicine (as relevant)

- See the expiry date on the product container.
- · When medicines no longer required.
- Take unwanted medicines to your local pharmacy for safe disposal.

#### 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.

### 5. 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	
<ul><li>Dry mouth</li><li>Fatigue</li><li>Changes in appetite</li></ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.	

#### Serious side effects

Serious rare side effects	What to do
<ul> <li>Severe increased heart rate</li> <li>Paranoia or anxiety (especially with higher doses)</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.

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 that you may experience, you can report unwanted side effects to <a href="mailto:info@evehealthgroup.com.au">info@evehealthgroup.com.au</a> and the Therapeutic Goods Administration (TGA) online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>.

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.

#### 6. Product details

This medicine is only available with a doctor's prescription.

#### What Dyspro Pastilles contains

Active ingredients	CBD 35mg cannabidiol	
(main ingredient)	CBG 25mg cannabigerol	
(main ingredient)	CBN 15mg cannabinol	
Other ingredients Water		
(inactive ingredients)	Sugar (sucrose)	
	Pectin (vegan)	
	Colouring agent	
	Flavouring agent	
	Citric acid	
Potential allergens	Nil known	

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

#### What Dyspro Pastilles looks like

Dyspro Pastilles are cube shaped soft chewy gummy pastilles. Flavour is printed on the side of the container.

#### Who distributes Dyspro Pastilles

Quest Biotech Pharma Pty Ltd, Perth WA 6000 info@evehealthgroup.com.au

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#### Product order codes:

Product Description	Form	Legal Schedule	Product Code
	(pack)		
Dyspro Pastilles	Pastilles	Controlled Drug	EVE-PSL-DYS1-60
CBD 35mg	(60)	Schedule 8, Category 3	
CBG 25mg			
CBN 15mg			