

# Gold Cross Codeine Linctus

## 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.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using Gold Cross Codeine Linctus?

Gold Cross Codeine Linctus contains the active ingredient codeine phosphate hemihydrate. Gold Cross Codeine Linctus is used to relieve unproductive, dry coughs associated with colds and flu.

For more information, see Section [1. Why am I using Gold Cross Codeine Linctus?](#) in the full CMI.

### 2. What should I know before I use Gold Cross Codeine Linctus?

Do not use if you have ever had an allergic reaction to Gold Cross Codeine Linctus 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 Gold Cross Codeine Linctus?](#) in the full CMI.

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

Some medicines may interfere with Gold Cross Codeine Linctus 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 Gold Cross Codeine Linctus?

- Adults: take 5 mL every 4 hours.

More instructions can be found in Section [4. How do I use Gold Cross Codeine Linctus?](#) in the full CMI.

### 5. What should I know while using Gold Cross Codeine Linctus?

|                             |                                                                                                                                                                                                                                                                                                       |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Things you should do        | <ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Gold Cross Codeine Linctus.</li><li>Tell your doctor if you become pregnant while taking Gold Cross Codeine Linctus.</li></ul>                                                            |
| Things you should not do    | <ul style="list-style-type: none"><li>Do not take more than the recommended dose unless your doctor tells you to.</li><li>Do not use Gold Cross Codeine Linctus if you are breastfeeding.</li><li>Do not use Gold Cross Codeine Linctus if you have asthma or other breathing difficulties.</li></ul> |
| Driving or using machines   | <ul style="list-style-type: none"><li>Do not drive or operate machinery until you know how Gold Cross Codeine Linctus affects you.</li></ul>                                                                                                                                                          |
| Drinking alcohol            | <ul style="list-style-type: none"><li>Do not drink alcohol while using Gold Cross Codeine Linctus.</li></ul>                                                                                                                                                                                          |
| Looking after your medicine | <ul style="list-style-type: none"><li>Store below 30 °C in a cool, dry place where children cannot reach it.</li></ul>                                                                                                                                                                                |

For more information, see Section [5. What should I know while using Gold Cross Codeine Linctus?](#) in the full CMI.

### 6. Are there any side effects?

Some people may experience headaches, constipation, nausea or vomiting while taking Gold Cross Codeine Linctus. Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you experience confusion, blurred vision, rapid heartbeat, breathlessness or swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin while taking Gold Cross Codeine Linctus.

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.

## WARNINGS

### Limitations of use

Gold Cross Codeine Linctus should only be used when your doctor decides that other treatment options are not able to effectively manage your cough or you cannot tolerate them.

### Hazardous and harmful use

Gold Cross Codeine Linctus poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

### Life threatening respiratory depression

Gold Cross Codeine Linctus can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Gold Cross Codeine Linctus and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

### Use of other medicines while using Gold Cross Codeine Linctus

Using Gold Cross Codeine Linctus with other medicines that can make you feel drowsy such as sleeping tablets (e.g., benzodiazepines), pain relievers, antihistamines, antidepressants, antipsychotics, gabapentanoids (e.g., gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Gold Cross Codeine Linctus.

# Gold Cross Codeine Linctus

Active ingredient: Codeine phosphate hemihydrate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Gold Cross Codeine Linctus. **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 Gold Cross Codeine Linctus.**

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

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

## 1. Why am I using Gold Cross Codeine Linctus?

Gold Cross Codeine Linctus contains the active ingredient **codeine phosphate hemihydrate**. Gold Cross Codeine Linctus is a cough suppressant.

**Gold Cross Codeine Linctus is used** for the relief of unproductive, dry coughs associated with colds and flu.

## 2. What should I know before I use Gold Cross Codeine Linctus?

### Warnings

- Do not give Gold Cross Codeine Linctus to children under the age of 12 years.
- Do not give Gold Cross Codeine Linctus to children 12 to 18 years who have recently had surgery on their adenoids or tonsils to treat sleep apnoea.

### Do not use Gold Cross Codeine Linctus if:

- You are allergic to codeine, morphine, oxycodone 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 breathing difficulties such as asthma, bronchitis or emphysema.
- You are suffering from diarrhoea caused by poisoning or antibiotics.
- You are known to be an ultra-rapid metaboliser of codeine.
- You are taking a monoamine oxidase inhibitor antidepressant or within 10 days of stopping such treatment
- You have a serious head injury
- You have been drinking alcohol
- You are breastfeeding

- If the packaging shows signs of tampering.

**Check with your doctor if you have or have had any of the following medical conditions:**

- Breathing disorders including sleep-related, asthma or lung disease
- Lung, heart, liver or kidney problems, including difficulty urinating
- A history of drug dependence, including alcohol dependence
- Addison's disease (Low adrenal gland function)
- An underactive thyroid gland
- Are a heavy drinker
- A recent head injury or brain tumour
- Pancreatitis or gall bladder disease
- Have had recent biliary tract (gall bladder) surgery
- Are about to have surgery under a general anaesthetic
- Know you are a CYP2D6 ultra-rapid metaboliser of codeine
- Take any medicines for any other condition
- Are pregnant or intending to become pregnant.

**Pregnancy and breastfeeding**

**Do not take Gold Cross Codeine Linctus during the third trimester of pregnancy or during labour, especially if the baby is premature.**

This medicine can cause breathing problems and signs of withdrawal in the baby.

Opioid analgesics cross the placenta. Regular use during pregnancy may cause physical dependence in the foetus, leading to withdrawal symptoms in the newborn.

**Do not take Gold Cross Codeine Linctus if you are breastfeeding or planning to breastfeed.**

This medicine passes into breast milk and may affect the baby. If you require Gold Cross Codeine Linctus, breastfeeding should be stopped, and alternative arrangements should be made for feeding the baby during the treatment period.

**Addiction**

You can become addicted to Gold Cross Codeine Linctus even if you take it exactly as prescribed. Gold Cross Codeine Linctus may become habit forming causing mental and physical dependence. If abused, it may become less able to relieve your cough.

**Dependence**

As with all other opioid containing products, your body may become used to you taking Gold Cross Codeine Linctus. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Gold Cross Codeine Linctus suddenly, so it is important to take it exactly as directed by your doctor.

**Tolerance**

Tolerance to Gold Cross Codeine Linctus may develop, which means that the effect of the medicine may

decrease. If this happens, more may be needed to maintain the same effect.

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?](#)

**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.

**Some medicines may interfere with Gold Cross Codeine Linctus and affect how it works.**

- Central nervous system (CNS) depressants such as tranquillisers, sedatives, opioid pain killers, barbiturates, or medicines to help you sleep or relieve anxiety
- Quinidine (a medicine to treat abnormal or irregular heartbeat)
- Cimetidine (a medicine to treat reflux or stomach ulcers)
- Monoamine oxidase inhibitors (MAOIs) (medicines for treating depression or mood swings, such as phenelzine, tranylcypromine or moclobemide) taken within the last 10 days
- Antihistamines (medicines for the treatment of allergies such as hay fever, insect bites and some cold remedies)
- Medicines used to treat nausea or vomiting.

The above medicines may either reduce the effectiveness of Gold Cross Codeine Linctus, reduce their own effectiveness and/or react with Gold Cross Codeine Linctus resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Gold Cross Codeine Linctus.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Gold Cross Codeine Linctus.**

**4. How do I use Gold Cross Codeine Linctus?**

**How much to take**

The recommended dose of Gold Cross Codeine Linctus for adults is 5 mL.

The directions given to you by your doctor may be different from the information in this leaflet. If you are unsure what dose to take, ask your doctor or pharmacist.

**When to take Gold Cross Codeine Linctus**

Take every 4 to 6 hours or as directed by your doctor. Ask your doctor if you are not sure how long to take this medicine for.

## If you forget to take Gold Cross Codeine Linctus

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 Gold Cross Codeine Linctus

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Gold Cross Codeine Linctus that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- Slow, unusual, or difficult breathing
- Drowsiness, dizziness, or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits.

If you think that you have used too much Gold Cross Codeine Linctus, 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.**

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take Gold Cross Codeine Linctus as stated on the labelling. If overdose symptoms occur, seek immediate medical advice.

## 5. What should I know while using Gold Cross Codeine Linctus?

### Things you should do

- Take Gold Cross Codeine Linctus exactly as your doctor has prescribed.
- Tell your doctor if you feel Gold Cross Codeine Linctus is not helping your condition.
- Always keep any appointments with your doctor to check your progress. Your doctor will check whether you need to keep taking Gold Cross Codeine Linctus.
- Tell your doctor if you become pregnant while you are using Gold Cross Codeine Linctus.

### Things you should not do

- Do not take any other medicines while you are taking Gold Cross Codeine Linctus without first telling your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

### Driving or using machines

**Do not drive or use any machines or tools until you know how Gold Cross Codeine Linctus affects you.**

Gold Cross Codeine Linctus may cause dizziness, light-headedness, drowsiness and problems with vision in some people.

### Drinking alcohol

**Do not drink alcohol while using Gold Cross Codeine Linctus.**

This includes medicines that contain alcohol.

Alcohol may make some of the unwanted side effects of Gold Cross Codeine Linctus worse.

### Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, you may experience some, or all, of the following withdrawal symptoms:

- Nervousness, restlessness, agitation, trouble sleeping or anxiety
- Body aches, weakness, or stomach cramps
- Loss of appetite, nausea, vomiting or diarrhoea
- Increased heart rate, breathing rate or pupil size
- Watery eyes, runny nose, chills or yawning
- Increased sweating.

### Looking after your medicine

- Store below 30 °C.

Follow the instructions on the medicine label 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 windowsills.

**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                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| <b>Digestive system:</b> <ul style="list-style-type: none"> <li>Constipation</li> <li>Dry mouth</li> <li>Nausea or vomiting</li> <li>Loss of appetite</li> <li>Difficulty swallowing</li> </ul> <b>Nervous system:</b> <ul style="list-style-type: none"> <li>Drowsiness</li> <li>Dizziness</li> <li>Restlessness or nervousness</li> <li>Excitability</li> <li>Headache</li> <li>Sleep disturbances</li> </ul> <b>Skin reaction:</b> <ul style="list-style-type: none"> <li>Mild skin rashes</li> <li>Itch</li> </ul> <b>Reproductive system</b> <ul style="list-style-type: none"> <li>Impotence or erectile dysfunction</li> <li>Amenorrhoea</li> <li>Infertility</li> </ul> | 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                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Nervous system related:</b> <ul style="list-style-type: none"> <li>Confusion</li> <li>Mood swings</li> <li>Tremors or shivering</li> <li>Increased sweating</li> <li>Seizures</li> <li>Problems breathing while sleeping (sleep apnoea)</li> </ul> <b>Allergy related:</b> <ul style="list-style-type: none"> <li>Skin rash, itching or hives on the skin</li> <li>Flushing of the face</li> <li>Shortness of breath, difficulty breathing</li> <li>Swelling of the face or lips</li> </ul> <b>Heart related</b> <ul style="list-style-type: none"> <li>Rapid heartbeat</li> <li>Low blood pressure</li> </ul> <b>Urinary related</b> <ul style="list-style-type: none"> <li>Problems passing urine</li> </ul> <b>Eye related</b> | 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. |

| Serious side effects                                                       | What to do |
|----------------------------------------------------------------------------|------------|
| <ul style="list-style-type: none"> <li>Blurred or double vision</li> </ul> |            |

**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 Gold Cross Codeine Linctus contains

|                                                 |                                                                                             |
|-------------------------------------------------|---------------------------------------------------------------------------------------------|
| <b>Active ingredient (main ingredient)</b>      | Codeine phosphate hemihydrate 5 mg/mL                                                       |
| <b>Other ingredients (inactive ingredients)</b> | Sucrose (sugar)<br>Glycerol<br>Methyl hydroxybenzoate<br>Propylene glycol<br>Purified water |
| <b>Potential allergens</b>                      | Contains the preservative methyl hydroxybenzoate.                                           |

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

### What Gold Cross Codeine Linctus looks like

Gold Cross Codeine Linctus is a clear, almost colourless liquid

Registration number: AUST R 27219

### Who distributes Gold Cross Codeine Linctus

iNova Pharmaceuticals (Australia) Pty Limited  
Level 10, 12 Help Street  
Chatswood NSW 2067  
Tel (toll free): 1800 630 056

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