

## WARNINGS

### Limitations of use

Rikodeine should only be used when your doctor or pharmacist decides that other treatment options are not able to effectively manage your cough, or you cannot tolerate them.

### Hazardous and harmful use

Rikodeine poses risks of abuse, misuse and addiction which can lead to overdose and death.

### Life threatening respiratory depression

Rikodeine 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 Rikodeine and after a dose increase, if you are older, or have an existing problem with your lungs.

### Use of other medicines while using Rikodeine

**Using Rikodeine with other medicines that can make you feel drowsy such as sleeping tablets (e.g., benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g., gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death.**

You must not drink alcohol while using Rikodeine.

# Rikodeine<sup>®</sup> Oral Liquid (rye-co-deen)

Active ingredient(s): *Dihydrocodeine tartrate and sorbitol (die-hydro-co-deen tahr-treyt + sore-be-tol)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Rikodeine. **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 Rikodeine.**

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

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

### 1. Why am I taking Rikodeine?

Rikodeine is a cough suppressant and contains the active ingredients, dihydrocodeine tartrate and sorbitol.

Rikodeine is used to give temporary relief for an unproductive and dry cough, which will not go away.

### 2. What should I know before I take Rikodeine?

#### Warnings

**Do not give Rikodeine to children aged under 6 years.**

**Only give Rikodeine to children aged 6 – 11 years on the advice of a doctor, pharmacist, or nurse practitioner.**

**Do not take Rikodeine if:**

- You are allergic to dihydrocodeine, other opioids, 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 severe lung or breathing problems
- The expiry date printed on the packaging has passed
- The packaging shows signs of tampering.

#### Check with your doctor or pharmacist if you:

- Have any of the following medical conditions:
  - Kidney or liver disease
  - Impaired function of the adrenal or thyroid gland
  - Asthma, emphysema, or any breathing problems
  - Increased prostate size
  - Narrowing of urinary tract
  - Biliary tract disease or inflammation of the pancreas
  - A condition associated with fits or convulsions
  - Diarrhoea
  - Muscle disorders - serious muscle weakness
  - Inflammatory or obstructive bowel disorders
  - Low blood pressure
  - Take any medicines for any other condition
  - Are allergic to foods, dyes, preservatives, or any other medicines
  - Have had a head injury or increased pressure in the head
  - Regularly drink large amounts of alcohol.

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 or pharmacist if you are pregnant or intend to become pregnant.

Taking Rikodeine regularly during the last trimester of pregnancy may risk causing breathing problems or withdrawal symptoms in the newborn baby.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

#### Addiction

You can become addicted to Rikodeine even if you take it exactly as prescribed. Rikodeine may become habit forming causing mental and physical dependence. If abused, it

may become less able to provide temporary relief of an unproductive and dry cough.

### Dependence

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

### Tolerance

Tolerance to Rikodeine may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

### Withdrawal

Continue taking Rikodeine for as long as your doctor or pharmacist tells you. If you stop taking 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.

## 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.

**Rikodeine may increase the effects of alcohol.**

**Some medicines may interfere with Rikodeine and affect how it works.**

**These include:**

- Any medicine causing sleepiness or drowsiness
- Sedating antihistamines (medicines used to treat hay fever and allergies)
- Tranquillisers (medicines for anxiety or nerves)
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- Medicines containing alcohol (ethanol), e.g., some cough syrups
- Medicines used to treat depression
- Medicines used to treat mental illness
- Medicines to treat high blood pressure
- Medicines to treat diarrhoea, nausea, or vomiting
- Monoamine oxidase inhibitors (medicines used to treat depression) taken within the last 10 days
- Pain relief medication such as codeine, morphine, and pethidine
- Other cough suppressants
- Quinidine (used to treat abnormal heart rhythms)
- Medicines used to treat alcohol and/or opioid dependence (e.g., naltrexone, buprenorphine, or methadone)

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

## 4. How do I take Rikodeine?

### How much to take

- Adults and children 12 years and over: take 5 to 10 mL every four to six hours. If you are elderly take a 5 mL dose until you know how the medicine affects you.
- For children between 6 to 11 years: give 2.5 to 5 mL every four to six hours (only on the advice of a doctor, pharmacist, or nurse practitioner).

### When to take it

- Only use Rikodeine when you need to stop your cough
- Do not take more than 6 doses over a 24 hour period.

### How to take it

Accurately measure the dose with a medicine measure. Using a medicine measure ensures that you will get the correct dose. You can buy a medicine measure from your pharmacist.

### How long to take Rikodeine

Stop using this medicine when the cough has gone. If the coughing continues or gets worse, talk to your doctor.

### If you take too much Rikodeine

**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.

Symptoms of overdose include:

- Slow, unusual or difficult breathing
- Extreme sleepiness progressing to unconsciousness
- Slow or weak heartbeat
- Cold, clammy skin
- Pinpoint pupils
- Flabby muscles

You should follow the above steps even if someone other than you have accidentally used Rikodeine that was prescribed for you.

If you think you or someone else may have used too much Rikodeine, 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 dihydrocodeine, you may experience signs of overdose even when you take Rikodeine as stated on the labelling. If overdose symptoms occur, seek immediate medical advice.

## 5. What should I know while taking Rikodeine?

### Things you should do

- Take Rikodeine exactly as your doctor or pharmacist has prescribed
- Tell your doctor if you become pregnant while taking Rikodeine
- Remind your doctor, dentist, or pharmacist you visit that you are taking Rikodeine
- If you are having surgery, tell the surgeon or anaesthetist that you are taking Rikodeine as it may affect other medicines used during surgery.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how Rikodeine affects you.

Rikodeine may cause drowsiness, dizziness, or light-headedness and problems with vision in some people.

### Drinking alcohol

#### Do not drink alcohol while taking Rikodeine.

Drinking alcohol increases the likelihood of becoming drowsy.

### Looking after your medicine

Keep Rikodeine in the bottle until it is time to use it.

Store Rikodeine below 30°C 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 window sills.

Keep medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### 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 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Drowsiness, inability to sleep</li> <li>• Sweating</li> <li>• Confusion or dizziness</li> <li>• Nausea or vomiting</li> <li>• Constipation, severe abdominal pains (colic) or diarrhoea</li> <li>• Dry mouth</li> </ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Itchy skin and swelling under the skin</li> <li>• Weakness</li> <li>• Difficulty passing urine</li> </ul>	

As with many other opiates, abuse of dihydrocodeine has been reported.

If you think you are having an allergic reaction to Rikodeine, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

Symptoms usually include some or all of the following:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the lips/mouth face, lips, tongue, or other parts of the body
- Hay fever
- Rash, itching or hives on the skin
- Fainting

### 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.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What Rikodeine contains

<b>Active ingredients (main ingredient)</b>	Dihydrocodeine tartrate Sorbitol
<b>Other ingredients (inactive ingredients)</b>	Sucrose Citric acid anhydrous Methyl hydroxybenzoate Amaranth C116185 Strawberry flavour Water

### What Rikodeine looks like

Rikodeine is a clear, red, strawberry flavoured liquid. It is packed in 100 mL and 200 mL bottles.

Registration number: AUST R 10587.

### Who distributes Rikodeine

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

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