

Rikodeine(TM) Oral Liquid

(rye-co-deen)

Dihydrocodeine tartrate and sorbitol (die-hydro-co-deen + sore-be-tol)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rikodeine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Rikodeine is used for

This medicine is used to give temporary relief of an unproductive and dry cough, which will not go away.

It belongs to a group of medicines called cough suppressants.

Rikodeine has been recommended for your use only.

Do not give it to anyone else even if you think their condition is the same as yours.

Your doctor may have recommended Rikodeine for another purpose.

If you are not sure why you are using this medicine ask your doctor or pharmacist.

Before you take Rikodeine

When you must not take it

Do not take Rikodeine if you have an allergy to:

- * any medicine containing dihydrocodeine
- * any of the other ingredients listed at the end of this leaflet
- * any other similar medicines

Some of the symptoms of an allergic reaction may include:

- * shortness of breath
- * wheezing or difficulty breathing
- * swelling of the face, lips, tongue, or other parts of the body
- * rash, itching or hives on the skin

Do not take Rikodeine:

- * if you are having an acute attack of asthma
- * if you have any lung or breathing problems

Do not take this medicine after the expiry date printed on the label or if the packaging shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take Rikodeine:

Tell your doctor or pharmacist if you:

- * are allergic to foods, dyes, preservatives or any other medicines
- * have any of the following 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
- * have had a head injury or increased pressure in the head
- * regularly drink large amounts of alcohol
- * are pregnant or breast feeding or intend to become pregnant or breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using Rikodeine during pregnancy.

If you have not told your doctor or pharmacist any of the above, tell them before you start taking Rikodeine.

Taking other medicines

- * Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Rikodeine may increase the effects of alcohol and interact with other medicines such as:

- Antipsychotics (e.g. olanzapine)
- Sedating antihistamines (e.g. dexchlorpheniramine)
- Tranquillisers (e.g. diazepam)
- Sedatives (e.g. nitrazepam).
- * Rikodeine may not be as effective if you are taking quinidine (a heart medicine).
- * There may be an increase in constipation or difficulty in urinating with medicines such as tricyclic antidepressants and some antihistamines.
- * Medicines for high blood pressure may have an increased effect, by lowering blood pressure even further.
- * There may be an increased risk of severe constipation when taken with medicines for diarrhoea such as Lomotil(TM) and Imodium(TM).
- * Anxiety, confusion or severe respiratory depression may occur with monoamine oxidase inhibitor antidepressants such as moclobemide and phenelzine.
- * Medicines such as codeine, morphine and pethidine may increase the risk of Rikodeine side effects.
- * There is a possibility of interaction with medicines, such as naloxone, taken to reverse the effect of narcotic drugs.

Do not take medicines that might make you drowsy while you are taking Rikodeine unless otherwise advised by your doctor.

How to take Rikodeine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

If you are an adult or over 12 years, take 5 to 10 mL every four to six hours.

If you are elderly use the smaller dose until you know how the medicine affects you.

For a child between 4 to 5 years, give 2.0 to 2.5 mL every four to six hours.

For a child between 6 to 12 years, give 2.5 to 5 mL every four to six hours.

Do not give this medicine to a child under the age of 4 years.

Do not take more than 6 doses in a day.

How to take it

Accurately measure the dose with a medicine measure.

Using a medicine measure will make sure that you get the correct dose.

You can buy a medicine measure from your pharmacist.

When to take it

Only use this medicine when needed to help stop the cough.

Do not take more than 6 doses in a day.

How long to take it

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

Immediately telephone your doctor or the Poisons Information Centre (in Australia call 13 11 26; in New Zealand call toll free 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Rikodeine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Rikodeine

Things you must do

If you are about to be started on any new medicine remind your doctor and pharmacist that you are taking Rikodeine.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things to be careful of

Be careful driving or operating machinery until you know how Rikodeine affects you.

This medicine may cause tiredness, drowsiness, dizziness, or light-headedness in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, any dizziness or light-headedness may be worse.

If you feel light-headed or dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rikodeine.

This medicine helps most people with coughing, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * drowsiness, inability to sleep
- * sweating
- * confusion or dizziness
- * nausea or vomiting
- * constipation, severe abdominal pains (colic) or diarrhoea

- * dry mouth
- * itchy skin and swelling under the skin
- * weakness
- * difficulty passing urine

The above list includes the more common side effects of your medicine. They are usually mild.

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

All medicines can have side effects and this may occur with the normal use of Rikodeine in a few people. Tell your doctor or pharmacist if you do not feel well while you are using Rikodeine.

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:

- * wheezing
- * swelling of the lips/mouth
- * difficulty in breathing
- * hayfever
- * lumpy rash ("hives")
- * fainting

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Rikodeine

Storage

Keep your Rikodeine in the bottle until it is time to take it.

If you take it out of the bottle it may not keep as well.

Keep your Rikodeine in a cool, dry place where the temperature stays below 30 degrees C.

Do not store Rikodeine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Rikodeine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Rikodeine Oral Liquid (AUST R 10587) is a clear, red, strawberry flavoured liquid. It is packed in 100mL and 200mL bottles.

Do not use this medicine if there are visible signs of tampering.

Ingredients

Each 10mL of Rikodeine Oral Liquid contains dihydrocodeine tartrate 19 mg and sorbitol 4.4 g.

It also contains:

- * sucrose,
- * citric acid anhydrous,
- * methyl hydroxybenzoate,
- * amaranth CI16185,
- * strawberry flavour
- * water

This medicine does not contain alcohol, lactose or gluten.

Manufacturer

Rikodeine Oral Liquid is made by iNova Pharmaceuticals (Australia) Pty Limited (ABN 88 000 222 408), 9-15 Chilvers Road Thornleigh, NSW 2120.

(TM) = Trademark

This leaflet was prepared in February
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