

ACTACODE

Codeine Phosphate Linctus

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ACTACODE.

It does not contain all of the available information about ACTACODE.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ACTACODE against the benefits he/she expects it will have.

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 is ACTACODE

The name of your medicine is ACTACODE.

The active ingredient is called Codeine Phosphate.

ACTACODE belongs to a group of medicines called cough suppressants.

What ACTACODE is used for

ACTACODE is used for

the relief of unproductive, dry coughs associated with colds and flu.

Ask your doctor if you have any questions about why ACTACODE has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

ACTACODE linctus is available only with a doctor's prescription.

Before you take ACTACODE

When you must not take it

Do not take ACTACODE if you are allergic to:

- Codeine or any of the ingredients listed at the end of this leaflet
- Morphine
- Oxycodone

Some of the symptoms of an allergic reaction to ACTACODE may include red, itchy skin rashes, difficulty breathing, hay fever, swelling of the face or throat or faintness.

ACTACODE should not be taken if you are experiencing breathing difficulties such as asthma, bronchitis or emphysema.

Do not use ACTACODE if you are suffering from diarrhoea caused by poisoning or antibiotics.

Do not use ACTACODE after the expiry date (EXP.) printed on the pack.

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

Do **not** purchase or use ACTACODE if the packaging is torn or shows signs of tampering.

Do **not** give it to children **under the age of 12 years** unless your doctor has prescribed it for them.

Like all medicines, ACTACODE should not be used during pregnancy without first consulting your doctor.

ACTACODE is distributed to the breast milk so it is **not** recommended for nursing mothers.

Elderly patients are more likely to have less effective kidney function due to age. This may increase the risk of side effects.

You should discuss how much ACTACODE to take with your doctor or pharmacist.

Before you start to take it

You must tell your doctor if you are:

1. allergic to any other medicines or any foods, dyes or preservatives.
2. you have any other medical conditions/ health problems, including:
 - a breathing disorder
 - heart disease
 - a history of asthma
 - lung disease
 - liver disease, hepatitis
 - kidney disease or difficulty urinating
 - Addison's disease (low activity of the adrenal gland)
 - an underactive thyroid gland
3. you are a heavy drinker
4. you have had a recent head injury or brain tumour
5. you have had recent biliary tract surgery

If you have not told your doctor about any of the above, tell them before you take any ACTACODE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with ACTACODE.

These include:

- CNS depressants such as tranquillisers, sedatives, pain killers, barbiturates, medicines to help you sleep or relieve anxiety
- Quinidine (a medicine to treat abnormal or irregular heart beat)
- Cimetidine (a medicine to treat reflux or stomach ulcer)
- Monoamine oxidase inhibitors (medicines for treating depression or mood swings, such as phenelzine, tranlycypromine 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)

The above medicines may either reduce the effectiveness of ACTACODE, reduce their own effectiveness and/or react with ACTACODE 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 ACTACODE.

How to take ACTACODE

a) how much to take

The recommended doses of ACTACODE is:

Adults: 5 mL every four to six hours.

b) how to take it

The linctus should be swallowed neat followed by a glass of water.

c) how long to take it

Continue taking ACTACODE as long as your doctor recommends it.

If symptoms persist, see your doctor.

d) If you forget to take it

Take your dose as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

Do not try to make up for missed doses by taking more than one dose at a

time. This may increase the chance of you getting an unwanted effect. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose):

Immediately phone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think you or anyone else may have taken an overdose of ACTACODE. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol (including any barbiturates or narcotics) which has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much ACTACODE you may have symptoms of weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and hypotension.

While you are using ACTACODE

Things you must do:

Use ACTACODE exactly as directed or as your

doctor has prescribed.

Tell your doctor if you feel ACTACODE is not helping your condition.

Your doctor needs to check your progress and see whether you need to keep taking ACTACODE.

Always discuss with your doctor any problems or difficulties during or after taking ACTACODE.

Things you must not do:

Do not take any other medicines while you are taking ACTACODE without first telling your doctor.

Do not drive or operate machinery until you know how ACTACODE affects you.

ACTACODE may cause dizziness in some people and may affect alertness.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Things to be careful of:

Be careful drinking alcohol while taking ACTACODE.

If you drink alcohol, it could make some of the unwanted side effects of ACTACODE worse.

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking

ACTACODE.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness, and dizziness, which may further affect the risk when driving or using dangerous machinery.

ACTACODE may be habit forming if used for extended periods of time.

Side effects

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

ACTACODE helps most people with the medical condition listed in the beginning of this leaflet, but it may have unwanted side effects in some people, especially in elderly patients or those with underlying disorders.

All medicines have side effects. Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Common Side Effects:

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

- constipation
- nausea (feeling sick)
- vomiting
- dizziness
- drowsiness
- skin rashes

Some side effects are potentially serious.

Contact your doctor immediately if you notice any of the following side effects:

- breathing difficulties
- fast or irregular heart beat
- difficulty in urinating (passing water)
- itchy, raised or red skin rash

Some people may get other side effects of ACTACODE.

Check with your doctor as soon as possible if you have any problems while taking ACTACODE even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using ACTACODE

Storage

Keep ACTACODE 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.

Keep ACTACODE in a

cool dry place where the temperature stays below 30°C and protect from light.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines. Do not take ACTACODE if it does not look quite right.

Keep your medicine in the bottle it was provided in until it is time to take it.

Disposal

If your doctor tells you to stop taking this medication OR it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

a) What it looks like

ACTACODE is a linctus and is supplied in a glass bottle containing 100 mL.

b) Ingredients

ACTACODE codeine linctus contains codeine phosphate 5 mg/mL.

ACTACODE also contains the following excipients:

- Propylene glycol
- methyl hydroxybenzoate

- sucrose
- glycerol
- water - purified

The Australian Registration Number for ACTACODE is: AUST R 19643.

Sponsor or Supplier

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