

ACTACODE linctus

(oral liquid)

codeine phosphate hemihydrate

Consumer Medicine Information

WARNINGS

Hazardous and harmful use

Actacode contains codeine and poses risks of hazardous and harmful use which can lead to overdose and death. Assess the patient's risk of hazardous and harmful use before prescribing and monitor the patient regularly during treatment

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of Actacode. Be aware of situations which increase the risk of respiratory depression, modify dosing in patients at risk and monitor patients closely, especially on initiation or following a dose increase

Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Limit dosages and durations to the minimum required and monitor patients for signs and symptoms of respiratory depression and sedation. Caution patients not to drink alcohol while taking Actacode.

What is in this leaflet

This leaflet answers some common questions 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 they expect it will have for you.

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 ACTACODE is used for

ACTACODE contains codeine phosphate as the active ingredient. It belongs to a group of medicines called cough suppressants.

ACTACODE is used for the relief of unproductive, dry and intractable

coughs associated with colds and flu.

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

Your doctor may have prescribed it for another purpose.

ACTACODE is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take ACTACODE if you have ever had an allergic reaction to:

- codeine
- morphine
- oxycodone
- any of the ingredients listed at the end of this leaflet.

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

Do not take ACTACODE if you are experiencing breathing difficulties such as asthma, bronchitis, emphysema or other severe/acute respiratory diseases.

Do not take it if you are suffering from diarrhoea caused by poisoning or antibiotics.

Do not take ACTACODE if you have recently ingested a large amount of alcoholic beverages.

Do not take ACTACODE if you have had recent biliary tract surgery.

Do not take ACTACODE if you recently have had a head injury or conditions that raise the pressure within your head.

Do not take ACTACODE if you have been taking monoamine oxidase inhibitors (medicines for treating depression or mood swings, such as phenelzine, tranlycypromide or moclobemide) within the last 10 days.

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

Do not take it if the packaging is torn or shows signs of tampering.

Do not give it to children under the age of 12 years.

Do not take it if you are aged between 12 to 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Do not take it if you are pregnant without first consulting with your doctor.

Do not take it if you are breast feeding or planning to breastfeed.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any medical conditions, especially the following:

- a breathing disorder
- heart disease
- a history of asthma
- lung disease or a history of asthma
- liver disease, hepatitis
- kidney disease or difficulty urinating
- diarrhoea
- recent urinary tract surgery
- a prostate disorder
- Addison's disease (low activity of the adrenal gland)
- an underactive thyroid gland
- a history of drug dependence, including alcohol dependence
- you are a heavy drinker
- you have had a recent head injury or brain tumour
- you have had recent biliary tract surgery
- if you about to have surgery under a general anaesthetic
- if you are under 18 and have undergone adenoidectomy and/or tonsillectomy

- if you know you are a CYP2D6 ultra-rapid metaboliser.

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, 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).

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

Use in the elderly

Elderly patients may be more sensitive to the effects or side effects of this medicine.

How to take it

How much to take

Your doctor will tell you the dose you need to take. This will depend on your age and other pre-existing health conditions.

The usual recommended dose of ACTACODE for adults is 5 mL every four to six hours.

How long to take it

Continue taking ACTACODE as long as your doctor recommends it.

If symptoms persist, see your doctor.

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.

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 telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much 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.

Symptoms of overdose may include weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and hypotension.

While you are taking it

Things you must do

Take ACTACODE exactly as directed by your doctor.

Tell your doctor if you feel this medicine is not helping your condition.

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

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

You should tell any other doctors or dentists treating you that you are 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 it affects you.

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

Do not give this medicine to anyone else, even if their 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 this medicine.

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.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take ACTACODE as recommended by your doctor. If symptoms such as slow or shallow breathing, confusion, sleepiness, small pupils or circulatory problems occur, seek immediate medical advice.

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, but it may have unwanted side effects in some people, especially in elderly patients or those with underlying disorders.

All medicines can 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.

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

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

These side effects are common.

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

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if

you do think the problems are not connected with this medicine or are not listed in this leaflet.

Some people may get other side effects while taking ACTACODE.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep ACTACODE in a cool dry place, protected from light, where the temperature stays below 30°C.

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.

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

Store 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.

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

What it looks like

ACTACODE linctus is a thick, almost colourless and almost odourless syrup free from visible contamination.

Available in 100 mL glass bottles.

Ingredients

Active ingredient:

Each one mL contains 5 mg codeine phosphate.

Inactive ingredients:

- propylene glycol
- hydroxybenzoic acid esters (present in Nipastat)
- potassium sorbate
- sucrose
- glycerol
- hydrochloric acid
- sodium hydroxide
- water – purified.

ACTACODE linctus does not contain glucose, lactose, tartrazine or any other azo dyes.

Sponsor

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AUST R 124245.

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