

# ASPEN CODEINE tablets

## 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 ASPEN CODEINE tablets?

ASPEN CODEINE tablets contain the active ingredient codeine phosphate hemihydrate. ASPEN CODEINE tablets are used for the treatment of mild to moderate pain.

For more information, see Section [1. Why am I using ASPEN CODEINE tablets?](#) in the full CMI.

### 2. What should I know before I use ASPEN CODEINE tablets?

Do not use if you have ever had an allergic reaction to codeine, morphine, oxycodone 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 ASPEN CODEINE tablets?](#) in the full CMI.

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

Some medicines may interfere with ASPEN CODEINE tablet 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 ASPEN CODEINE tablets?

- Adults: 1 to 2 tablets every four to six hours.

More instructions can be found in Section [4. How do I use ASPEN CODEINE tablets?](#) in the full CMI.

### 5. What should I know while using ASPEN CODEINE tablets?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using ASPEN CODEINE tablets.</li><li>Tell your doctor if you become pregnant while taking ASPEN CODEINE tablets.</li></ul>
<b>Things you should not do</b>	<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 ASPEN CODEINE tables if you are breastfeeding.</li><li>Do not use ASPEN CODEINE tables if you have asthma or other breathing difficulties.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Do not drive or operate machinery until you know how ASPEN CODEINE tablets affect you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking ASPEN CODEINE tablets.</li><li>If you drink alcohol, it could make some of the unwanted side effects of ASPEN CODEINE tablets worse.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Store below 30°C in a cool and dry place where children cannot reach it.</li><li>Protect from light.</li></ul>

For more information, see Section [5. What should I know while using ASPEN CODEINE tablets?](#) in the full CMI.

### 6. Are there any side effects?

Some people may experience headaches, constipation, nausea or vomiting while taking ASPEN CODEINE tablets. 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 ASPEN CODEINE tablets.

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.

**WARNING:****Limitations of use**

ASPEN CODEINE tablets should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

**Hazardous and harmful use**

ASPEN CODEINE tablets pose 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**

ASPEN CODEINE tablets 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 ASPEN CODEINE tablets 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 ASPEN CODEINE tablets**

Using ASPEN CODEINE tablets 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. 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 ASPEN CODEINE tablets.

# ASPEN CODEINE tablets

**Active ingredient:** *codeine phosphate hemihydrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ASPEN CODEINE tablets. **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 ASPEN CODEINE tablets.**

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

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

## 1. Why am I using ASPEN CODEINE tablets?

ASPEN CODEINE tablets contain the active ingredient **codeine phosphate hemihydrate**. Codeine phosphate hemihydrate belongs to a group of medicines called analgesics, which are used to block pain. It is an opioid analgesic, and it acts by blocking pain and your emotional response to pain.

**ASPEN CODEINE tablets are used for the treatment of mild to moderate pain.**

## 2. What should I know before I use ASPEN CODEINE tablets?

**Warnings****Do not use ASPEN CODEINE tablets if:**

- you are allergic to codeine, morphine, oxycodone or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include red, itchy skin rashes; difficulty breathing; faintness; hay fever and swelling of the face or throat. Always check the ingredients to make sure you can use this medicine.
- you are experiencing breathing difficulties such as asthma, bronchitis or emphysema.
- you have had recent biliary tract surgery.
- you have recently ingested a large amount of alcoholic beverages.
- you recently have had a head injury or conditions that raise the pressure within your head.
- you are suffering from diarrhoea caused by poisoning or antibiotics.
- you have been taking monoamine oxidase inhibitors (medicines for treating depression or mood swings, such as phenelzine, tranylcypromine or moclobemide) within the last ten days.
- the expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

**Check with your doctor if you:**

- are allergic to any other medicines or any foods, dyes or preservatives.
- have any other medical conditions including:

- breathing disorder, lung disease or a history of asthma
- heart disease
- liver disease, hepatitis
- kidney disease or difficulty urinating
- depression
- an underactive thyroid gland
- Addison's disease (low activity of the adrenal glands)
- inflammatory bowel disease or other gastro-intestinal problems
- diarrhoea
- gallbladder disease or gallstones
- prostate disorder.
- are a heavy drinker or drug user.
- have had a recent head injury.
- have recent biliary tract surgery.
- are about to have surgery under a general anaesthetic.

## Pregnancy and breastfeeding

**Do not use ASPEN CODEINE tablets if you are pregnant or intend to become pregnant. ASPEN CODEINE tablets given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.**

**Do not use ASPEN CODEINE tablets if you are breastfeeding or intend to breastfeed.** This medicine is distributed to the breast milk.

## Use in children

**ASPEN CODEINE tablets should not be given to children under the age of 12 years unless your doctor has prescribed it for them.**

## Use in elderly

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 ASPEN CODEINE tablets to take with your doctor or pharmacist.

## Addiction

You can become addicted to ASPEN CODEINE tablets even if you take it exactly as prescribed. ASPEN CODEINE tablets may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

## Dependence

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

## Tolerance

Tolerance to ASPEN CODEINE tablets 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 ASPEN CODEINE tablets and affect how it works. These include:**

- medicines to help you sleep or relieve anxiety
- anticholinergics, medicines to treat muscle spasms
- medicines used to treat diarrhoea
- medication for epilepsy
- medicines used to treat high blood pressure
- diuretics or fluid tablets
- other opioid analgesics used to block pain
- antihistamines (medicines used to treat allergies such as hay fever, insect bites and some cold remedies)
- monoamine oxidase inhibitors (medicines for treating depression) taken within the last 10 days
- Metoclopramide, a medicine used to relieve nausea and vomiting
- antidepressant medicines used to treat depression
- Naloxone or Naltrexone, medicines used to counteract the effects of opioid analgesics.
- medicines used to relax muscles
- quinidine (a medicine used to treat abnormal or irregular heart beat)
- Cimetidine (a medicine used to treat reflux or stomach ulcer).

The above medicines may either reduce the effectiveness of ASPEN CODEINE tablets, reduce their own effectiveness and/or react with ASPEN CODEINE tablets resulting in untoward or sometimes dangerous side effects.

**This list is not exhaustive. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ASPEN CODEINE tablets.**

## 4. How do I use ASPEN CODEINE tablets?

### How much to take

- The recommended dose of ASPEN CODEINE tablets is:  
**Adults: 1 to 2 tablets every four to six hours**

### How to take it

- The tablets should be swallowed whole with a glass of water.

## How long to take it

- Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and 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.

## If you forget to use ASPEN CODEINE tablets

**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.** 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 use too much ASPEN CODEINE tablets

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 ASPEN CODEINE tablets 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, unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits.

If you think that you have used too much ASPEN CODEINE tablets, 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 breakdown

codeine, you may experience signs of overdose even when you take ASPEN CODEINE tablets as stated on the labelling. If overdose symptoms occur, seek immediate medical advice.

## 5. What should I know while using ASPEN CODEINE tablets?

### Things you should do

- Use this medicine exactly as directed or as prescribed by your doctor.
- Tell your doctor if you feel this medicine is not helping your condition.
- Visit your doctor regularly, as your doctor needs to check your progress and see whether you need to keep taking ASPEN CODEINE tablets.
- Always discuss with your doctor any problems or difficulties during or after taking ASPEN CODEINE tablets.
- You should tell any other doctors or dentists treating you that you are taking ASPEN CODEINE tablets.
- Tell your doctor if you become pregnant while you are using ASPEN CODEINE tablets.

### Things you should not do

- Do not take any other medicines while you are taking ASPEN CODEINE tablets without first telling your doctor.
- Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

### Driving or using machines

**Do not drive or operate machinery until you know how ASPEN CODEINE tablets affect you.**

ASPEN CODEINE tablets may cause dizziness in some people and therefore may affect alertness. Make sure you know how you react to ASPEN CODEINE tablets before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Be careful drinking alcohol while taking ASPEN CODEINE tablets. If you drink alcohol, it could make some of the unwanted side effects of ASPEN CODEINE tablets worse.

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

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

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in the blister pack until it is time to take them.

- Store below 30°C. Protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**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?

ASPEN CODEINE tablets help most people in the treatment of mild to moderate pain. However it may have unwanted side effects in some people, especially in elderly patients or those with underlying disorders.

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>Gastrointestinal-related:</b> <ul style="list-style-type: none"><li>• stomach cramps</li><li>• dry mouth</li><li>• loss of appetite</li><li>• constipation</li><li>• nausea (feeling sick)</li><li>• vomiting</li></ul> <b>Head and neurology-related:</b> <ul style="list-style-type: none"><li>• dizziness</li><li>• drowsiness</li><li>• feeling faint</li><li>• excitability</li><li>• unable to sleep</li><li>• unusual dreams</li></ul> <b>Skin-related:</b> <ul style="list-style-type: none"><li>• skin rashes</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>General</b> <ul style="list-style-type: none"><li>• muscle stiffness</li><li>• difficulty in urinating (passing water)</li></ul>	<b>Call your doctor straight away, or go straight to the</b>

<b>Heart-related:</b> <ul style="list-style-type: none"><li>• heartbeat irregularities</li></ul> <b>Head and neurology-related:</b> <ul style="list-style-type: none"><li>• blurred or double vision</li></ul> <b>Allergy-related:</b> <ul style="list-style-type: none"><li>• itchy, raised or red skin rash</li><li>• breathing difficulties</li><li>• swelling of face or lips</li></ul>	<b>Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>
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**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 ASPEN CODEINE tablets contain

<b>Active ingredient (main ingredient)</b>	Codeine phosphate hemihydrate, 30 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• maize starch</li><li>• lactose monohydrate</li><li>• magnesium stearate</li></ul>

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

### What ASPEN CODEINE tablets look like

ASPEN CODEINE tablet is a white unscored tablet that is available in blister packs of 10, 20 and 100 tablets (AUST R 276146).

Not all pack sizes are commercially available.

### Who distributes ASPEN CODEINE tablets

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos Street  
St Leonards NSW 2065  
Australia  
[www.aspenpharmacare.com.au](http://www.aspenpharmacare.com.au)

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