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 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?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ASPEN CODEINE tablets. • Tell your doctor if you become pregnant while taking ASPEN CODEINE tablets.
Things you should not do	• Do not take more than the recommended dose unless your doctor tells you to. • Do not use ASPEN CODEINE tables if you are breastfeeding. • Do not use ASPEN CODEINE tables if you have asthma or other breathing difficulties.
Driving or using machines	• Do not drive or operate machinery until you know how ASPEN CODEINE tablets affect you.
Drinking alcohol	• Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking ASPEN CODEINE tablets. If you drink alcohol, it could make some of the unwanted side effects of ASPEN CODEINE tablets worse.
Looking after your medicine	• Store below 30°C in a cool and dry place where children cannot reach it. • Protect from light.

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.
- **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 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 the 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 heartbeat)
- 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.

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.

This list is not exhaustive.

4. How do I use ASPEN CODEINE tablets?

How much to take

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

How to take it

To obtain tablet, press through foil immediately before taking.
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 take too many ASPEN CODEINE tablets

If you think that you or someone other than you have taken too many ASPEN CODEINE tablets, urgent medical attention is needed.

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
- drowsiness, dizziness, unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits
- confusion, memory loss
- difficulty walking
- changes in behaviour or personality.

You should immediately:

- phone triple zero (000) for an ambulance, or
- 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.

Report any other medicine or alcohol which has been taken.

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 like 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

Store ASPEN CODEINE in the blister pack protected from light, where the temperature stays below 30°C.

Keep it 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 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.

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
Gastrointestinal-related: • stomach cramps • stomach pain that may be felt in the back • dry mouth • loss of appetite • constipation • changes in bowel habits • nausea (feeling sick) • vomiting. **Head and neurology-related:** • dizziness • drowsiness • feeling faint • excitability • sleep disturbances such as a sudden awakening from sleep with shortness of breath • trouble with sleeping (either not enough or too much) • unusual dreams. **Skin-related:** • skin rashes. **Other:** • snoring • fever and chills.	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**
• trouble swallowing • chest discomfort such as pressure, heartburn or tightness.	**Speak to your doctor if you have any of these side effects that may be associated with long-term use.**

Serious side effects

Serious side effects	What to do
General • muscle stiffness • difficulty in urinating (passing water). **Heart-related:** • heartbeat irregularities **Head and neurology-related:** • blurred or double vision. **Allergy-related:** • itchy, raised or red skin rash • breathing difficulties • swelling of face or lips.	**Call your doctor or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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. 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

Active ingredient (main ingredient)	codeine phosphate hemihydrate: 30 mg/tablet
Other ingredients (inactive ingredients)	• maize starch • lactose monohydrate • magnesium stearate.
Potential allergens	• sugars as lactose.

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

What ASPEN CODEINE tablets look like

ASPEN CODEINE is a white, plain, round biconvex tablet. Available in blister packs of 20 tablets.

Australian Registration number: AUST R 276146.

Who distributes ASPEN CODEINE tablets

Aspen Pharmacare Australia Pty Ltd
Sydney NSW
Australia

www.aspenpharma.com.au

This leaflet was revised in August 2026.