

ASPEN CODEINE TABLETS

Consumer Medicine Information

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 poses 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.

What is in this leaflet

This leaflet answers some common questions about Aspen Codeine tablets.

It does not contain all of the available information about Aspen Codeine tablets.

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 Aspen Codeine tablets against the benefits he/she expect 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 Aspen Codeine tablets

The name of your medicine is Aspen Codeine tablets.

The active ingredient is called 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.

What Aspen Codeine tablets is used for

Aspen Codeine tablets is used for the treatment of mild to moderate pain.

Your doctor, however, may have prescribed Aspen Codeine tablets for another purpose.

Ask your doctor if you have any questions about why Aspen Codeine tablets has been prescribed for you.

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

Aspen Codeine tablets is available only with a doctor's prescription.

Before you take Aspen Codeine tablets

When you must not take it

Do not take Aspen Codeine tablets if you are allergic to:

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

Some of the symptoms of an allergic reaction to Aspen Codeine tablets may include red,

itchy skin rashes; difficulty breathing; faintness; hay fever and swelling of the face or throat.

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

Do not take Aspen Codeine tablets if you have had recent biliary tract surgery.

Do not take Aspen Codeine tablets if you have recently ingested a large amount of alcoholic beverages.

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

Do not use Aspen Codeine tablets if you are suffering from diarrhoea caused by poisoning or antibiotics.

Do not take Aspen Codeine tablets if 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.

Do not use Aspen Codeine tablets 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 Aspen Codeine tablets if the packaging is torn or shows signs of tampering. The tablets should not be taken if they show visible signs of deterioration.

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

Like all medicines Aspen Codeine tablets should not be used during pregnancy without first consulting your doctor.

Aspen Codeine tablets 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 Aspen Codeine tablets to take with your doctor or pharmacist.

Before you start to take it

You must tell your doctor if you are:

Allergic to any other medicines or any foods, dyes or preservatives.

You have any other medical conditions/health problems including:

- A 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
- A prostate disorder

You are a heavy drinker or drug user

You have had a recent head injury

You have recent biliary tract surgery

You are about to have surgery under a general anaesthetic

You are pregnant or intend to become pregnant

You are breastfeeding or intend to breastfeed

Your doctor will discuss the risks and benefits of using Aspen Codeine tablets during pregnancy or when breastfeeding.

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

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 Aspen Codeine tablets.

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 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. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Aspen Codeine tablets.

How to take 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.

Aspen Codeine tablets given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

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):

If you or someone else receive too much (overdose), and experience one or more of the symptoms below 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 or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much Aspen Codeine tablets 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 break down codeine, you may experience signs of overdose even when you take Aspen Codeine tablets as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

While you are using Aspen Codeine tablets

Things you must do:

Use Aspen Codeine tablets exactly as directed or as prescribed by your doctor.

Tell your doctor if you feel Aspen Codeine tablets 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.

Things you must not do:

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

Do not drive or operate machinery until you know how Aspen Codeine tablets affects 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.

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 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.

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.

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 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.

Side effects

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

Aspen Codeine tablets helps 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 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:

- stomach cramps
- dry mouth
- loss of appetite
- constipation
- nausea (feeling sick)
- vomiting
- dizziness
- drowsiness
- feeling faint
- excitability
- skin rashes
- unable to sleep
- unusual dreams

Some side effects are potentially serious.

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

- itchy, raised or red skin rash
- swelling of face
- muscle stiffness
- breathing difficulties
- heartbeat irregularities
- blurred or double vision

- difficulty in urinating (passing water)

Some people may get other side effects of Aspen Codeine tablets that are not listed in this leaflet.

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

After using Aspen Codeine tablets

Storage

Keep medicine 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 Aspen Codeine tablets 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 Aspen Codeine tablets if the tablets do not look quite right.

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

Disposal

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.

Product description

What it looks like

Aspen Codeine tablet is a white unscored tablet that is available in blister packs of 10, 20 and 100 tablets.

Ingredients

Each Aspen Codeine tablet contains 30 mg of Codeine phosphate hemihydrate.

Aspen Codeine tablets also contain the following excipients:

maize starch, lactose monohydrate, and magnesium stearate.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos St
St Leonards NSW 2065

The Australian Registration Number for Aspen Codeine tablets is: AUST R 276146.

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