

CODEINE PHOSPHATE HEMIHYDRATE TABLETS

(Code-een Foss-fate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Codeine Phosphate hemihydrate tablets.

It does not contain all of the available information about Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate 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 CODEINE PHOSPHATE HEMIHYDRATE tablets

The name of your medicine is CODEINE PHOSPHATE HEMIHYDRATE 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 CODEINE PHOSPHATE HEMIHYDRATE tablets is used for

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

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

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

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

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

Before you take CODEINE PHOSPHATE HEMIHYDRATE tablets

When you must not take it

Do not take Codeine Phosphate hemihydrate tablets if you are allergic to:

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

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

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

Do not take Codeine Phosphate hemihydrate if you have had recent biliary tract surgery.

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

Do not take Codeine Phosphate hemihydrate if you recently have

had a head injury or conditions that raise the pressure within your head.

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

Do not take Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate 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, Codeine Phosphate hemihydrate should not be used during pregnancy without first consulting your doctor.

Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate 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, 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
3. You are a heavy drinker or drug user
4. You have had a recent head injury
5. You have recent biliary tract surgery
6. You are about to have surgery under a general anaesthetic
7. You are pregnant or intend to become pregnant
8. You are breastfeeding or intend to breastfeed

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

If you have not told your doctor about any of the above, tell them before you take any Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate tablets, reduce their own effectiveness and/ or react with Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate tablets.

How to take CODEINE PHOSPHATE HEMIHYDRATE tablets

- a. **how much to take**
The recommended dose of Codeine Phosphate hemihydrate tablets is:
Adults: 1 to 2 tablets every four to six hours.
- b. **how to take it**
The tablets should be swallowed whole with a glass of water.
- c. **how long to take it**
Continue taking Codeine Phosphate hemihydrate tablets for as long as your doctor tells you to.
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 telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken an overdose of Codeine Phosphate hemihydrate. 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 Codeine Phosphate hemihydrate you may have symptoms of weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and hypotension.

While you are using Codeine Phosphate hemihydrate tablets

Things you must do:

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

Tell your doctor if you feel Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate tablets.

Always discuss with your doctor any problems or difficulties during or after taking Codeine Phosphate hemihydrate tablets.

You should tell any other doctors or dentists treating you that you are taking Codeine Phosphate hemihydrate tablets.

Things you must not do:

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

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

Codeine Phosphate hemihydrate may cause dizziness in some people and therefore may affect alertness. Make sure you know how you react to Codeine Phosphate hemihydrate

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 Codeine Phosphate hemihydrate tablets. If you drink alcohol, it could make some of the unwanted side effects of Codeine Phosphate hemihydrate worse.

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

Codeine Phosphate hemihydrate tablets 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 Codeine Phosphate hemihydrate tablets.

Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate tablets that are not listed in this leaflet.

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

After using CODEINE PHOSPHATE HEMIHYDRATE tablets

Storage

Keep it 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 Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate 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 your doctor tells you to stop taking this medication OR it has passed their expiry date, ask your pharmacist what to do with any left over.

Product description

a. **What it looks like**

Codeine Phosphate hemihydrate is a white unscored tablet that is available in blister packs of 20 and 100 tablets.

b. **Ingredients**

Each Codeine Phosphate hemihydrate tablet contains 30 mg of codeine phosphate hemihydrate.

Codeine Phosphate hemihydrate 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 Codeine Phosphate hemihydrate tablets is: AUST R276146.

This leaflet was prepared in Aug 2016