

[Medicine name][®] *(If you want to include phonetic spelling, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

Consumer Medicine Information

Date of Dispensing

This Core leaflet covers both prescription and non-prescription products containing codeine, and therefore must be modified to suit the particular product being written about. Information in the CMI must be consistent with the product's Product Information (PI).

When writing about consumers seeking advice from health professionals, the schedule of the product should be taken into consideration. Thus:

- *S4 products should direct consumers to seek advice from their **doctor or pharmacist**, and*
- *S3 products should direct consumers to seek advice from their **pharmacist or doctor**.*

What is in this leaflet

This leaflet answers some common questions about [Medicine name]. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking [Medicine name] against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

Below are further statements that may be included in this section.

It is only available from your pharmacist.

This medicine is only available on a prescription from your doctor.

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

Do not take codeine if you have alcohol dependence.

Do not take codeine during labour, especially if the baby is premature.

The medicine may produce withdrawal effects in the newborn baby.

Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor (or doctor or pharmacist).

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- a history of drug dependence, including alcohol dependence

Before you take/give [Medicine name]

When you must not take it

Do not take [Medicine name] if you have an allergy to:

- any medicine containing codeine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have or have had any of the following medical conditions:

What [Medicine name] is used for

Codeine is used to (*insert indication as specified in the ARTG, or for a non-validated grandfathered product, as specified on the product label*).

- *List multiple indications in dot points*

Codeine phosphate belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

- recent surgery on the stomach or intestines
- head injury
- prostate problems
- liver or kidney problems
- low blood pressure
- underactive thyroid

Tell your pharmacist or doctor if you take sedatives (medicines used to help you relax or sleep).

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.

Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Ask your pharmacist or doctor about taking codeine if you are breastfeeding.

A small amount of codeine passes into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking [Medicine name].

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and [Medicine name] may interfere with each other.

These include:

- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- medicines used to treat high blood pressure
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- metoclopramide, a medicine used to treat nausea and vomiting
- monoamine oxidase inhibitors, medicines used to treat depression, taken within the last 14 days
- other opioid analgesics used to treat pain

- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders

These medicines may be affected by [Medicine name] or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your pharmacist or doctor will have more information on medicines to be careful with or avoid while taking this medicine.

How to take [Medicine name]

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your pharmacist or doctor for help.

How much to take

Include dosage ranges, usual doses for each indication or patient group etc .as specified on the product label.

Do not take more than the recommended dose.

Talk to your doctor about pain control if the medicine is not helping.

If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine.

If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.

Elderly patients are more likely to have less effective kidney function due to age. This may increase the risk of side effects.

How to take it

Include specific instructions as specified on the product label.

When to take it

Include specific instructions as specified on the product label.

How long to take it

Include specific instructions as specified on the product label.

If you forget to take it

If it is less than 'x' hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine 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 side effect.

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering 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 (in Australia, call 13 11 26; in New Zealand, call 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.

While you are using [Medicine name]

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Do not take [Medicine name] to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how [Medicine name] affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or use operate machinery.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Codeine may be habit forming.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking [Medicine name].

This medicine helps most people with (*indication*), but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

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

- nausea
- vomiting
- drowsiness
- dizziness
- constipation

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- shallow breathing or shortness of breath
- unusual or extreme mood swings

- dizziness, light-headedness
- flushing of the face
- fast heart beat

The above list includes serious side effects that may require medical attention. These side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rashes

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using [Medicine name]

Storage

Keep your medicine in the original pack until it is time to take.

Keep your medicine in a cool dry place where the temperature stays below x°C.

Do not store [Medicine name] or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

Include identifying details as appropriate, such as dose form, colour and markings of tablets, colour and consistency of liquids, pack sizes, etc.

Ingredients

[Medicine name] contains x mg of (*generic name*) as the active ingredient.

It also contains:

- *list excipients in dot points*

Where Australian Food Standard codes exist, these could follow each Australian Approved name.

As appropriate, the CMI may include a negative list of ingredients. For example: This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

(use appropriate heading)

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark *or*

™ = Trademark (*if appropriate*)

This leaflet was prepared in month/year.

Include AUST R number(s)

You may want to include a document code and/or a reference to the approved PI.