

[Medicine name][®] *(include phonetic spelling)*

Generic names *(include phonetic spelling)*

Consumer Medicine Information

This Core leaflet has been developed for OTC paracetamol/codeine combination analgesic products. Information in the CMI must be consistent with the product's Product Information (PI).

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.

What [Medicine name] is used for

[Medicine name] is an analgesic (pain reliever). It works to *(insert indication consistent with that in the ARTG, or for a non-validated grandfathered product, as specified on the evaluated and approved product label)*.

- *List multiple indications in dot points if necessary*

It contains paracetamol and codeine phosphate.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Codeine phosphate is an opioid pain reliever.

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

This medicine may be addictive if taken for more than a few days at a time.

It is only available from your pharmacist.

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 paracetamol
- 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 any of the following conditions:

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

Do not take this medicine if you regularly drink large quantities of alcohol.

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.

Before you start to take it

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

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

- liver or kidney disease
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- a history of drug or alcohol dependence
- recent surgery on the stomach or intestines
- head injury
- enlarged prostate
- low blood pressure
- underactive thyroid.

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

Codeine may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

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

A small amount of codeine passes into the breast milk. It may cause breathing problems in newborn infants.

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

Taking other medicines

Do not take with other medicines containing paracetamol.

It is important to check the labels of all other medicines you are taking to make sure they do not contain paracetamol. Taking too much paracetamol may cause serious liver damage.

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.

[Medicine name and some other medicines may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- medicines used to relieve stomach cramps or spasms
- medicines used to prevent travel sickness
- medicines used to treat Parkinson's disease
- medicines used to treat high blood pressure
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- monoamine oxidase inhibitors, medicines used to treat depression, if taken within the last 14 days
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- other opioids, used to treat pain or suppress coughs
- alcohol

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

How to take [Medicine name]

Follow all directions for use written on the medicine's label.

Do not take more than the recommended dose on the label or for a longer period of time.

If you do not understand the instructions on the label, 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. Non-validated grandfathered products will require full evaluation and approval, including of the CMI.

Do not take more than the recommended dose (or number of doses in a 24-hour period).

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

Adults: Only take [Medicine name] for a few days at a time unless your doctor tells you to take it for longer.

Children and adolescents aged 12-17: Only take the medicine for 48 hours unless your doctor tells you to take it for longer.

If your symptoms persist, worsen or new symptoms develop, talk to your pharmacist.

Include specific instructions as specified on the product label.

If you forget to take it

This section is not relevant for OTC medicines as they are only indicated for use when necessary and for short-term use.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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.

Taking too much paracetamol can lead to delayed, serious liver damage. You may need urgent medical attention.

While you are using [Medicine name]

Things you must do

Only take the medicine as recommended on the label.

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 with other medicines containing paracetamol unless your doctor or pharmacist tells you to.

Adults: Do not take for more than a few days at a time unless your doctor tells you to.

Children and adolescents: Do not take for longer than 48 hours unless your doctor tells you to.

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

Things to be careful of

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

Codeine may be habit forming.

Too much paracetamol may cause delayed, serious liver damage.

Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.

Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

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.

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 who need a pain reliever, 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 or dyspepsia
- 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:

- unusual or extreme mood swings
- flushing of the face
- fast heart beat.

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

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

- 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

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

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 paracetamol and x mg of codeine phosphate (or in mg/mL if a liquid).

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.