

PRODEINE

paracetamol and codeine phosphate hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prodeine.

It does not, however, 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 doctor or pharmacist has weighed the risks of you taking this medicine 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 Prodeine is used for

Prodeine contains paracetamol and codeine.

Codeine phosphate hemihydrate 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.

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

Paracetamol and codeine work together to stop the pain messages from getting through to the brain.

Prodeine is a type of analgesic intended for short term use to relieve moderate pain and fever.

Your pharmacist or doctor, however, may prescribe Prodeine for another purpose.

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

Prodeine may be habit-forming if taken frequently or over long periods.

Before you take it

When you must not take it

Do not take Prodeine if you have:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema (a serious lung disease)
- glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
- known CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- had your tonsils or adenoids removed and are aged between 12 - 18 years of age
- severe liver or kidney disease
- diarrhoea caused by antibiotics or poisoning
- chronic constipation

Do not take Prodeine if you are allergic to any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take codeine if you have alcohol dependence.

Do not give Prodeine to children under 12 years of age.

Prodeine is not recommended for children under 12 years old.

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

This may produce withdrawal effects in the newborn baby.

Do not take Prodeine if you are breastfeeding or planning to breastfeed.

Prodeine passes into breast milk and there is a possibility your baby may be affected.

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

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

Do not take Prodeine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take Prodeine if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservative or dyes
- aspirin or any other NSAID medicine.

Tell your pharmacist or doctor if you plan to have surgery.

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

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

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

Tell your pharmacist or doctor if you are breastfeeding or planning to breastfeed.

Prodeine passes into breast milk and there is a possibility that your baby may be affected.

Your pharmacist or doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

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

- difficulty in breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)
- known analgesic intolerance
- heart, liver or kidney problems
- underactive thyroid
- a history of drug dependence, including alcohol dependence
- chronic alcohol use including recent cessation of alcohol intake
- pre-existing opioid dependence
- recent surgery of the stomach or intestine
- prostate problems
- low blood pressure
- low glutathione reserves
- Gilbert's syndrome
- Multiple sclerosis
- head injury or trauma
- urinary, bowel or gallbladder conditions
- problems with the adrenal glands
- myasthenia gravis, a muscle disorder
- convulsions, fits or seizures

- if you know you are a CYP 2D6 ultra-rapid metaboliser

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

Taking other medicines

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

Some medicines may interfere with the absorption of Prodeine. These include:

- medicines used to help relax, sleep or relieve anxiety, such as barbiturates and sedatives
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- medicines used to treat epilepsy or fits
- medicines which thin the blood such as warfarin
- other opioid analgesics used to treat pain
- antidepressants
- monoamine oxidase inhibitors, medicine used to treat depression, taken within the last 14 days
- flucloxacillin, zidovudine or rifampicin, medicines used to treat infections
- metoclopramide or domperidone, medicines used to control nausea and vomiting
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- alcohol

- chloramphenicol, an antibiotic used to treat ear and eye infection
- 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
- cholestyramine, a medicine used to lower high cholesterol levels
- chelating resin
- buprenorphine
- naltrexone

These medicines may be affected by Prodeine or may affect how well Prodeine works. You may need to use different amounts of your medicine, or take different medicines. Your pharmacist or doctor will advise you.

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

How to take it

How much to take

The standard dose for this medicine is:

Adults and children 12 years or over:

One or two tablets every 3 to 4 hours as needed for relief. Do not take more than 8 caplets in 24 hour period.

Children should not take Prodeine for more than 48 hours, unless your pharmacist or doctor advises to do so.

Do not give Prodeine to children under 12 years of age.

Prodeine is not recommended for use over an extended period of time.

Do not take more than the recommended dose.

Talk to your pharmacist or doctor about pain control if Prodeine is not helping.

If your body cannot metabolise codeine properly, you may be getting reduced benefit from this 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

Swallow the tablets whole with a full glass of water or other liquid.

Prodeine can be taken with or without food.

If you forget to take it

You may take Prodeine as soon as you remember or if you think you need it.

Do not take a double dose to make up for the dose you have missed.

This may increase the chance of getting unwanted side effect.

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

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 your nearest hospital, if you think that you or anyone else may have taken too much Prodeine.

Do this even if there are no signs of discomfort or poisoning.

You may need medical attention.

Large amounts of paracetamol, one of the active ingredients, can cause liver damage. Children who take too much Prodeine can also suffer extreme drowsiness, rash or have trouble seeing.

While you are taking it

Things you must do

Tell your doctors, dentists and pharmacists who are treating you that you are taking Prodeine.

If you are about to be started on any new medicine, tell your pharmacist or doctor that you are taking Prodeine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

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 Prodeine.

Things you must not do

Children:

Do not give this medicine for more than 48 hours unless a doctor tells you.

Adults:

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

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

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

Do not use this medicine to treat any other complaints unless your pharmacist or doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Prodeine affects you.

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

Avoid alcohol while taking Prodeine as it may interfere with

the effects of the medicine and may increase the risk of liver side effects.

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

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your pharmacist or doctor has weighed the risk of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

It helps most people with their condition but it may have some unwanted side effects in some people.

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

- constipation
- vomiting
- nausea
- dizziness
- drowsiness
- indigestion
- sweating
- difficulty in passing urine

These are mild side effects of this medicine and usually short-lived.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat

- severe stomach pain, nausea and vomiting
- wheezing or difficulty breathing, shallow breathing or shortness of breath, swelling of the face, lips, tongue or other parts of the body
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- skin rashes

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Prodeine. You may need urgent medical attention or hospitalization.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your pharmacist or doctor.

Storage

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

Keep the medicine in a cool place where the temperature stays below 30°C.

Do not store it or any other medicines in the bathroom, near a sink, or on a window sill.

Do not leave it in the car.

Heat and damp 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

If your pharmacist or doctor tells you to stop taking Prodeine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Prodeine is available as capsule-shaped tablets or 'caplets', which are plain on one side and a breakline on the other.

Prodeine is available in boxes of 24 and 40 caplets.

Ingredients

Active Ingredients:

- 500mg paracetamol per tablet
- 9.6 mg codeine phosphate hemihydrate per tablet

Inactive Ingredients:

- purified talc
- magnesium stearate
- sodium starch glycollate
- compap L

Prodeine does not contain aspirin, sucrose, lactose, gluten or tartrazine.

Manufacturer

Prodeine is supplied in Australia by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

This leaflet was prepared in September 2017.

Australian Registration Number
AUST R 200605

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