

# Prodeine<sup>®</sup>

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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**WARNING:** Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

### 1. Why am I using Prodeine?

Prodeine contains the active ingredients paracetamol and codeine phosphate hemihydrate. Prodeine is used to relieve acute moderate pain and fever.

For more information, see Section [1. Why am I using Prodeine?](#) in the full CMI.

### 2. What should I know before I use Prodeine?

Do not use if you have ever had an allergic reaction to Prodeine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Prodeine?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Prodeine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use Prodeine?**

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

More instructions can be found in Section [4. How do I use Prodeine?](#) in the full CMI.

### **5. What should I know while using Prodeine?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Prodeine.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor or pharmacist if you are taking any other medicines that you use to help you relax, anything that contains alcohol (like cough syrup) or other medicines that treat pain.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take more than the recommended dose unless your doctor tells you to.</li> <li>• Do not give this medicine to children under 12 years of age.</li> <li>• Do not take Prodeine during the third trimester of pregnancy or if you are in labour, especially if the baby is expected to be premature.</li> </ul>
<b>Driving or using machines</b>	Prodeine may cause drowsiness in some people. If this happens, do not drive or operate machinery.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Do not drink alcohol while taking Prodeine as</li> </ul>

	it may interfere with the effects of the medicine and may increase the risk of liver side effects.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 30° C.</li> <li>• Store in a cool, dry place away from young children.</li> </ul>

For more information, see Section [5. What should I know while using Prodeine?](#) in the full CMI.

## **6. Are there any side effects?**

Prodeine may be habit forming if taken frequently or over long periods. Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea or vomiting; drowsiness or dizziness; constipation; stomach pain; skin rashes; sweating. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## **WARNING:**

### **Limitations of use**

Prodeine should only be used if your doctor decides other treatment options are not able to effectively manage your pain or you cannot tolerate them.

### **Hazardous and harmful use**

Prodeine contains codeine which may be habit forming. Prodeine poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will assess your risks and monitor you regularly during treatment.

### **Life threatening respiratory depression**

Serious, life-threatening, or fatal respiratory depression (shallow or difficulty breathing) may occur with the use of Prodeine even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Prodeine 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 Prodeine**

Using Prodeine 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 minimize the dose and duration of use and monitor

you regularly for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking Prodeine.

## Prodeine®

**Active ingredient(s):** *paracetamol and codeine phosphate hemihydrate*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using Prodeine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Prodeine.**

#### Where to find information in this leaflet:

- [1. Why am I using Prodeine?](#)
- [2. What should I know before I use Prodeine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Prodeine?](#)
- [5. What should I know while using Prodeine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Prodeine?

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

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**Prodeine contains the active ingredients paracetamol and codeine phosphate hemihydrate.**

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 for the short term relief of acute moderate pain and fever.**

## **2. What should I know before I use Prodeine?**

### **Warnings**

#### **Do not use Prodeine if:**

- you are allergic to paracetamol or codeine phosphate hemihydrate, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- you are allergic to aspirin or anti-inflammatory medications
- you have severe and/or acute respiratory diseases

- you have acute breathing difficulties such as bronchitis, unstable asthma, emphysema (serious lung disease), respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing).
- you have a Glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency)
- you are an ultra-rapid metaboliser of CYP 2D6 (a fast metaboliser of codeine by the CYP 2D6 enzyme)
- you have had your tonsils or adenoids removed and are aged between 12 and 18 years of age
- you have severe liver or kidney disease
- you are suffering from diarrhea caused by poisoning or antibiotics
- you have chronic constipation

**Do not take codeine if you have a history of drug dependence, including alcohol dependence.**

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

**Do not take Prodeine during the third trimester of pregnancy.**

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

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

**Do not take this medicine after the expiry date (EXP) printed on the pack.**

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

**Do not take this medicine if the packaging is torn or shows signs of tampering.**

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

**Check with your doctor if you:**

- plan to have surgery
- have difficulty breathing, experience wheezing, chronic cough, asthma or other chronic breathing conditions.

**have any form of problems with breathing as a result of emphysema, kyphoscoliosis or obesity**

- have a known analgesic intolerance
- have or have had heart, liver or kidney problems
- underactive thyroid
- have a history of drug dependence, including alcohol dependence
- experience chronic alcohol use including recent cessation of alcohol intake
- have a pre-existing opioid dependence
- have low glutathione reserves
- have Gilbert's syndrome
- have had recent surgery of the stomach or intestine
- have prostate problems
- have multiple sclerosis
- have low blood pressure
- have had a head injury or trauma
- have urinary, bowel or gallbladder conditions

- have chronic constipation
- have problems with the adrenal glands
- have myasthenia gravis, a muscle disorder
- have convulsions, fits or seizures
- if you know you are a CYP 2D6 ultra-rapid metaboliser

**Tell your doctor or pharmacist** about anything listed above before you start taking Prodeine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Prodeine passes into breast milk and there is a possibility your baby may be affected.

**Do not take Prodeine during the third trimester of pregnancy.**

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

This may produce withdrawal effects in the newborn baby.

## **If you are over 65 years of age**

Talk **to** your doctor or pharmacist 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.

## **Addiction**

You can become addicted to Prodeine even if you take it exactly as prescribed. Prodeine may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

## **Dependence**

As with all other opioid containing products, your body may become used to you taking Prodeine. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Prodeine suddenly, so it is important to take it exactly as directed by your doctor.

## **Tolerance**

Tolerance to Prodeine may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

## Withdrawal

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.

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

### 3. What if I am taking other medicines?

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

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

- medicines used to help relax, sleep or relieve anxiety, such as barbiturates, sedatives, tranquillisers, hypnotics, gabapentinoids, cannabis and centrally-active anti-emetics

- benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- antihistamines (medicines used to treat allergies)
- medicines used to treat epilepsy or fits
- medicines which thin the blood such as warfarin
- other opioid analgesics used to treat pain
- 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 heartbeat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- medicines used to treat depression
- 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

- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- medicines used to control electrolytes levels in kidney disease

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.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Prodeine.**

## **4. How do I use Prodeine?**

### **How much to take**

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**

Follow the instructions provided and use Prodeine until your doctor tells you to stop.

## When to take Prodeine

- Prodeine should be used for the temporary relief of acute moderate pain and fever as per the instructions given to you by your doctor.
- **Prodeine is not recommended for 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.

## How to take Prodeine

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 use Prodeine

Prodeine should be used exactly as your doctor has instructed.

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 Prodeine**

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately 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 Prodeine 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 that you have taken too much Prodeine, you may need urgent medical attention.

### **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.

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.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take Prodeine as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

## **5. What should I know while using Prodeine?**

### **Things you should 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 about pain control if Prodeine is not helping.

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

## **Things you should not do**

### **Children:**

- **Do not give this medicine to children under 12 years of age**
- **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.**

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Prodeine affects you.**

Prodeine may cause drowsiness in some people. If this happens, do not drive or operate machinery.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Do not drink while taking **Prodeine**.

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

## **Looking after your medicine**

- Store below 30° C.

Follow the instructions in the carton on how to take care of your medicine properly.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it. A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.**

## **Getting rid of any unwanted medicine**

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.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

### Less serious side effects

Less serious side effects	What to do
<p><b>Stomach and urinary related:</b></p> <ul style="list-style-type: none"><li>• constipation</li><li>• vomiting or nausea</li><li>• indigestion</li><li>• difficulty in passing urine</li></ul> <p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"><li>• ringing in the ear</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>These are mild side effects of this medicine and usually short-lived.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dizziness</li> <li>● drowsiness</li> <li>● dry mouth</li> <li>● headache</li> </ul> <p><b>Allergy related</b></p> <ul style="list-style-type: none"> <li>● sweating</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergy related</b></p> <ul style="list-style-type: none"> <li>● wheezing or difficulty breathing, shallow breathing or shortness of breath, swelling of the face, lips, tongue or other parts of the body</li> <li>● flushing of the face</li> </ul> <p><b>Skin related</b></p> <ul style="list-style-type: none"> <li>● painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills</li> <li>● severe blisters and bleeding in the lips,</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>eyes, mouth, nose and genitals</p> <ul style="list-style-type: none"> <li>● skin rashes</li> </ul> <p><b>Stomach and liver related</b></p> <ul style="list-style-type: none"> <li>● hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)</li> <li>● severe stomach pain, nausea and vomiting</li> </ul> <p><b>Neurological and behavioural</b></p> <ul style="list-style-type: none"> <li>● unusual or extreme mood swings</li> <li>● dizziness, light-headedness</li> <li>● fast heartbeat</li> </ul> <p><b>Metabolism related:</b></p> <ul style="list-style-type: none"> <li>● Symptoms of rapid breathing, rapid heart rate and changes in consciousness caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due</li> </ul>	

Serious side effects	What to do
to low levels of a protein called glutathione).	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before** you decide to stop taking any of your medicines.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Prodeine contains

<b>Active ingredient</b>	Paracetamol and codeine phosphate hemihydrate.
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	COMPAP L, sodium starch glycollate, purified talc, magnesium stearate

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Prodeine looks like**

Prodeine is available as white capsule shaped tablets plain on one side and a break line on the other (Aust R 200605).

Prodeine is available in packs of 24 and 40\* tablets.

\*pack size currently not marketed

## **Who distributes Prodeine**

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Toll Free Number (medical information): 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

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