## Chemists' Own Cold & Flu Relief

Active ingredients: Paracetamol, Pseudoephedrine hydrochloride

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Chemists' Own Cold & Flu Relief. 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 Chemists' Own Cold & Flu Relief.

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

- 1. Why am I using Chemists' Own Cold & Flu Relief?
- 2. What should I know before I use Chemists' Own Cold & Flu Relief?
- 3. What if I am taking other medicines?
- 4. How do I use Chemists' Own Cold & Flu Relief?
- 5. What should I know while using Chemists' Own Cold & Flu Relief?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using Chemists' Own Cold & Flu Relief?

Chemists' Own Cold & Flu Relief contains the active ingredient paracetamol and pseudoephedrine hydrochloride. Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever. Pseudoephedrine hydrochloride belongs to a group of medicines called sympathomimetic decongestants. It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, making it easier to breathe.

Chemists' Own Cold & Flu Relief is used to [insert indication].

# 2. What should I know before I use Chemists' Own Cold & Flu Relief?

#### Warnings

#### Do not use Chemists' Own Cold & Flu Relief if:

 you are allergic to paracetamol, pseudoephedrine hydrochloride, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some to the symptoms of an allergic reaction 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.
- You have very high blood pressure
- Severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- Taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days.

#### Check with your doctor or pharmacist if you:

- have any other medical conditions such as:
  - liver or kidney disease
  - high blood pressure
  - overactive thyroid gland
  - diabetes
  - heart disease and poor blood flow in the blood vessels of the heart
  - glaucoma (high pressure in the eyes)
  - prostate problems
- take any medicines for any other condition.
- have allergies to any other medicines, foods, preservatives or dyes.

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

Do not take this medicine if you are pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Paracetamol may be used if you are breastfeeding. Small amounts of pseudoephedrine pass into the breast milk.

Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are pregnant or breastfeeding.

### 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 and Chemists' Own Cold & Flu Relief 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 use to treat epilepsy or fits
- Chloramphenicol, an antibiotic used to treat ear and eye infections

- Medicines used to treat depression
- Medicines used to treat heart conditions
- Medicines used to treat high blood pressure
- Medicines used to treat urinary tract infections and bladder problems
- Medicines used to treat behavioural disorders
- Phenylephrine, a medicine used to treat congestion
- Appetite suppressants
- Alcohol

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Chemists' Own Cold & Flu Relief.

# 4. How do I use Chemists' Own Cold & Flu Relief?

#### How much to take / use

- Adults and Children 12 years & over: Take 2 tablets every 4 to 6 hours.
- No more than 4 doses in 24 hours.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

# When to take / use Chemists' Own Cold & Flu Relief

Chemists' Own Cold & Flu Relief should be used every 4 to 6 hours when required.

#### How to take Chemists' Own Cold & Flu Relief

Take with water.

# If you use too much Chemists' Own Cold & Flu Relief

If you think that you have used too much Chemists' Own Cold & Flu Relief, 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.

## 5. What should I know while using Chemists' Own Cold & Flu Relief?

#### Things you should 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 this medicine. Remind any doctor, dentist or pharmacist you visit that you are using Chemists' Own Cold & Flu Relief.

### Things you should not do

- Do not give to children under 12 years.
- Do not exceed the recommended dose unless a pharmacist or doctor has told you to.
- Do not take with other medicines containing paracetamol unless advised to by a doctor or pharmacist.
- Do not take for longer than a few days at a time (adults) or 48 hours (children and adolescents) unless advised to by a doctor.
- If you forget to take it,
  - If it is less than 2 3 hours before your next dose, skip the dose you missed and take your next dose when you are meant to take it.
  - Otherwise, take it as soon as you remember and then go back to taking it as you normally would.
  - Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting unwanted side effects.
- Do not take this medicine to treat any other complaints unless told to by your pharmacist or doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Chemists' Own Cold & Flu Relief affects you.

Chemists' Own Cold & Flu Relief may cause dizziness in some people. If this happens, do not drive or operate machinery.

### **Drinking alcohol**

#### Tell your doctor or pharmacist if you drink alcohol.

Only drink small quantities of alcohol (wine, beer or spirits) while taking this medicine. Drinking large quantities or alcohol while taking paracetamol may increase the risk of liver side effects.

#### Looking after your medicine

• Store your medicine below 30°C.

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

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 window sills.

Keep it where young children cannot reach it.

#### 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.

#### Less serious side effects

Less serious side effects	What to do
<ul> <li>Nausea or dyspepsia</li> <li>Drowsiness</li> <li>Difficulty sleeping</li> <li>Nervousness</li> <li>Excitability</li> <li>Restlessness</li> <li>Dizziness</li> <li>Fear or anxiety</li> <li>Rapid heart beat</li> <li>Tremors</li> <li>Hallucinations</li> </ul>	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

#### Serious side effects

Serious side effects	What to do
<ul> <li>Urine retention</li> <li>Shortness of breath</li> <li>Wheezing or difficulty breathing</li> <li>Swelling of the face, lips, tongue or other parts of the body</li> <li>Rash, itching, or hives on the skin.</li> </ul>	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.

Pseudoephedrine may cause sleeplessness if taken up to several hours before going to bed.

Children and people over 65 years of age may have an increased chance of getting side effects.

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

<u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

#### What Chemists' Own Cold & Flu Relief contains

Active ingredient	Paracetamol	
(main ingredient)	Pseudoephedrine hydrochloride	
Other ingredients	• crospovidone	
(inactive ingredients)	<ul> <li>magnesium stearate</li> </ul>	
(	<ul> <li>microcrystalline cellulose</li> </ul>	
	<ul> <li>povidone</li> </ul>	
	<ul> <li>pregelatinised maize starch</li> </ul>	
	stearic acid	
	<ul> <li>purified water</li> </ul>	

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

#### What Chemists' Own Cold & Flu Relief looks like

Chemists' Own Cold & Flu Relief tablets are white, round tablets with a break-line on one side.

The medicine is sold in carton containing either 12 tablets in a blister pack or 24 tablets in 2 blister packs.

(AUST R 308956).

# Who distributes Chemists' Own Cold & Flu Relief

Chemists' Own Cold & Flu Relief are supplied in Australia by:

Arrotex Pharmaceuticals Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121 www.chemistsown.com.au

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