

# CHEMISTS OWN PARACETAMOL PLUS CODEINE & CALMATIVE TABLETS

Paracetamol 500mg, Codeine Phosphate 10mg, Doxylamine Succinate 5.1mg tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Chemists Own Paracetamol Plus Codeine & Calmative tablets. It does not contain all of the information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Chemists Own Paracetamol Plus Codeine & Calmative tablets against the benefits this medicine is expected to have for you.

**Talk to your doctor or pharmacist if you have any concerns about taking this medicine.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What is Chemists Own Paracetamol Plus Codeine & Calmative tablets

The name of your medicine is Chemists Own Paracetamol Plus Codeine & Calmative tablets.

It contains the active ingredients paracetamol, codeine phosphate and doxylamine succinate.

Paracetamol is an analgesic. It also helps in reducing fever. Codeine phosphate is an analgesic and doxylamine succinate is an antihistamine with calmative effects.

In combination, paracetamol, codeine phosphate and doxylamine produce greater analgesia than any of these drugs alone. Chemists Own Paracetamol Plus Codeine & Calmative tablets contain no aspirin.

### What Chemists Own Paracetamol Plus Codeine & Calmative tablets is used for

Chemists Own Paracetamol Plus Codeine & Calmative tablets provide effective temporary relief of moderate to severe pain and discomfort associated with:

- Headache (including tension and migraine)
- Period Pain
- Toothache
- Muscle Pain
- Backache
- Rheumatic Pain
- Neuralgia
- Pain associated with trauma or surgery
- Other pain where a combined analgesic & calmative action is required.

**Your doctor or pharmacist may recommend Chemists Own Paracetamol Plus Codeine & Calmative tablets for another reason.**

**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 Chemists Own Paracetamol Plus Codeine & Calmative tablets

#### *When you must not take it*

**Do not take Chemists Own Paracetamol Plus Codeine & Calmative tablets if you have an allergy to:**

- paracetamol, codeine or doxylamine, or any of the ingredients listed at the end of this leaflet
- you have had an allergic reaction to other opioid analgesics such as morphine or pethidine
- you have had an allergic reaction to other antihistamines.

Symptoms of an allergic reaction to these medicines 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 have or have had any of the following medical conditions:**

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems

**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 if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.**

**Do not take this medicine if you are breastfeeding or plan to breastfeed.**

**It passes into the breast milk and there is a possibility that the baby may be affected.**

**Do not take Chemists Own Paracetamol Plus Codeine & Calmative tablets if the packaging is torn or shows signs of tampering.**

**Do not take Chemists Own Paracetamol Plus Codeine & Calmative tablets if the expiry date (EXP) printed on the pack has passed.**

**Do not take this medicine if you are CYP2D6 ultra-rapid metaboliser.** Aged between 12 – 18 years in whom respiratory function might be compromised, including post tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, due to an increased

risk of developing serious and life-threatening adverse reactions

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

**If you are not sure whether you should start taking Chemists Own Paracetamol Plus Codeine & Calmative tablets, contact your doctor or pharmacist.**

**Do not give Chemists Own Paracetamol Plus Codeine & Calmative tablets to a child under 12 years.**

### Before you start to take it

*Tell your doctor if:*

- **you have any allergies to any other medicines or any other substances**, such as foods, preservatives or dyes
- **you have a history of drug or alcohol dependence**
- aged between 12 – 18 years in whom respiratory function might be compromised, including post tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, due to an increased risk of developing serious and life-threatening adverse reactions
- **you are pregnant or intend to become pregnant**  
Your doctor will discuss the possible risks and benefits of using Chemists Own Paracetamol Plus Codeine & Calmative tablets during pregnancy.
- **you are breast-feeding or plan to breast-feed**  
Your doctor will discuss the possible risks and benefits of using Chemists Own Paracetamol Plus Codeine & Calmative tablets during breast-feeding.
- **you have or have had any medical conditions, especially the following:**
  - kidney or liver disease
  - difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
  - glaucoma a history of drug or alcohol dependence
  - recent surgery on the stomach or intestines
  - head injury
  - enlarged prostate
  - low blood pressure
  - underactive thyroid
  - epilepsy

**If you have not told your doctor or pharmacist about any of the above, tell them before you take any Chemists Own Paracetamol Plus Codeine & Calmative tablets.**

*Taking other medicines*

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

Do not take Chemists Own Paracetamol Plus Codeine & Calmative tablets with any other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

Taking too much paracetamol may cause serious liver damage.

Some medicines may interfere with Chemists Own Paracetamol Plus Codeine & Calmative tablets.

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 Chemists Own Paracetamol Plus Codeine & Calmative tablets, 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 may have more information on medicines to be careful with or avoid while taking Chemists Own Paracetamol Plus Codeine & Calmative tablets.

**If you have not told your doctor or pharmacist about any of the above, tell them before you take any Chemists Own Paracetamol Plus Codeine & Calmative tablets.**

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### How to take Chemists Own Paracetamol Plus Codeine & Calmative tablets

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

Elderly patients are more likely to have side effects from taking these medicines.

#### *How much to take*

Adults and children over 12 years: Take 1-2 tablets every 4-6 hours as necessary.

Do not exceed 8 tablets in a 24-hour period. Do not give to children under 12 years of age.

Talk to your doctor or pharmacist if you do not understand the instructions on the box.

#### *How to take it*

Swallow Chemists Own Paracetamol Plus Codeine & Calmative tablets with a glass of water. Chemists Own Paracetamol Plus Codeine & Calmative tablets can be taken with or without food.

#### *How long to take it*

**WARNING:** Keep to the recommended dose.

**Adults:** Do not take this medicine for longer than a few days at a time unless advised to by a doctor.

**Adolescents and children over 12 years of age:** Do not take this medicine for longer than 48 hours at a time unless advised to by a doctor.

Chemists Own Paracetamol Plus Codeine & Calmative tablets is for minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful.

Codeine may be habit forming if taken frequently and over a long period of time.

**If you are not sure how long to take Chemists Own Paracetamol Plus Codeine & Calmative tablets, talk to your doctor or pharmacist.**

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

#### *If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (Australia 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Chemists Own Paracetamol Plus Codeine & Calmative tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep this telephone number handy.**

If you have taken too much Chemists Own Paracetamol Plus Codeine & Calmative tablets you may feel drowsy, sick in the stomach, or restless.

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While you are using Chemists Own Paracetamol Plus Codeine & Calmative tablets

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#### *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.

**If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Chemists Own Paracetamol Plus Codeine & Calmative tablets.**

**Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking Chemists Own Paracetamol Plus Codeine & Calmative tablets.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Chemists Own Paracetamol Plus Codeine & Calmative tablets.**

#### *Things you must not do*

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

**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 (12-17 years) : Do not take for longer than 48 hours unless your doctor tells you to.**

**Do not give Chemists Own Paracetamol Plus Codeine & Calmative tablets to anyone else, even if they have the same condition as you.**

**Do not use Chemists Own Paracetamol Plus Codeine & Calmative tablets to treat any other complaints unless your doctor or pharmacist tells you to.**

**Do not drink alcohol.**

#### *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 Chemists Own Paracetamol Plus Codeine & Calmative tablets affect you.**

Chemists Own Paracetamol Plus Codeine & Calmative tablets may cause drowsiness or sleepiness in some people. If this happens, do not drive or use operate machinery. Make sure you know how you react to Chemists Own Paracetamol Plus Codeine & Calmative tablets before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

About 8% of people are poor metabolisers of codeine and Chemists Own Paracetamol Plus Codeine & Calmative tablets may not work as well if you are one of those people.

**Talk to your doctor or pharmacist if this medicine is not relieving your pain.**

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### Side Effects

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**Check with your doctor or pharmacist as soon as possible if you have any problems while taking Chemists Own Paracetamol Plus Codeine & Calmative tablets, even if you do not think the problems are related with the medicine or are not listed in this leaflet.**

Like other medicines, Chemists Own Paracetamol Plus Codeine & Calmative tablets can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

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

- drowsiness or sleepiness

- dry mouth, nose and throat
- constipation
- nervousness and irritability
- anxiety
- hallucinations
- twitching or jerking muscles
- fast heart beat
- nausea or dyspepsia
- vomiting
- dizziness

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
- difficult or painful urination
- seizures (fits).

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 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
- rash, itching or hives on the skin
- shortness of breath

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

**Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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**After taking Chemists Own Paracetamol Plus Codeine & Calmative tablets**

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### *Storage*

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

If you take the tablets out of the pack they will not keep well.

**Keep the tablets in a cool dry place where the temperature stays below 25°C. Do not store Chemists Own Paracetamol Plus Codeine & Calmative tablets or any other medicine in the bathroom or near a sink. Do not leave it in the car or on the window sills.**

**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*

**If your doctor or pharmacist tells you to stop taking Chemists Own Paracetamol Plus Codeine & Calmative tablets or the**

**tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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### Product Description

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#### *What it looks like*

Chemists Own Paracetamol Plus Codeine & Calmative tablets are white capsule-shaped tablets with a breakline on one side. They are available in blister packs of 20 and 40 tablets.

#### *Ingredients*

Each Chemists Own Paracetamol Plus Codeine & Calmative tablet contains the following active ingredients:

- Paracetamol 500mg
- Codeine Phosphate 10mg
- Doxylamine Succinate 5.1mg

The following inactive ingredients are found in Chemists Own Paracetamol Plus Codeine & Calmative tablets:

- Starch maize
- Hydroxypropylcellulose
- Sodium lauryl sulphate
- Pregelatinized maize starch
- Silica - colloidal anhydrous
- Talc-purified
- Stearic acid
- Povidone
- Magnesium stearate

Chemists Own Paracetamol Plus Codeine & Calmative tablets is free from preservatives, artificial flavours, artificial colours, yeast, gluten, wheat, lactose or sugar or sucrose.

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### Supplier/Distributor

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Arrow Pharmaceuticals Pty Ltd.  
15-17 Chapel street,  
Cremorne, VIC 3121

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### Distributor

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Arrow Pharma Pty Ltd  
15 – 17 Chapel Street  
Cremorne  
Victoria  
3121

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