Paracetamol and Codeine Phosphate Hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about *Chemists' Own Pain Tablets*. It does not contain all the available 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 Pain Tablets* against the benefits this medicine is expected to have for you.

Keep this information with the tablets.

You may need to read it again.

What are Chemists' Own Pain Tablets

The active ingredients in these medicines are paracetamol and codeine phosphate hemihydrate.

Paracetamol *and codeine phosphate hemihydrate* belongs to a group of medicines called analgesics.

Analgesics are pain relievers used to treat pain. Codeine phosphate hemihydrate belongs to a group of medicine known as 'opioid analgesics'.

Chemists' Own Pain Tablets contain no aspirin.

Chemists' Own Pain Tablets are available as round tablets with 'CO' embossed on one side and a breakbar to allow the tablet to be split in half.

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

What Chemists' Own Pain Tablets are used for

*Chemists' Own Pain Tablets*are for the temporary relief of strong pain. They provide effective temporary relief of

pain and discomfort associated with:

- Backache
- Headache
- Migraine Headache
- Muscle Pain
- Neuralgia
- Rheumatic Pain
- Toothache
- Period Pain
- Tension Headache
- Symptoms of Colds and Flu
- Pain associated with trauma or surgery.

Your doctor or pharmacist may recommend *Chemists' Own Pain Tablets* for another reason. If you want more information ask your doctor or pharmacist.

Before you take Chemists' Own Pain Tablets

When you must not take it

Do not take Chemists' Own Pain Tablets if:

 you have an allergy to:

 Paracetamol or Codeine Phosphate hemihydrate, or any of the ingredients listed under "Product Description" at the end of this leaflet.
 The Symptoms of an allergic reaction

 may include a rash, asthma attack or hay fever.

- Do not take this medicine if you have any of the following conditions:

 Acute breathing difficulties such as bronchitis, unstable asthma or emphysema
 - Glucose-6-phosphate-dehydrogenase deficiency (an enzyme deficiency)
 - Ultra-rapid metaboliser of CYP 2D6
 - Liver failure
 - chronic constipation

- Diarrhoea caused by antibiotics or poisoning

- Do not take this medicine if you have a history of drug dependence, including alcohol dependence.
- Do not take this medicine if you have experienced systemic allergy (generalised rash or shortness of breath) to morphine or oxycodone.
- Do not take this medicine if you have a history of intolerance to paracetamol and/or codeine.
- Do not take this medicine if you are under 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.
- Do not take this medicine during the third trimester of pregnancy.
- Do not take this medicine during labour, especially if the baby is premature.

This medicine contains codeine, which may produce withdrawal effects in the newborn baby.

- Do not take this medicine if you are breastfeeding planning to breastfeed. The medicine passes into breast milk and may affect the baby.
- Do not use this medicine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date it may have no effect at all, or worse, have an entirely unexpected effect.

- Do not use this medicine if the packaging is torn or shows signs of tampering.
- Do not use this medicine to treat any other complaint unless your doctor says it is safe.
- Chemists' own pain Tablets is not recommended for children under 12 years.

Before you start to take Chemists' Own Pain Tablets

Tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- Aspirin or any other NSAID medicine
- Any other substances, such as foods, preservatives or dyes
- Any ingredients listed under "product Description" at the end of this leaflet
- Difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions

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

- Lung, heart, liver or kidney problems
- Difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- A history of drug dependence, including alcohol dependence
- You drink large quantities of alcohol
- Recent cessation of alcohol intake
- Low glutathione reserves
- Gilbert's syndrome
- Gall bladder problems or your gall bladder has been removed
- Multiple sclerosis
- Recent stomach, intestine or urinary tract surgery
- Irritable bowel syndrome or other bowel problems
- Prostate problems
- Under active thyroid gland or problems with your adrenal glands
- Head injury
- Fits or Seizures
- Brain tumours

Tell your doctor if you are pregnant or are planning to become pregnant.

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

If you have not told your doctor about any of these things, tell them before you take any Chemists' own pain tablets.

Taking other medicines

You should also tell your doctor about any other medicines that you have bought without a prescription from either your pharmacy, supermarket or health food shop.

Tell your doctor if you are using any other medicines.

Including any of the following medicines:

- Any medicine causing sleepiness or drowsiness
- Tranquillisers (medicines for anxiety and nerves)
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- Medicines used to treat alcohol and/or opioid dependence (eg naltrexone or buprenorphine)
- Medicines containing alcohol (ethanol), e.g. some cough syrups
- Cough suppressants or antitussives
- Antihistamines (medicines used to treat allergies)
- Medicines used to treat depression
- Medicines used to treat mental illness
 Warfarin, a medicine used to prevent blood clots
- Medicines to treat epilepsy
- Other pain relief medication
- Medicines used to treat high blood
 pressure
- Medicines used to relax musclesMetoclopramide, a medicine used to

control, nausea or vomiting

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- Propantheline, a drug used to treat stomach ulcers
- Cholestyramine (medicine used to treat bile problems and/or high cholesterol
- Chelating resin
- Chloramphenicol (antibiotic used to treat ear and eye infections)
- Flucloxacillin, zidovudine or rifampicin (medicines used to treat infections)
- Medicines for diarrhoea, such as Kaolin, pectin and loperamide
- Medicines used to treat parkinson's disease.
- Medicines used to relieve stomach cramps or spasms
- quinidine, a medicine used to treat abnormal or irregular heartbeat.

These medicines may be affected by Chemists own pain tablets or may affect how well Chemists own pain tablets works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take Chemists' Own Pain Tablets

The label on your pack of Chemists' own pain tablets will tell you how to take your medicine and how often.

If you are unsure about the directions ask your doctor or pharmacist.

Do not take more than the dose your doctor or pharmacist has directed.

The dosage recommended by the doctor may be different to the recommended dosage.

The recommended dose of Chemists' own pain tablets is:

Adults: 1 tablet for mild to moderate pain. 2 tablets for severe pain.

This dosage may be repeated in 4-6 hours if necessary.

Do not take more than 8 tablets in 24 hours.

Do not take more than the recommended dose.

Taking more than the recommended dose may cause liver damage.

Talk to your doctor about pain control if the medicine is not helping.

If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine.

How to take it

Swallow the tablets with water.

The directions given to you by your doctor or pharmacist may be different from the information in this leaflet. If you are unsure what dose to take ask your pharmacist or doctor.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to a hospital straight away, even if you feel well, because of the risk of delayed, serious liver damage.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers of these places handy.

If you take too many tablets you may feel nauseous, light headed, dizzy or drowsy.

While you are taking Chemists' Own Pain Tablets

Things you must do

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking *Chemists' Own Pain Tablets.*

Tell all of the doctors, dentists, and pharmacists that are treating you that you are

taking Chemists' Own PainTablets. Things you must not do

Do not give *Chemists' Own Pain Tablets* to anyone else, even if they have the same condition as you.

Do not use *Chemists' Own Pain Tablets* to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

This medication may cause dizziness. If affected, do not drive a vehicle or operate machinery. If you drink alcohol, dizziness or drowsiness could be worse. Be careful driving or operating machinery until you know how Chemists' Own Pain Tablets affect you.

Codeine may be habit forming if taken frequently and over a long period. Please ask your doctor or pharmacist if you are concerned about this.

About 8% of people are poor metabolisers of codeine and Chemists' Own Pain Tablets may not work as well if you are one of those people.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Chemists' own pain tablets.

Like other medicines, Chemists' Own Pain Tablets can cause some side effects. If they occur, they are most likely minor and temporary. However, sometimes they are serious and need medical treatment.

If you have any questions, ask your doctor or pharmacist.

Tell your doctor if you notice any of these side effects and they worry you.

- skin rashes
- dry mouth
- dizziness
- drowsiness
- nausea and vomiting
- stomach pain
- constipation
- Sweating

Tell your doctor as soon as possible if you notice any of these following:

- Shortness of breath
- Mouth ulcers, fever and sore throat
- Bleeding, bruising more easily
- Unusual or extreme mood swings
- Dizziness, light-headedness
- Flushing of the face
- Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

The above list includes serious side effects that may require medical attention. These side effects are rare.

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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare. If you are taking Chemists' own pain tablets regularly, you may also need to take laxatives to prevent constipation.

Some people may get other side effects not listed above.

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

After taking Chemists' Own Pain Tablets

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 Chemists' own pain tablets in a cool dry place where the temperature stays below 30°C.

Do not store *Chemists' Own Pain Tablets* or any other medicine in the bathroom or near a sink.

Do not leave this medicine in the car on hot days.

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 tells you to stop taking *Chemists' Own Pain Tablets* or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Chemists' Own Pain Tablets are White, round flat bevelled edged tablets, with "CO" embossed on one side and a break bar. They are available in blister packs containing 24 and 40 tablets or in glass bottles containing 40 tablets.

Ingredients

Chemists' Own Pain Tablets

Each *Chemists' Own Pain Tablets* contain the following active ingredients:

Paracetamol 500 mg

• Codeine Phosphate hemihydrate 10 mg The following inactive ingredients are found in *Chemists' Own Pain Tablets:*

- Starch maize
- Cellulose microcrystalline
- Silica colloidal anhydrous
- Povidone
- Croscarmellose sodium
- Stearic acid
- Magnesium stearate

Chemists' Own Pain Tablets do not contain lactose, sucrose, gluten, tartrazine or azo dyes.

Manufacturer

Supplied by: -Chemists own Arrow Pharma Pty Ltd 15-17 Chapel Street Cremorne VIC 3121

Website: www.chemistsown.com.au

The Australian Registration number for *Chemists' Own Pain Tablets* in blister packs is AUST R 93836.

The Australian Registration number for *Chemists' Own Pain Tablets* in glass bottles is AUST R 93828.

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