Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Chemists' Own® Strong Pain Extra 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 Strong Pain Extra 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 Chemists' Own Strong Pain Extra used for

Chemists' Own Strong Pain Extra is used to relieve moderate to severe pain.

Chemists' Own Strong Pain Extra contains paracetamol and codeine.

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

Paracetamol also acts in the brain to reduce fever. Codeine phosphate is an opioid pain reliever.

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/give Chemists' Own Strong Pain Extra

When you must not take it

Do not take *Chemists' Own strong pain* extra 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 Strong Pain Extra is not recommended for children under 12 years.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- Aspirin or any other NSAID medicineAny other substances, such as foods,
- preservatives or dyes Any ingredients listed under "product
- Description" at the end of this leafletDifficulty 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 strong pain extra.

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 muscles
- Metoclopramide, a medicine used to control, nausea or vomiting
- 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 strong pain extra or may affect how well Chemists own strong pain extra works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take Chemists' Own Strong Pain Extra

The label on your pack of Chemists' Own Strong Pain Extra will tell you how to take your medicine and how often. If you are unsure about the directions ask your doctor or pharmacist.

The usual dose of Chemists' Own Strong Pain Extra is:

Adults:

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

You should not take more than 8 tablets in a 24-hour period.

If Chemists' Own Strong Pain Extra is not adequately controlling your pain, do not increase the dose. Please see your doctor. Chemists' Own Strong Pain Extra is not recommended for children under 12 years. Swallow tablets whole with a little water or other liquid.

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

If you take too much (overdose)

Immediately telephone your doctor or 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 Chemists' Own Strong Pain Extra.

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 Strong Pain Extra

Things you must do

Take Chemists' Own Strong Pain Extra exactly as your pharmacist or doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are taking Chemists' Own Strong Pain Extra.

Tell your doctor or pharmacist if you become pregnant while taking Chemists' Own Strong Pain Extra.

Things you must NOT do

Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe. Do not give this medicine to anyone else even if they have the same symptoms as you.

Things to be careful of

Chemists' Own Strong Pain Extra may cause dizziness or drowsiness in some people, especially after the first dose.

If affected do not drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or drowsy. Children should not ride bikes if affected and should be supervised to avoid potential harm.

Do not drink alcohol.

Drinking alcohol increases the likelihood of becoming drowsy.

Chemists' Own Strong Pain Extra may be habit forming if taken in high doses for extended periods of time.

Please ask your doctor or pharmacist if you are concerned about this. About 8% of people are poor metabolisers of codeine and Chemists' Own Strong Pain Extra 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 strong pain extra.

Like other medicines, Chemists' Own Strong Pain Extra 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 strong pain extra 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 Strong Pain Extra

Storage

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

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

Keep Chemists' Own Strong Pain Extra in a cool dry place where the temperature stays below 30°C.

Heat and dampness can destroy some medicines. Do not leave Chemists' Own Strong Pain Extra in the car on hot days.

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

Keep Chemists' Own Strong Pain Extra

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.

Disposal

If your pharmacist or doctor tells you to stop taking the tablets, ask your pharmacist what to do with any tablets that are left over.

This is not all the information that is available on Chemists' Own Strong Pain Extra.

If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product description

Chemists' Own Strong Pain Extra comes as a white, scored, capsule shaped tablet.

A box contains 24 or 40 tablets.

Active ingredients

Each Chemists' Own Strong Pain Extra tablet contains:

- Paracetamol 500 mg
- Codeine Phosphate 15 mg

Other ingredients:

- Starch maize
- Hydroxypropylcellulose
- Starch-Pregelantinised maize
- Sodium lauryl sulphate
- Talc-purified
- Silica colloidal anhydrous
- Magnesium stearate

Supplier

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

Aust R number: 208276

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