

Codapane

Paracetamol / Codeine phosphate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Codapane.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Codapane is used for

Codapane is used to relieve temporary, moderate to severe pain and discomfort associated with:

- headache, migraine headache, tension headache
- earache
- toothache
- dental procedures
- muscle pain
- period pain
- arthritis, rheumatics, oosteoarthritis
- back pain
- neuralgia
- sore throats and symptoms of cold and flu.

Codapane is also used to reduce fever and/or the discomfort associated with fever.

Codapane contains the active ingredients 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.

Ask your doctor or pharmacist if you have any questions about why Codapane has been recommended for you.

Your doctor or pharmacist may have recommended Codapane for another reason.

Codapane is not recommended for use in children under 7 years of age.

Codapane may be habit forming if taken in high doses for extended periods of time.

Before you take Codapane

When you must not take it

Do not take Codapane if you are allergic to medicines containing paracetamol or codeine phosphate or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Codapane if you:

- drink large quantities of alcohol
- experiencing breathing difficulties such as bronchitis, unstable asthma or emphysema.

Do not take Codapane if the expiry date (EXP) printed on the pack has passed.

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

Do not take Codapane if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to take it

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.

Codapane may be used during pregnancy if advised by your doctor. However, it is recommended that non-drug therapies, such as rest and massage, be tried first.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Codeine passes into breast milk. In general, single use of Codapane, as advised by your doctor, is possible during breastfeeding. Repeat use is not recommended unless your doctor has explicitly advised you to do so. If your baby has difficulty breastfeeding or shows symptoms such as unusual sleepiness or lethargy, contact your doctor immediately.

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

- lung, liver or kidney problems
- drug dependence, including alcohol dependence.

Your doctor or pharmacist may want to take special care if you have any of these conditions.

Tell your doctor or pharmacist if you plan to have surgery.

Taking other medicines

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

Some medicines may be affected by Codapane, or may affect how well it works. These include:

- monoamine oxidase inhibitors (medicines used to treat depression) taken within the last 10 days
- salicylates or non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin or ibuprofen
- diflunisal, an anti-inflammatory medicine
- anticholinergic (medicines used to relieve stomach cramps or spasms, to prevent travel sickness, or to treat Parkinson's disease)
- chloramphenicol, a medicine used to treat infections
- cholestyramine, a medicine used to treat high blood cholesterol, and/or other conditions
- any medicine causing sleepiness or drowsiness
- medicines used to treat anxiety, nerves, depression or other mental disorders
- medicines used to thin the blood including Warfarin
- medicines used in epilepsy
- other strong pain relievers.
- medicines used to treat high blood pressure
- medicines used to relax muscles

- medicines used to treat diarrhoea, nausea or vomiting, including metoclopramide, kaolin, pectin and loperamide

These medicines may be affected by Codapane or may affect how well Codapane works.

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Codapane.

How to take Codapane

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Keep to the recommended doses.

ADULTS AND

CHILDREN OVER 12 YEARS

Take 1 to 2 tablets every three to four hours if necessary.

Maximum 8 tablets in 24 hours.

Do not take Codapane for more than a few days at a time unless advised to by your doctor.

CHILDREN 7 TO 12 YEARS

Take half to 1 tablet every three to four hours if necessary.

Maximum 4 tablets in 24 hours.

Do not give children Codapane for more than 48 hours at a time unless advised to by a doctor.

Codapane is not recommended for children under 7 years of age.

How to take Codapane

Swallow the tablets with a glass of water.

If required, Codapane tablets can be halved along the breakline.

If you take too much Codapane (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Codapane.

Do this even if you feel well because of the risk of delayed, serious liver damage.

You may need urgent medical attention.

If you take too much Codapane, you may have stomach pain and feel nauseous, lightheaded, dizzy or drowsy, or have difficulty breathing.

While you are taking Codapane

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Codapane.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Codapane.

If you become pregnant while taking Codapane, tell your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Codapane.

If you are about to have any blood test, tell your doctor that you are taking this medicine.

If your symptoms do not improve within a few days, or if they become worse, tell your doctor.

Things you must not do

Do not use Codapane to treat any other conditions unless your doctor tells you to.

Do not take Codapane with other products containing paracetamol, unless advised to do so by your doctor.

Things to be careful of

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take Codapane as recommended by your doctor. If symptoms such as blurred vision, dizziness, sleepiness, abdominal pain, or circulatory problems occur, contact your doctor immediately.

Be careful driving or operating machinery until you know how Codapane affects you.

Codapane may cause drowsiness, dizziness or light headedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous. Children should not ride bikes if affected and should be supervised to avoid potential harm.

Be careful when drinking alcohol while taking Codapane.

Combining Codapane and alcohol can make you more sleepy, dizzy or lightheaded.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Codapane.

Codapane helps most people manage pain and fever, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

The side effects listed above are serious and require urgent medical attention or hospitalisation. These side effects are very rare.

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

- shortness of breath
- signs of infrequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding, bruising more easily
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face

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

- heartburn
- constipation
- nausea, vomiting
- stomach pain
- dizziness
- drowsiness
- skin rashes
- sweating.

The above list includes the more mild side effects of Codapane.

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

Other side effects not listed above may also occur in some people.

After taking Codapane

Storage

Keep Codapane 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.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Codapane or any other medicine in the bathroom or near a sink.

Do not leave Codapane in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If you stop taking Codapane, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Codapane is a round white tablet marked "P" breakline "C" on one side, "α" on the other.

Codapane is available in packs of 24 tablets.

Codapane is a pharmacist only medicine which can be purchased from your pharmacy without a doctor's prescription. Your pharmacist's advice is required for purchase.

Ingredients

The active ingredients in Codapane are paracetamol and codeine phosphate.

Each Codapane tablet contains 500mg of paracetamol and 8 mg of codeine phosphate.

The tablets also contain the following inactive ingredients:

- crospovidone
- silica - colloidal anhydrous
- stearic acid
- magnesium stearate
- sodium lauryl sulfate.

The tablets contain maize starch.

Manufacturer

Codapane is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration number:

Codapane - AUST R 50763

This leaflet was prepared on

28 May 2010.