

# Codapane Forte

*Paracetamol and codeine phosphate hemihydrate*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Codapane Forte.

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 has weighed the risks of you taking Codapane Forte against the benefits this medicine is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What Codapane Forte is used for

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Codapane Forte is used to relieve moderate to severe pain, and fever.

Codapane Forte contains paracetamol and codeine. These ingredients work together to stop the pain messages from reaching the brain.

Paracetamol also acts in the brain to reduce fever.

**Ask your doctor if you have any questions about why Codapane Forte has been prescribed for you.**

Your doctor may have prescribed Codapane Forte for another reason.

This medicine may be addictive after repeated administration.

Codapane Forte is not recommended for children under 12 years of age.

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

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### Before you take Codapane Forte

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*When you must not take it*

**Do not take Codapane Forte if you have an allergy to:**

- any medicine containing paracetamol or codeine
- any of the ingredients listed at the end of this leaflet
- any other similar medicines, such as morphine and oxycodone.
- Aspirin or any other NSAID medicine.

Some of the symptoms of an allergic reaction 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 Codapane Forte if you:**

- breathing difficulties, such as asthma, bronchitis or emphysema
- Glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency)
- Ultra-rapid metaboliser of CYP2D6
- diarrhoea caused by poisoning or antibiotic therapy

- history of intolerance to paracetamol and/or codeine
- Liver failure
- Alcohol dependence.

**Do not take Codapane Forte if you are aged between 12 to 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.**

**Do not take Codapane Forte during the third trimester of pregnancy.**

**Do not take Codapane Forte during labour especially if the baby is premature.**

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

**Do not take Codapane Forte if you are breastfeeding or planning to breastfeed.**

This medicine passes into breast milk and may affect the baby. If you require Codapane Forte therapy, breastfeeding should be stopped and alternative arrangements should be made for feeding the baby during treatment period.

**Do not take Codapane Forte after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

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

**Codapane Forte is not recommended for children under 12 years.**

### *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- lung disease, such as asthma, bronchitis or emphysema
- liver disease, hepatitis, or are taking other drugs that may affect the liver
- kidney disease or difficulty urinating
- irritable bowel syndrome or other bowel problems
- diarrhoea caused by poisoning
- recent gastrointestinal or urinary tract surgery
- prostate problems
- history of fits, convulsions or seizures
- depression
- a history of drug dependence, including alcohol dependence
- you drink large quantities of alcohol
- recent cessation of alcohol
- low glutathione reserves
- Gilbert's syndrome
- Gall bladder problems or your gall bladder has been removed
- Multiple sclerosis
- an underactive thyroid gland or adrenal glands not working properly (e.g. Addison's disease)
- head injury or brain tumour
- if you are under 18 and have undergone adenoidectomy and/or tonsillectomy
- if you know you are a CYP 2D6 ultra-rapid metaboliser.

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

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

Your doctor can discuss with you the risks and benefits of taking Codapane Forte while being pregnant.

**Tell your doctor if you plan to have surgery that requires a general anaesthetic.**

Codapane Forte may affect other medicines used during surgery.

**If you have not told your doctor about any of the above, tell him/her before you start taking Codapane Forte.**

### *Taking other medicines*

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

Some medicines and Codapane Forte may interfere with each other. These include:

- any medicine causing sleepiness or drowsiness
- tranquillisers (medications for anxiety and nerves)
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- cough suppressants or antitussives
- Medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone or buprenorphine)
- Antihistamines (medicines used to treat allergies)
- medicines used to treat depression
- medicines used to treat mental illness
- 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
- other pain relievers
- diflunisal, an anti-inflammatory medicine
- anticholinergics (medicines used to relieve stomach cramps or spasms, to prevent travel

sickness, or to treat Parkinson's disease)

- medicines which thin the blood, such as warfarin
- medicines used to relax muscles
- medicines to treat epilepsy
- chloramphenicol, a medicine used to treat ear and eye infections
- flucloxacillin, rifampicin or zidovudine, medicines used to treat infections
- medicines used to lower high blood pressure
- medicines used to treat diarrhoea, including kaolin, pectin and loperamide
- metoclopramide, a medicine used to treat nausea and vomiting
- colestyramine, a medicine used to treat high blood cholesterol, and/or other conditions
- chelating resin.

These medicines may be affected by Codapane Forte 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 Codapane Forte.

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## How to take Codapane Forte

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**Always follow the directions given to you by your doctor or pharmacist.**

These directions may differ from the information contained in this leaflet.

**If you do not understand the directions on the box, ask your doctor or pharmacist for help.**

### *How much to take*

Adults:

The usual dose of Codapane Forte is 1 to 2 tablets.

This dosage may be repeated every 4 to 6 hours if needed.

**Do not take more than 8 tablets in 24 hours.**

**If Codapane Forte is not adequately relieving your pain, do not increase the dose. Please see your doctor.**

Codapane Forte is not recommended for children under 12 years.

#### *How to take it*

**Swallow Codapane Forte with a glass of water.**

#### *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 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 Codapane Forte. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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

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## While you are taking Codapane Forte

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### *Things you must do*

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

**If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Codapane Forte.**

**Tell your doctor if you become pregnant while taking Codapane Forte.**

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

It may interfere with the results of some tests.

### *Things you must not do*

**Do not give Codapane Forte to anyone else, even if they have the same condition as you.**

**Do not use Codapane Forte to treat any other complaints unless your doctor tells you to.**

**Do not take alcoholic drinks.** Combining Codapane Forte and alcohol can make you drowsier.

### *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 Forte as recommended by your doctor. If symptoms such as blurred vision, dizziness, sleepiness, abdominal pain, or circulatory problems occur, contact your doctor immediately.**

Codapane Forte may cause dizziness or drowsiness in some people, especially after the first dose.

**If you are 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.

Codapane Forte may be addictive if taken in high doses for extended periods of time.

**Ask your doctor or pharmacist if you are concerned about this.**

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## Side effects

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

Like other medicines, Codapane Forte 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

**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:**

- constipation
- nausea (feeling sick)
- vomiting
- Stomach pain
- dizziness, light-headedness
- drowsiness
- skin rashes
- sweating.

These are the more common side effects of Codapane Forte. They are usually mild.

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

- Shortness of breath
- fever, sore throat or mouth ulcers
- bleeding or bruising more easily than normal

- 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).
- difficulty passing 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

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

Some people may get other side effects that are not listed above.

If you are taking Codapane Forte regularly, you may also need to take laxatives to prevent constipation.

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

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## After taking Codapane Forte

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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 box and blister pack they will not keep well.

**Keep Codapane Forte tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store Codapane Forte or any other medicine in the bathroom or near a sink. Do not leave it in the car or on 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 tells you to stop taking Codapane Forte 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*

Codapane Forte tablets are white, oblong, convex tablets with "PC/F" ("PC" over breakline over "F") on one side and "α" on the other.

They are available in packs of 20s.

### *Ingredients*

The active ingredients in Codapane Forte tablets are paracetamol (present as "Compap L") and codeine phosphate hemihydrate. Each tablet contains 500 mg paracetamol and 30 mg codeine phosphate hemihydrate.

The tablets also contain the following inactive ingredients:

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

Codapane Forte tablets contain maize starch.

They do not contain lactose or sugar.

### *Supplier*

Codapane Forte is supplied in Australia by:

Alphapharm Pty Limited  
(ABN 93 002 359 739)  
Level 1, 30 The Bond  
30-34 Hickson Road  
Millers Point NSW 2000

www.mylan.com.au

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