CODALGIN® FORTE

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking CODALGIN FORTE, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the <u>full CMI</u>. Read before taking CODALGIN FORTE.

1. Why am I taking CODALGIN FORTE?

CODALGIN FORTE contains the active ingredients paracetamol and codeine phosphate hemihydrate. CODALGIN FORTE is used for the short-term management of severe pain when all other pain management options have not worked. For more information, see Section 1. Why am I using CODALGIN FORTE? in the full CMI.

2. What should I know before I take CODALGIN FORTE?

Do not use if you have ever had an allergic reaction to CODALGIN FORTE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or breastfeeding or plan to become pregnant or breastfeed.

You may develop addiction, dependence, and tolerance. For more information, see Section 2. What should I know before I take CODALGIN FORTE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CODALGIN FORTE and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take CODALGIN FORTE?

The standard dose for adults is 1 or 2 tablets for severe pain, taken every 4 to 6 hours if necessary. More instructions can be found in Section 4. How do I take CODALGIN FORTE? in the full CMI.

5. What should I know while taking CODALGIN FORTE?

Things you should do

 Tell your doctor, dentist or pharmacist you visit that you are taking CODALGIN FORTE.

	 Talk to your doctor about pain control if the medicine is not helping. Tell your doctor if you become pregnant while taking CODALGIN FORTE.
Things you should not do	 Do not take more than the recommended dose, unless your doctor tells you to. Do not take more than 8 tablets a day. Do not give CODALGIN FORTE to children under 12. Do not take high doses of the medicine for long periods of time, unless your doctor tells you to.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how CODALGIN FORTE affects you as it may cause dizziness, drowsiness, or light- headedness in some

	people, especially after the first dose.
Drinking alcohol	 Do not drink alcohol while taking CODALGIN FORTE.
Looking after your medicine	 Store below 30°C. Keep medicines where children cannot reach them. A locked cupboard at least one- and-a-half metres above the ground is a good place to store medicines.

For more information, see Section <u>5. What should I know while taking CODALGIN FORTE?</u> in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist immediately if you notice any of the following side effects 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. They may be the signs of an allergic reaction. Tell your doctor or pharmacist if you notice any of the following and they worry you: nausea or vomiting; constipation; drowsiness or dizziness. These are more common side effects of your medicine. They are usually mild. For more information, including what to do if you

have any side effects, see Section <u>6. Are there any side</u>
effects? in the full CMI.

WARNING:

Limitations of Use

You should only take CODALGIN FORTE when your doctor decides that other treatment options are not able to effectively manage your pain, or you cannot tolerate them.

Hazardous and Harmful Use

CODALGIN FORTE poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life Threatening Respiratory Depression

CODALGIN FORTE can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when taken as recommended. These problems can occur at any time during use, but the risk is higher when first starting CODALGIN FORTE and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of Other Medicines While Taking CODALGIN FORTE

Taking CODALGIN FORTE with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing

problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking CODALGIN FORTE.

CODALGIN® FORTE

Active ingredients: paracetamol and codeine phosphate hemihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CODALGIN FORTE. Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CODALGIN FORTE.

Where to find information in this leaflet:

- 1. Why am I taking CODALGIN FORTE?
- 2. What should I know before I take CODALGIN FORTE?
- 3. What if I am taking other medicines?
- 4. How do I take CODALGIN FORTE?
- 5. What should I know while taking CODALGIN FORTE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking CODALGIN FORTE?

CODALGIN FORTE contains the active ingredients paracetamol and codeine phosphate hemihydrate.

Paracetamol and codeine phosphate hemihydrate work together to stop the pain messages from getting through to the brain. Your doctor may have prescribed CODALGIN FORTE for another purpose.

CODALGIN FORTE is used to relieve severe pain for which other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain.

2. What should I know before I take CODALGIN FORTE?

Warnings

Do not take CODALGIN FORTE if:

- you are allergic to paracetamol or codeine phosphate hemihydrate, or any of the ingredients listed at the end of this leaflet.
 - Always check the ingredients to make sure you can take CODALGIN FORTE.
- you have acute breathing difficulties such as bronchitis, unstable asthma or emphysema.

- you have Glucose-6-phosphatedehydrogenase deficiency (an enzyme deficiency).
- you are a CYP 2D6 ultra-rapid metaboliser (a fast metaboliser of codeine by the CYP 2D6 enzyme).
- you have diarrhoea caused by antibiotics or poisoning.
- you have liver failure.

Do not take CODALGIN FORTE if you have a history of drug dependence, including alcohol dependence.

Do not take CODALGIN FORTE if you have experienced systemic allergy (generalised rash or shortness of breath) to morphine or oxycodone.

Do not take CODALGIN FORTE if you have a history of intolerance to paracetamol and/or codeine.

Do not take CODALGIN FORTE if you are under 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Do not take CODALGIN FORTE during the third trimester of pregnancy.

Do not take CODALGIN FORTE during labour especially if the baby is premature.

Do not take CODALGIN FORTE if you are breastfeeding or planning to breastfeed.

Do not take CODALGIN FORTE after the expiry date 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 take CODALGIN FORTE if the packaging is torn or shows signs of tampering.

Do not take CODALGIN FORTE to treat any other complaint unless your doctor says it is safe.

CODALGIN FORTE is not recommended for children under 12 years.

Check with your doctor if you have or have had any of the following medical conditions:

- lung, heart, liver or kidney problems
- problems with your pancreas
- low blood pressure
- difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- sleep problems such as sleep apnoea
 CODALGIN FORTE can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.
- a history of drug dependence, including alcohol dependence
- you drink large quantities of alcohol
- mild-to-moderate hepatocellular insufficiency
- severe renal insufficiency and sepsis
- chronic alcohol use including if you recently stopped drinking alcohol
- poor nutrition and other sources of low glutathione reserves

- Gilbert's syndrome (a liver condition that can sometimes make your skin or eyes look yellow)
- gall bladder problems or your gall bladder has been removed
- multiple sclerosis (a disease that affects the nerves and can cause problems with movement, vision, or feeling)
- 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
- fits or seizures
- head injury
- brain tumours

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or plan to become pregnant.

Do not take CODALGIN FORTE during the third trimester of pregnancy.

Do not take CODALGIN FORTE during labour, especially if the baby is premature.

CODALGIN FORTE can cause breathing problems and may produce withdrawal effects in the newborn baby.

Do not take CODALGIN FORTE if you are breastfeeding or plan to breastfeed.

CODALGIN FORTE passes into breast milk and may affect the baby.

Addiction

You can become addicted to CODALGIN FORTE even if you take it exactly as prescribed. CODALGIN FORTE may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking CODALGIN FORTE. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking CODALGIN FORTE suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to CODALGIN FORTE may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

3. What if I am taking other medicines?

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

Some medicines may interfere with CODALGIN FORTE and affect how it works.

These include:

- any medicine causing sleepiness or drowsiness
- tranquillisers (medicines for anxiety and nerves)
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- gabapentin and pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)
- 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
- 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

- medicines which thin the blood
- medicines to treat epilepsy
- other pain relief medication
- medicines used to treat high blood pressure
- medicines used to relax muscles
- medicines used to treat diarrhoea, 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 used to control electrolytes levels in kidney disease

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CODALGIN FORTE.

4. How do I take CODALGIN FORTE?

How much to take

- The recommended dose of CODALGIN FORTE is:
 Adults: 1 or 2 tablets for severe pain. This dosage may be repeated in 4-6 hours if necessary.
- Follow the instructions provided.
- 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.

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 doctor or pharmacist.

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

Depending on your body's individual ability to break down codeine, you may be getting reduced benefit or experience signs of overdose even when you take CODALGIN FORTE as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

How to take CODALGIN FORTE

Swallow the tablets with water.

How long to take it for

 Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take CODALGIN FORTE

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

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

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

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

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

If you take too much CODALGIN FORTE

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally taken CODALGIN FORTE that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits
- Mental impairment

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think that you have taken too much CODALGIN FORTE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while taking CODALGIN FORTE?

Things you must do

Take CODALGIN FORTE exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while taking CODALGIN FORTE.

Tell your doctor, dentist or pharmacist you visit that you are taking CODALGIN FORTE.

If your pain gets worse after you take CODALGIN FORTE, do not take more without first talking to your doctor.

Talk to your doctor, if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking CODALGIN FORTE.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Things you must not do

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

Adults should not take more than 8 tablets a day.

 Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Taking more than the recommended dose can cause liver damage.

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

 Do not give CODALGIN FORTE to anyone else, even if they have the same symptoms as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CODALGIN FORTE affects you.

CODALGIN FORTE may cause dizziness, lightheadedness, drowsiness and problems with vision in some people, especially after the first dose.

Children should not ride bikes if affected and should be supervised to avoid potential harm.

Drinking alcohol

Do not drink alcohol while taking CODALGIN FORTE.

Drinking alcohol increases the likelihood of becoming drowsy.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop taking CODALGIN FORTE suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size

- watery eyes, runny nose, chills or yawning
- increased sweating

CODALGIN FORTE given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn. Withdrawal symptoms in the newborn can also occur with long-term use during pregnancy.

Looking after your medicine

Store below 30°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it 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.

When to dispose of your medicine

- If you no longer need to take it
- After the expiry date
- The tamper evident seal has been damaged when you receive it

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related	Speak to your doctor if
constipation	you have any of these less serious side effects.
indigestion	
nausea or vomiting	
stomach pain	
severe abdominal pain	
have difficulty	
swallowing,	
regurgitation, chest pain	
that is not related to	
your heart, especially	
if you have been using	

Less serious side effects	What to do
CODALGIN FORTE for a long time	
Head and neurology related	
 drowsiness or sleepiness dry mouth headache ringing in the ears 	
Skin related	
sweatingReproductive related:	
 low libido impotence or Erectile dysfunction loss of menstrual cycle infertility 	
Sleep related	
sleep apnoeaGeneral:	
weaknessanorexiafatiguelow blood pressure	

Serious side effects

Serious side effects	What to do
 Allergy related flushing of the face shortness of breath, wheezing or difficulty breathing skin rash, itching or hives on the skin swelling of the face, lips, tongue or other parts of the body Bleeding related bleeding, bruising more easily Eyes related blurred vision Head and neurology related dizziness, lightheadedness unusual or extreme mood swings confusion seizures 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
Heart related	
fast heartbeat	
Infection related	
 mouth ulcers, fever and sore throat 	
Liver related	
 hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine) 	
Metabolism related:	
 Symptoms of rapid breathing, rapid heart rate, changes in consciousness, drowsiness, nausea or vomiting caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione) 	
Skin related	
 painful red areas with blisters and peeling 	

Serious side effects	What to do
layers of skin which may be accompanied by fever and/or chills	
 severe blisters and bleeding in the lips, eyes, mouth, nose and genitals 	
 yellowing of the skin and eyes (jaundice) 	
Urinary related	
problems passing urinedark coloured urine	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

CODALGIN FORTE is only available with a doctor's prescription.

What CODALGIN FORTE contains

Active ingredients (main ingredient)	Paracetamol Codeine phosphate hemihydrate
Other ingredients	Colloidal anhydrous silica
(inactive ingredients)	Crospovidone
	Magnesium stearate
	Maize starch
	Microcrystalline cellulose
	Povidone
	Pregelatinised maize starch
	Stearic acid

Do not take this medicine if you are allergic to any of these ingredients.

What CODALGIN FORTE looks like

CODALGIN FORTE is a white, capsule shaped tablet, plain on one side and with a break bar on the other side (AUST R 226337)

It comes in boxes of 20 tablets.

Who distributes CODALGIN FORTE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in November 2025.

CODALGIN® is a Viatris company trade mark

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