

# CODALGIN FORTE

(CODE-AL-JIN)

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about CODALGIN FORTE.

It does not contain all of the available information about these products.

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 or your child taking CODALGIN FORTE against the benefits he/she expects it will have.

**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.

### What is it used for

The name of your medicine is CODALGIN FORTE tablets.

The active ingredients are called paracetamol and codeine phosphate.

Paracetamol belongs to a group of medicines called analgesics. Analgesics are used to block pain. It is also antipyretic which means that it helps reduce your body temperature if you have a fever.

Codeine phosphate also belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

CODALGIN FORTE tablets are available only with a doctor's prescription.

These products are used to treat a number of medical conditions:

CODALGIN FORTE is used for the:

- Relief of moderate to severe pain

Your doctor or pharmacist, however, may have prescribed CODALGIN FORTE or for another purpose.

**Ask your doctor or pharmacist if you have any questions about why either of these products has been prescribed for you.**

**If you have any concerns, you should discuss this with your doctor or pharmacist.**

### Before you take it

#### *When you must not take it*

**Do not take these products if you are allergic to:**

- CODALGIN FORTE or any of the ingredients listed at the end of this leaflet.
- Morphine
- Oxycodone

Some of the symptoms of an allergic reaction may include red, itchy skin rashes, difficulty breathing, hay fever, swelling of the face or throat or faintness.

**You should not take CODALGIN FORTE if you are experiencing breathing difficulties such as asthma, bronchitis or emphysema. Do not take CODALGIN FORTE if you are suffering from diarrhoea caused by poisoning or antibiotics. Do not take CODALGIN FORTE if you have a Glucose-6-**

**phosphate deficiency (an enzyme deficiency).**

**Do not take CODALGIN FORTE if you have alcohol dependence.**

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

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

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

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

The medicine passes into breast milk and may affect the baby.

**Do not use these products after the expiry date (EXP.) printed on the pack.**

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

**Do not purchase or use these products if the packaging is torn, shows signs of tampering or visible signs of deterioration.**

**Do not give CODALGIN FORTE to children under the age of 7 years.**

**Like all medicines, this should not be used during pregnancy without first consulting with your doctor.**

CODALGIN FORTE is distributed to the breast milk, so it is not recommended for nursing mothers. If you have any concerns you should discuss this with your doctor or pharmacist.

Elderly patients are more likely to have less effective kidney or liver function due to age. This may increase the risk of side effects.

**You should discuss how much CODALGIN FORTE to take with your doctor or pharmacist.**

#### *Before you start to take it*

**You must tell your doctor or pharmacist if you are:**

1. allergic to any other medicines or any foods, dyes or preservatives.
2. you have any other medical conditions/health problems, including:
  - liver disease, hepatitis
  - kidney disease or difficulty urinating
  - difficulty breathing, lung problems, wheezing, chronic cough, asthma, or other chronic breathing conditions
  - inflammatory bowel disease or other gastrointestinal problems.
  - convulsions or epilepsy
  - depression
  - Addison's disease (low activity of the adrenal gland)
  - an underactive thyroid gland
  - prostate problems
3. you are a heavy drinker or drug user, or have a history of alcohol dependence or drug dependence.
4. you are about to have surgery under a general anaesthetic.
5. you have recently had gastrointestinal tract or urinary tract surgery.
6. you have had a recent head injury or brain tumour.

**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 or pharmacist about any of the above, tell them before you take any CODALGIN FORTE.**

#### *Taking other medicines*

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

**Do not take with other medicines containing paracetamol, unless your doctor says you can.**

Some medicines may interfere with CODALGIN FORTE.

These include:

- any medicine causing sleepiness or drowsiness
- barbiturates
- medication for epilepsy
- salicylates or NSAIDs, medicines used for pain relief and arthritis
- medicines to help you sleep, or relieve anxiety
- medicines used to treat depression, including monoamine oxidase inhibitors taken within the last 10 days
- medicines to reduce blood pressure
- medicines which thin the blood
- medicines to treat diarrhoea, nausea or vomiting
- chloramphenicol (antibiotic used to treat ear and eye infections)
- rifampicin and zidovudine (medicines for infection)

CODALGIN FORTE may reduce the effectiveness of the above medicines, as well as the above medicines may either reduce the effectiveness of CODALGIN FORTE or react with them, resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking CODALGIN FORTE.

### How to take it

#### *How much to take*

The label on your pack of CODALGIN FORTE will tell you how to take your medicine and how often.

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

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

**The recommended doses for CODALGIN FORTE tablets are:**

**Adults and children over 12 years:** 1 to 2 tablets every four hours as necessary.

Do not take more than eight CODALGIN FORTE tablets in 24 hours.

**Children 7 to 12 years:** Half a tablet every four hours as necessary.

Children must not take more than three CODALGIN FORTE tablets in 24 hours.

CODALGIN FORTE is not suitable for children under 7 years of age.

#### *How to take it*

Swallow the medicine with water. If the dose is one-half tablet, there is a break line on the tablet to help you divide it.

#### *How long to take it*

Continue taking CODALGIN FORTE for no longer than a few days at a time unless your doctor advises otherwise.

For children 7- 12 years): Do not take for longer than 48 hours at a time unless your doctor advises otherwise.

If pain persists, see your doctor.

#### *If you forget to take CODALGIN FORTE*

**Take your dose as soon as you remember, and then go back to taking it as you would normally.**

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

**If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.**

**Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of you getting an unwanted effect.**

**If you have trouble remembering when 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 the emergency department at your nearest hospital, if you think that you or anyone else may have taken too much CODALGIN FORTE. Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage. Also report any other medicine (including any barbiturates or narcotics) or alcohol which has been taken. You may need urgent medical attention.**

**Keep telephone numbers for these places handy.**

If you take too much CODALGIN FORTE you may have the following symptoms: weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and hypotension.

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#### *While you are using it*

##### *Things you must do:*

Use these products exactly as directed by a pharmacist or as your doctor has prescribed.

**Tell all your doctors, dentists and pharmacists that you are taking CODALGIN FORTE.**

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

**Tell your doctor if you feel that either of these products is not helping your condition.**

Your doctor needs to check your progress and see whether you need to keep taking CODALGIN FORTE.

**Always discuss with your doctor any problems or difficulties during or after taking these products.**

##### *Things you must not do:*

**Do not take any other medicines while you are taking these products without first telling your doctor or pharmacist.**

**Do not drive or operate machinery until you know how CODALGIN FORTE affects you.**

These products may cause dizziness in some people and therefore may affect alertness. Make sure you know how you react to CODALGIN FORTE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

##### *Things to be careful of:*

**Do not drink alcohol while taking CODALGIN FORTE.**

If you drink alcohol, it could make some of the unwanted side effects of these products worse.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness, and dizziness, which may further affect the risk when driving or using dangerous machinery.

CODALGIN FORTE may be habit forming if used for extended periods of time.

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#### *Side effects*

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

These products help most people with medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people, especially in elderly patients or those with underlying disorders.

All medicines 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.

Ask your doctor or pharmacist any questions you may have.

##### **Common Side Effects:**

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

- nausea (feeling sick)
- stomach pain
- constipation
- dizziness
- drowsiness
- lethargy
- vomiting
- skin rashes
- sweating

Some side effects are potentially serious.

**Contact your doctor immediately if you notice any of the following side effects:**

- Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Breathing difficulties
- Bleeding or bruising more easily than normal
- Difficulty in urinating (passing water)
- Itchy, raised or red skin rash

Some people may get other side effects.

**Check with your doctor as soon as possible if you have any problems while taking**

**CODALGIN FORTE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

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#### *After using it*

##### *Storage*

**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.

**Keep CODALGIN FORTE in a cool dry place where the temperature stays below 30°C and protect from light.**

**Do not store it, or any other medicines, in a bathroom or near a sink.**

**Do not leave it in the car or on windowsills.**

Heat and dampness can destroy some medicines.

**Do not take CODALGIN FORTE if the tablets do not look quite right.**

Keep your tablets in the packaging they were provided in until it is time to take them.

##### *Disposal*

**If your doctor or pharmacist tells you to stop taking the tablets OR they have passed their expiry date, ask your pharmacist what to do with any left over.**

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#### *Product description*

##### *What it looks like*

CODALGIN FORTE tablets are white, capsule-shaped tablets plain on one face with a single break bar on the other side.

They are presented in blister packs of 20.

##### *Ingredients*

Active ingredients

Each CODALGIN FORTE tablet contains 500 mg of paracetamol and 30 mg of codeine phosphate.

Excipients

CODALGIN FORTE also contains the following inactive ingredients:

**maize starch, pregelatinised maize starch, povidone, microcrystalline cellulose, magnesium stearate, crospovidone, stearic acid and colloidal anhydrous silica.**

These tablets do not contain a colouring agent.

##### *Sponsor or Supplier*

Aspen Pharma Pty Ltd  
34-36 Chandos Street  
St Leonards NSW 2065  
Australia

The Australian Registration Number for CODALGIN FORTE tablets is AUST R 226337.

This leaflet was updated in Sep 2016.