

CODALGIN FORTE

paracetamol and codeine phosphate hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CODALGIN 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 or pharmacist has weighed the risks of you or your child taking CODALGIN FORTE against the benefits they expect it will 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.

What CODALGIN FORTE is used for

CODALGIN FORTE is used for the relief of moderate to severe pain which does not respond to milder analgesics.

The two active ingredients of this medicine are called paracetamol and codeine phosphate hemihydrate.

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 hemihydrate 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take CODALGIN FORTE

When you must not take it

Do not take CODALGIN FORTE if you have an allergy to:

- any medicine containing paracetamol or codeine phosphate hemihydrate
- morphine

- oxycodone
- any of the ingredients listed at the end of this leaflet

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 this medicine if you have or have had any of the following medical 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
- Diarrhoea caused by poisoning or antibiotics
- 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 are aged below 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.

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.

Like all medicines, this should not be used during pregnancy or breastfeeding 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.

Do not give CODALGIN FORTE to children under the age of 12 years.

Do not take this medicine 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.

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, heart, liver or kidney problems
- difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- 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
- Diarrhoea caused by poisoning
- 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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor 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 any that you get without a prescription from your 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
- Tranquillisers (medicines for anxiety and nerves)
- Benzodiazepines (medicines used as sedatives or to treat anxiety)
- Medicines used to treat alcohol and/or opioid dependence (e.g. 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
- 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, rifampicin or zidovudine (medicines for infection)

These medicines may be affected by CODALGIN 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take CODALGIN FORTE

How much to take

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

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 box, ask your doctor or pharmacist for help.

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.

CODALGIN FORTE is not suitable for children under 12 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.

If pain persists, see your doctor.

If you forget to take it

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.

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

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

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 Accident and Emergency at the 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
- hypotension (low blood pressure)

While you are taking CODALGIN FORTE

Things you must do

Use these products exactly as your doctor has prescribed.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CODALGIN FORTE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you feel this medicine 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 this medicine.

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 may cause liver damage.

Codeine may be habit forming.

Do not take CODALGIN FORTE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

CODALGIN FORTE may cause dizziness or drowsiness in some people, especially after the first dose.

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

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.

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 taken in high doses for extended periods of time.

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

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.

Do not be alarmed by the following lists 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 if you notice any of the following and they worry you:

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

The above list includes the more common side effects of your medicine.

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

- 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,

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 CODALGIN FORTE regularly, you may also need to take laxatives to prevent constipation.

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

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

After taking CODALGIN FORTE

Storage

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

If you take the tablets out of the pack, they may not keep well.

Keep CODALGIN FORTE in a cool dry place where the temperature stays below 30°C.

Do not store CODALGIN FORTE or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any that is left over.

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 available in blister packs of 20 tablets.

Ingredients

CODALGIN FORTE contains 500 mg of paracetamol and 30 mg of codeine phosphate hemihydrate as the active ingredients.

The tablets also contain the following inactive ingredients:

- colloidal anhydrous silica
- crospovidone
- magnesium stearate
- maize starch
- microcrystalline cellulose

- povidone
- pregelatinised maize starch
- stearic acid

Supplier

CODALGIN FORTE is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

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