

PACKAGE LEAFLET: INFORMATION FOR THE USER

Codalvonil 500 mg/30 mg, effervescent tablets

paracetamol and codeine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Codalvonil is and what it is used for
2. What you need to know before you use Codalvonil
3. How to use Codalvonil
4. Possible side effects
5. How to store Codalvonil
6. Contents of the pack and other information

1. What Codalvonil is and what it is used for

Codalvonil contains two pain-relieving substances (paracetamol and codeine) that work in different ways. Paracetamol has both pain-relieving and fever-reducing effects. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or more commonly, like in this product, in combination with other pain killers such as paracetamol.

Codalvonil is used for various kinds of aches and pains. Codalvonil can be used by people with sensitive stomachs or stomach ulcers and people who bleed easily.

2. What you need to know before you use Codalvonil

Do not use Codalvonil

- if you are allergic to paracetamol, codeine or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from bile duct problems.
- if you know that you metabolise very rapidly codeine into morphine.
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Codalvonil:

- if you have asthma
- if you have alcohol problems
- if you have liver damage
- if you are taking other medicines containing paracetamol

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek

immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

If you use other pain-relieving medicines containing paracetamol, you must not use Codalvonil unless you have first discussed it with your doctor or pharmacist.

Never take more Codalvonil effervescent tablets than your doctor has prescribed. **Higher doses than those recommended will not result in improved pain relief, but instead carry the risk of impaired respiratory function and very serious liver damage.** Symptoms of liver damage do not normally appear until after a few days have passed. It is therefore important that you seek medical advice as soon as possible if you have taken too large a dose.

If you use Codalvonil for a prolonged period there is a risk of you developing a dependency. Do not use Codalvonil for a prolonged period before first speaking to your doctor.

Other medicines and Codalvonil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines/natural remedies can affect or be affected by treatment with Codalvonil, for example

- Quinidine (medicine for irregular heart rhythm)
- Neuroleptics (medicine for psychological disorders)
- Antidepressants
- Warfarin (blood-thinning medicine). Contact your doctor if you take more than 2 effervescent tablets of Codalvonil a day for 5 days in a row. There is a risk that this may have an impact on the efficacy of warfarin.
- Probenecid (medicine for gout)
- Some medicines for epilepsy (phenytoin, phenobarbital and carbamazepine)
- Rifampicin (medicine for tuberculosis)
- Cholestyramine (medicine for high blood lipids). Codalvonil and cholestyramine should be taken at least one hour apart.
- Chloramphenicol for injection (medicine for bacterial infections). However, chloramphenicol for eye infections can be used.
- St John's wort extract (included in some herbal medicinal products)
- Metoclopramide (medicine for nausea).

Codalvonil with alcohol

The risk of liver damage from taking too much Codalvonil is increased by alcohol abuse.

Never take Codalvonil together with alcohol.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Codalvonil if you are pregnant or are planning to become pregnant unless your doctor has advised you to do so.

Do not take Codalvonil while you are breastfeeding. Codeine and morphine pass into breast milk.

Driving and using machines

Codalvonil can impair your ability to react and make you tired and drowsy, which you should bear in mind on occasions when full attention is required, for example, driving a car or doing precision work.

Codalvonil contains sodium

Each Codalvonil effervescent tablet contains 19 mmol (or 437 mg) sodium. To be taken into consideration by patients on a controlled sodium diet. Speak to your doctor for advice if you are not sure.

3. How to use Codalvonil

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

NB! Doses higher than those recommended may involve serious risks.

The usual dose for adults is: 1-2 effervescent tablets 1-4 times a day.

Dissolve the effervescent tablet in half a glass of water.

If you use more Codalvonil than you should

If you have taken more of the medicine than you should, always contact your doctor. *There is a risk of liver damage even if you feel well.* To prevent potential liver damage it is important for a doctor to start you on an antidote as soon as possible.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Codalvonil and see your doctor immediately if you experience symptoms of angioedema, such as

- **swollen face, tongue or pharynx**
- **difficulty to swallow**
- **hives and difficulties to breathe**

You may be having an allergic reaction

Common (may affect up to 1 in 10 people): Tiredness, nausea, constipation.

Uncommon (may affect up to 1 in 100 people): Convulsions in the bile ducts can occur in people with this tendency.

Rare (may affect up to 1 in 1,000 people): Skin rash, liver damage, impaired kidney function. Very severe hypersensitivity reaction with fever, rash, swelling and sometimes a fall in blood pressure (anaphylactic shock).

Very rare (may affect up to 1 in 10,000 people): Serious skin reactions. Inflammation of the pancreas.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

Liver damage can occur from use of paracetamol in connection with alcohol abuse. If you use Codalvonil for a prolonged period the risk of kidney damage cannot be ruled out.

5. How to store Codalvonil

Keep this medicine out of the sight and reach of children.

Do not use Codalvonil after the expiry date which is stated on the tube after EXP. The expiry date refers to the last day of that month.

Store in the original package. Keep the tube tightly closed in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Codalvonil contains

- The active substances are paracetamol 500 mg and codeine phosphate hemihydrate 30 mg.
- The other ingredients are sodium hydrogen carbonate, citric acid, sodium dihydrogen citrate, mannitol, anhydrous sodium carbonate, povidone, sodium saccharin, sodium citrate, sodium chloride, magnesium stearate, sodium laurilsulfate and flavourings (orange and lemon).

What Codalvonil looks like and contents of the pack

White, circular flat tablets, 25 mm diameter.

Tubes of 25, 50 (2 x 25) and 100 (4 x 25) effervescent tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

To be completed nationally.

Manufacturer

Hermes Arzneimittel GmbH
Georg-Kalb-Straße 5-8
82049 Großhesselohe / München
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

To be completed nationally.

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