

Consumer Medicine Information

WARNINGS

Limitations of use

Because of the risks associated with the use of opioids, Codasig tablets should only be used in patients for whom other treatment options, including non-opioid analgesics, are ineffective, not tolerated or otherwise inadequate to provide appropriate management of pain (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Hazardous and harmful use

Codasig tablets poses risks of hazardous and harmful use which can lead to overdose and death. Assess the patient's risk of hazardous and harmful use before prescribing and monitor the patient regularly during treatment (see section 4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of Codasig tablets. Be aware of situations which increase the risk of respiratory depression, modify dosing in patients at risk and monitor patients closely, especially on initiation or following a dose increase (see section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol

Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Limit dosages and durations to the minimum required; and monitor patients for signs and symptoms of respiratory depression and sedation. Caution patients not to drink alcohol while taking Codasig tablets.

Please read this information before you start taking this medicine

What is in this Leaflet?

This leaflet answers some common questions about **CODASIG tablets**. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **CODASIG tablets** against the benefits this medicine is expected to have for you.

Keep this information with the medicine. You may need to read it again.

What are CODASIG tablets used for

This medicine may be addictive if taken for more than a few days at a time.

CODASIG tablets are used to relieve acute moderate pain and fever.

CODASIG tablets contain paracetamol and codeine phosphate hemihydrate. Paracetamol and codeine phosphate hemihydrate work together to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to reduce fever.

Your doctor may have given you this medicine for another use.

If you want more information, ask your doctor.

Before you take CODASIG tablets

When you must not take it

You should not take **CODASIG tablets** if you are allergic to paracetamol or codeine or any of the ingredients listed under 'Product Description'. The symptoms of an allergic reaction may include a rash, asthma attack or hay fever.

Do not take this medicine if you have any of the following conditions:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

Do not take this medicine if you regularly drink large quantities of alcohol.

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

The medicine may produce withdrawal effects in the newborn baby.

CODASIG tablets may be used during pregnancy. However, ask your doctor about the risks and benefits of taking **CODASIG tablets** while you are pregnant.

Do not take **CODASIG tablets** during labour, especially if the baby is premature.

This medicine may produce withdrawal effects in the newborn baby.

Do not use CODASIG tablets if you are breastfeeding or planning to breastfeed.

A small amount of codeine passes into the breast milk. It may cause breathing problems in newborn infants.

Do not use CODASIG tablets in children under 12 years.

Ask your doctor about taking **CODASIG tablets** if you are over 65 years of age and have kidney or respiratory problems.

Do not use it after the expiry date (EXP) 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 use **CODASIG tablets** if the packaging is torn or shows signs of tampering.

Before you start to take it

Do not take **CODASIG tablets** with other medicines containing paracetamol or codeine, unless advised to do so by a doctor.

You must tell your doctor if:

- You have allergies to any ingredients listed under "Product Description" at the end of this leaflet.
- You have any of these conditions:
 - Liver or kidney problems
 - Difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
 - You drink large quantities of alcohol
 - You have a history of drug or alcohol abuse
 - Recent surgery on the stomach or intestines
 - Head injury
 - Enlarged prostate
 - Low blood pressure
 - Underactive thyroid
 - You are a Ultra-rapid metaboliser of CYP2D6
 - You are aged below 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea

- You should tell your doctor if you are using any other medicines including any of the following medicines:
 - Any medicines causing sleepiness
 - Tranquillisers (medicines for anxiety and nerves)
 - Medicines which thin the blood (e.g. warfarin)
 - Medicines to treat epilepsy
 - Metoclopramide, a medicine used to control nausea and vomiting
 - Chloramphenicol, an antibiotic used to treat ear and eye infections
 - Medicines used to relieve stomach cramps or spasms
 - Medicines used to prevent travel sickness
 - Medicines used to treat Parkinson's disease
 - Medicines used to treat high blood pressure
 - Medicines for diarrhoea, such as kaolin, pectin and loperamide
 - Monoamine oxidase inhibitors, medicines used to treat depression, if taken within the last 14 days
 - Quinidine, a medicine used to treat abnormal or irregular heartbeat
 - Phenothiazines and antipsychotic agents, medicines used to treat mental disorders
 - Other opioids, used to treat pain or suppress coughs
 - Alcohol

These medicines may be affected by **CODASIG tablets** or affect how well **CODASIG tablets** work.

Your doctor can tell you what to do if you are taking any of these medicines.

You should also tell your doctor about any other medicines that you have bought without a prescription from either your pharmacy, supermarket or health food shop.

If you have not told your doctor about any of these things, tell him/her before you take any CODASIG tablets.

How to take CODASIG tablets

The label on your pack **CODASIG tablets** will tell you how to take your medicine and how often. If you are unsure about the directions, ask your doctor.

How much to take

The usual dose of **CODASIG tablets** are:
Adults and children over 12 years: 2 tablets.

This dosage may be repeated in 4-6 hours if necessary. You should not take more than 8 tablets in a 24-hour period.

How long to take it

Adults: Do not take this medicine for longer than a few days at a time unless advised to by a doctor.

Children aged over 12 years: Do not take this medicine for longer than 48 hours at a time, unless advised to by a doctor.

Keep to the recommended dose. If **CODASIG tablets** are not adequately controlling your pain, do not increase the dose. Please see your doctor.

How to take it

Swallow tablets whole with a little water or other liquid.

The directions given to you by your doctor may be different from the information in this leaflet. If you are unsure what dose to take, ask your doctor.

If you forget to take it

If you miss a dose, take it as soon as you remember. 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 missed.

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 your nearest hospital, if you think that you or anyone else may have taken too much **CODASIG tablets**.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention because of the risk of delayed, serious liver damage with an overdose of paracetamol.

Keep telephone numbers of these places handy.

If you take too many tablets you may feel nauseous, lightheaded, dizzy or drowsy.

While you are taking CODASIG tablets

Things you must do

Take **CODASIG tablets** exactly as your doctor has told you to. Tell all your doctors, dentists and pharmacists that you are taking **CODASIG tablets**.

Tell your doctor if you become pregnant while taking **CODASIG tablets**.

Things you must NOT do

Do not use this medicine to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else even if they have the same symptoms as you.

Adults: Do not take this medicine for longer than a few days at a time unless advised to by a doctor.

Children aged over 12 years: Do not take this medicine for longer than 48 hours at a time, unless advised to by a doctor.

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

Things to be careful of

CODASIG tablets may cause dizziness or drowsiness in some people, especially after the first dose.

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.

Codeine may be habit forming if taken in high doses for extended periods of time. Too much paracetamol may cause delayed, serious liver damage. Please ask your doctor if you are concerned about this.

About 8% of people are poor metabolisers of codeine. **CODASIG tablets** may not work as well if you are one of those people.

Side Effects

Tell your doctor as soon as possible if you do not feel well while taking **CODASIG tablets**.

Like other medicines, **CODASIG tablets** can cause some side effects. If they occur, they are most likely minor and temporary.

However, sometimes they are serious and need medical treatment.

Ask your doctor to answer any questions you may have.

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

Stomach problems such as:

- Nausea
- Vomiting
- Stomach pain
- Constipation

If you are taking **CODASIG tablets** regularly, you may also need to take laxatives to prevent constipation.

Difficulty thinking or working because of:

- Dizziness
- Drowsiness

Be careful driving or operating machinery until you know how **CODASIG tablets** affect you. The above list includes the more common side effects of your medicine. They are usually mild.

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

- cough suppression
- unusual or extreme mood swings
- flushing of the face
- fast heartbeat.

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

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

If you believe **CODASIG tablets** are not working well for you, do not increase the dose. Please see your doctor.

Some people may get other side effects not listed above.

Tell your doctor you notice anything else that making you feel unwell.

After taking CODASIG tablets

Storage

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

If you take the tablets out of the box or the blister pack, they will not keep well.

Keep **CODASIG tablets** in a cool dry place where the temperature stays below 30°C.

Heat and dampness can destroy some medicines.

Do not leave **CODASIG tablets** in the car on hot days.

Do not store **CODASIG tablets** or any other medicine in the bathroom or near a sink.

Keep **CODASIG tablets** 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.

Disposal

If your doctor tells you to stop taking the tablets, ask your pharmacist what to do with any tablets that are left over.

This is not all the information that is available on **CODASIG tablets**. If you have any more questions or are not sure about anything, ask your doctor.

Product Description

CODASIG tablets come as white to off white capsule shaped uncoated tablets, plain on one side and breakline on the other side.

It is available in packs of 20 and 40* tablets.

*Not all pack sizes may be marketed.

Active ingredients:

Each tablet contains:
Paracetamol 500 mg
Codeine Phosphate
Hemihydrate 15 mg

Other ingredients:

Starch - Potato, Lactose, Povidone, Docusate Sodium, Silica - colloidal anhydrous, Magnesium Stearate.

CODASIG tablets do not contain any gluten, sucrose, tartrazine or any azo dyes.

Name and Address of the sponsor

CODASIG tablets are supplied in Australia by:

Sigma Company Limited
3 Myer Place
Rowville VIC 3178
AUST R 226290

This leaflet was updated in June 2021.