Codagesic

contains the active ingredients paracetamol, codeine phosphate and doxylamine succinate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Codagesic.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Codagesic against the benefits they expected it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What Codagesic is used for

This product contains paracetamol, codeine phosphate and doxylamine succinate. It is used for the temporary relief from the symptoms of moderate to severe pain caused by headache, toothache, period pain, backache and pain associated with trauma or surgery. It also reduces fever.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Codeine phosphate 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.

Doxylamine succinate is an antihistamine with pronounced sedative effects.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

This medicine is only available from your pharmacist.

Before you take Codagesic

When you must not take it

Do not take Codagesic if you have an allergy to:

- Any medicine containing paracetamol, codeine, doxylamine or other antihistamines.
- 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:

- Glaucoma (high pressure in the eyes)
- Stomach or duodenal ulcer, or other stomach problems
- Prostate problems
- Bladder problem
- Acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- Chronic constipation
- Diarrhea caused by antibiotics or poisoning

Do not take codeine if you have alcohol dependence.

Do not take codeine during labour, especially if the baby is premature. This medicine may produce withdrawal effects in the newborn baby.

Do not take this medicine if you are also taking monoamine oxidase inhibitor (MAOI), a type of medicine used to treat depression.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

Do not give this medicine to newborn or premature babies.

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 pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- Liver or kidney disease
- Liver or kidney problems
- Epilepsy
- Difficulty breathing, wheezing chronic cough, asthma or other chronic breathing conditions
- A history of drug dependence, including alcohol dependence
- Recent surgery on the stomach or intestines
- Head injury
- Prostate problems
- Low blood pressure
- Underactive thyroid

Tell your pharmacist or doctor if you take sedatives (medicines used to help you relax or sleep).

Tell your pharmacist or doctor about taking this medicine if you are pregnant or plan to become pregnant.

Your pharmacist or doctor will discuss the benefits and possible risks of taking this medicine during pregnancy.

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

Small amounts of codeine and doxylamine are passed into breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Codagesic.

Taking other medicines

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

Some medicines and Codagesic may interfere with each other. These include:

- Warfarin, a medicine used to prevent blood clots
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Alcohol
- Medicines used to help you relax, sleep or relieve anxiety, such as barbiturates, sedatives and hypnotics
- Opioid analgesics, medicines used to treat pain
- Medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- Medicine used to treat high blood pressure
- Medicines for diarrhea, such as kaolin, pectin and loperamide
- Medicines used to treat depression especially monoamine oxidase inhibitors and tricyclic antidepressants, taken with in the last 14 days
- Other opioid analgesics used to treat pain
- Quinidine, a medicine used to treat abnormal or irregular heart beat
- Phenothiazines and antipsychotic agents, medicines used to treat mental disorders

These medicines may be affected by Codagesic 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 will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take Codagesic

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your pharmacist or doctor for help.

How much to take

Adults and children over 12 years - take 1 or 2 tablets with water, every 4 to 6 hours as needed for relief (maximum 8 tablets in 24 hours).

Not recommended for children under 12 years of age.

Do not take more than the recommended dose.

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

If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine.

If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.

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

How to take it

Take it with water.

When to take it

Take every 4 to 6 hours as needed for relief.

How long to take it

Take a maximum of 8 tablets in 24 hours.

Adults:

Only take this product for a few days at a time unless your doctor tells you to take it for longer.

Adolescents and children over 12 years:

Only give this product to adolescents and children over 12 years for up to 48 hours unless a doctor has told you to give it longer

If you forget to take it

If it is less then 3 hours before your next does, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicines 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 unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the 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 Codagesic. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Codagesic

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Keep to the recommended dose.

Things you must not do

Adolescents and children over 12 years:

Do not give this medicine for more than 48 hours at a time unless advised to by a doctor.

Adults:

Do not take for more than a few days at a time unless advised to by a doctor.

Do not drink alcohol while taking this medicine.

The sedation effect of alcohol may be increased.

Do not take Codagesic to treat any other complaints unless your pharmacist or 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

Be careful driving or operating machinery until you know how the medicine affects you.

This medicine may cause dizziness or sleepiness in some people. If this happens, do not drive, use or operate machinery.

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

Codeine may be habit forming.

Side effects

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

This medicine helps most people with the temporary relief from the symptoms of moderate to severe pain caused by headache, toothache, period pain, backache and pain associated with trauma or surgery. It also reduces fever, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have.

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

- Nausea or dyspepsia
- Vomiting
- Drowsiness or sleepiness
- Dizziness
- Constipation
- Dry mouth, nose and throat
- Nervousness and irritability
- Anxiety
- Hallucinations
- Twitching or jerking muscles
- Fast heart beat

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:

- Shallow breathing or shortness of breath
- Unusual or extreme mood swings, dizziness, light-headedness
- Flushing of the face
- Fast heart beat
- Difficult or painful urination
- Seizures (fits)

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 pharmacist or 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. These side effects are very rare for low doses of this medicine and when used for a short period of time.

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

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

After taking Codagesic

Storage

Keep your medicine in the original pack until it is time to take.

Keep your medicine in a cool dry place where temperature stays below 30°C.

Do not store Codagesic or any other medicine in the bathroom or near a sink. Do not leave it on a window sill 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

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

Product description

What it looks like

This product is a blister pack of 20 or 40 flat yellow tablets with a centre break line.

Ingredients

Codagesic contains 450mg of paracetamol, 9.75mg of codeine phosphate and 5mg of doxylamine succinate as the active ingredients.

It also contains:

- Cellulose - microcrystalline
- Crospovidone
- Magnesium stearate
- Povidone
- Quinoline Yellow
- Starch - pregelatinized
- Stearic Acid
- Sunset yellow FCF

Supplier

Codagesic is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

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