

PARACETAMOL + CODEINE

Paracetamol 500 mg, Codeine Phosphate 8 mg Tablets

WARNINGS

Limitations of use

Paracetamol + Codeine should only be used when your doctor decides that other treatment options are not able to effectively manage your pain, or you cannot tolerate them.

Hazardous and harmful use

Paracetamol + Codeine poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment

Life threatening respiratory depression

Paracetamol + Codeine can cause life-threatening or fatal breathing difficulties (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use but the risk is higher when first starting Paracetamol + Codeine and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

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

Using Paracetamol + Codeine with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Paracetamol + Codeine.

What is in this leaflet

This leaflet answers some common questions about Paracetamol + Codeine.

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 will have weighed the risks of you taking Paracetamol + Codeine against the benefits he/she expects 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 Paracetamol + Codeine is used for

Paracetamol + Codeine is used by adults and children aged 12 years and above for the temporary relief of pain and discomfort associated with:

- headache
- migraine headache
- tension headache
- period pain
- back pain
- muscle pain
- arthritis
- toothache
- dental procedures
- neuralgia
- sore throat
- cold and flu symptoms in adults only (18 years and older)

Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Paracetamol also helps reduce fever.

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.

This medicine is available only with a doctor's prescription.

Before you take Paracetamol + Codeine

When you must not take it

Do not take Paracetamol + Codeine if you have an allergy to:

- any medicine containing paracetamol, codeine or any other opiates
- 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 give this medicine to a child under 12 years of age. Paracetamol + Codeine is not suitable for use in children younger than 12 years.

Do not take Paracetamol + Codeine if you are taking any other paracetamol containing medicine.

Do not take Paracetamol + Codeine if you have:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- a drinking problem (alcoholism)
- diarrhoea caused by poisoning or a condition known as pseudomembranous colitis
- severe liver problems

Do not take Paracetamol + Codeine if you are under 18 years old

- and have had your tonsils and/or adenoids removed to treat obstructive sleep apnoea
- and have difficulty breathing
- for the treatment of cough or cold symptoms

Do not take Paracetamol + Codeine during labour, especially if the baby is premature.

This medication contains codeine, which may produce withdrawal effects in the new born baby.

Do not breast-feed if you are taking this medicine.

The active ingredient codeine passes into breast milk and there is a possibility that your baby may be affected.

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, kidney or liver problems
- head injury or a condition where there is raised pressure to the head
- prostate problems
- low blood pressure
- under active thyroid gland or problems with your adrenal glands

Tell your doctor if you have a history of drug abuse or if you drink alcohol.

Tell your doctor if you have had recent gastrointestinal tract surgery.

If you have not told your doctor about any of the above, tell him/her before you start taking Paracetamol + Codeine.

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.

Some medicines and Paracetamol + Codeine may interfere with each other. These include:

- other pain relief medication
- medicines which thin the blood such as warfarin
- medicines used to treat epilepsy

- chloramphenicol, an antibiotic used to treat infections
- rifampicin, a medicine used to treat tuberculosis and certain types of infection
- cholestyramine (to reduce blood fat levels)
- medicines used to treat diarrhoea, nausea or vomiting such as metoclopramide and domperidone
- any medicine causing sleepiness or drowsiness
- tranquillisers (medicines for anxiety and nerves)
- cimetidine, a medicine used to treat gastric ulcers and acid secretion
- some medicines used to treat depression including Monoamine Oxidase Inhibitors (MAOIs)
- medicines used to treat high blood pressure
- zidovudine, used for the treatment of HIV
- medicines used as sedatives or to treat anxiety

These medicines may be affected by Paracetamol + Codeine 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 Paracetamol + Codeine

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 carton, ask your doctor or pharmacist for help.

How much to take

It is important that you take Paracetamol + Codeine exactly as advised by your doctor.

Adults and Children over 12 years

The usual dose for adults and children over 12 years is 1 to 2 tablets every 4 – 6 hours as required.

Do not take more than 8 tablets in 24 hours.

Your doctor may however have prescribed a different dose.

How to take it

Swallow the tablets whole with a full glass of water.

Paracetamol + Codeine tablets may be broken in half if your doctor has prescribed a half dose.

When to take it

If you are not sure when to take Paracetamol + Codeine tablets, ask your doctor or pharmacist for advice.

If you forget to take it

If it is almost time for your next dose, 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 medicine 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 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 National Poisons

Information Centre (0800 POISON or 0800 764 766) 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 Paracetamol + Codeine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Paracetamol + Codeine

Things you must do

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Paracetamol + Codeine.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things you must not do

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

You should not take more than 8 tablets a day.

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

Do not drink alcohol while you are taking this medicine.

Drinking alcohol when taking Paracetamol + Codeine can increase the risk of side effects.

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.

Paracetamol + Codeine may be habit forming if taken in high doses for extended periods of time. Please ask your doctor or pharmacist if you are concerned about this.

Things to be careful of

Be careful driving or operating machinery until you know how Paracetamol + Codeine affects you.

This medicine may cause dizziness or light headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Children should not ride bikes if affected and should be supervised to avoid potential harm.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

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 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 or pharmacist if you notice any of the following and they worry you:

- constipation
- nausea, vomiting
- indigestion

- drowsiness
- dizziness
- sweating
- skin rash, facial flushing
- dryness of the mouth

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:

- tiredness, headache, being short of breath when exercising, dizziness and looking pale
- unusual or extreme mood swings
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- difficulty in passing urine, increased frequency in urination, pain when passing urine, spasms in the bladder

The above list includes serious side effects that may require medical attention. Serious 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, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- hives
- severe upper stomach pain, with nausea and vomiting

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

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 Paracetamol + Codeine

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Paracetamol + Codeine 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 your medicines where children cannot reach them.

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 medicine that is left over.

Product description

What it looks like

Paracetamol + Codeine tablets are white, round, 13 mm in diameter and 4 mm thick, with MYL on one side and a P above the breakline and a C below the breakline on the other side.

Ingredients

Paracetamol + Codeine tablets contain 500 mg of paracetamol and 8 mg of codeine as the active ingredients.

The tablets also contain:

- maize starch
- pregelatinised starch
- potassium sorbate
- povidone
- purified talc

- stearic acid

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

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