

CODEINE PHOSPHATE TABLETS (Noumed)

Codeine Phosphate Hemihydrate BP

Tablet, uncoated 15 mg, 30 mg & 60 mg

WARNINGS

Limitations of use

Codeine Phosphate Tablets (Noumed) 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

Codeine Phosphate Tablets (Noumed) 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

Codeine Phosphate Tablets (Noumed) can cause life-threatening or fatal breathing problems (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 Codeine Phosphate Tablets (Noumed) 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.

Use of other medicines while using Codeine Phosphate Tablets (Noumed)

Codeine Phosphate Tablets (Noumed) 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 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.

Do not drink alcohol while using Codeine Phosphate Tablets (Noumed)

You must not drink alcohol while using Codeine Phosphate Tablets (Noumed). Drinking alcohol while using Codeine Phosphate Tablets (Noumed) may result in severe drowsiness, decreased awareness, breathing problems, coma and death.

What is in this leaflet

Please read this leaflet carefully before you start using Codeine Phosphate Tablets (Noumed).

This leaflet answers some common questions about Codeine Phosphate Tablets (Noumed).

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 has weighed the risks of you using Codeine Phosphate Tablets (Noumed) against the benefits they expect it will have for you.

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

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

What is Codeine Phosphate Tablets (Noumed)

The name of your medicine is CODEINE PHOSPHATE TABLETS (Noumed).

The active ingredient is called codeine phosphate hemihydrate.

Codeine phosphate hemihydrate belongs to a group of medicines called analgesics, which are used to block pain.

It is an opioid analgesic, and it acts by blocking pain and your emotional response to pain.

What Codeine Phosphate Tablets (Noumed) are used for

Codeine phosphate is indicated for:

- the relief of mild to moderate pain (including pain associated with terminal illness, post-operative pain, headache and cough),
- the relief of symptoms of diarrhoea (except diarrhoea caused by poisoning).

Your doctor may have prescribed Codeine Phosphate Tablets (Noumed) for another reason.

Ask your doctor if you have any questions about why Codeine Phosphate Tablets (Noumed) has been prescribed for you.

Codeine Phosphate Tablets (Noumed) are available only with a doctor's prescription.

Codeine is an addictive substance.

Before you use Codeine Phosphate Tablets (Noumed)

When you must not use it

Do not use Codeine Phosphate Tablets (Noumed) if you have a known hypersensitivity/are allergic to:

- Codeine phosphate, other opioids (such as morphine or oxycodone), or any of the ingredients listed at the end of this leaflet;

Some of the symptoms of an allergic reaction to codeine phosphate may include red, itchy skin rashes; difficulty breathing; faintness; hay fever and swelling of the face or throat.

Do not use Codeine Phosphate Tablets (Noumed) if you:

- are aged less than 12 years;
- are an adolescents aged less than 18 years for pain following surgery to remove tonsils or adenoids;
- are an adolescents aged less than 18 years in whom respiratory function might be compromised;
- are breastfeeding;
- are experiencing breathing difficulties such as asthma, bronchitis, emphysema, obstructive airways disease;
- suffer acute alcoholism, or have recently ingested a large amount of alcoholic beverages;
- have recently had a head injury or a condition that raise the pressure within your head;
- are at risk of paralysis of the intestine;
- have liver failure;
- have heart failure secondary to chronic lung disease;
- are suffering from diarrhoea caused by poisoning or antibiotics;
- are taking monoamine oxidase inhibitors (medicines for treating depression or mood swings) or it is within fourteen days of stopping such treatment.

Do not give Codeine Phosphate Tablets (Noumed) to:

- Children aged less than 12 years;
- Adolescents aged less than 18 years for pain following surgery to remove tonsils or adenoids;
- Adolescents aged less than 18 years in whom respiratory function might be compromised;
- Women who are breastfeeding.

Do not use Codeine Phosphate Tablets (Noumed) after the expiry date (EXP) printed on the pack has been reached.

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

If you are not sure whether you should start using Codeine Phosphate Tablets (Noumed), talk to your doctor.

Codeine Phosphate Tablets (Noumed) should not be used during pregnancy without consulting your doctor.

Codeine phosphate hemihydrate is distributed to the breast milk so should not be used for breastfeeding mothers.

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

Before you start to use it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have any other medical conditions/health problems including:

- heart disease;
- depression;
- have recent removal of tonsils, adenoids or have had other throat surgery;
- have an underactive thyroid gland;
- have Addison's disease (low activity of the adrenal glands);
- have impaired kidney or liver function;
- a prostate disorder;
- shock/hypotension (sudden low blood pressure);
- myasthenia gravis (an autoimmune neuromuscular disease);
- convulsions / convulsive disorders;
- gallbladder disease or gallstones;
- recent gastro-intestinal surgery;
- urinary tract surgery;
- a breathing disorder; lung disease or history of asthma;
- obstructive bowel disorders;
- inflammatory bowel disease or other gastrointestinal disorders;
- CYP2D6 genetic polymorphism.

Check with your doctor if you:

- are taking monoamine oxidase inhibitors or it is within 14 days of stopping such treatment;
- have had a recent head injury;
- are about to have surgery under a general anaesthetic;
- are suffering from opioid dependence;
- are suffering from opioid withdrawal symptoms;
- are pregnant or intend to become pregnant;
- are breast feeding or intend to breastfeed;
- are a child aged less than 12 years;
- are an adolescents aged less than 18 years for pain following surgery to remove tonsils or adenoids;
- are an adolescents aged less than 18 years in whom respiratory function might be compromised;
- are elderly.

If you have not told your doctor about any of the above, tell them before you start using Codeine Phosphate Tablets (Noumed).

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Codeine Phosphate Tablets (Noumed).

Some medicines may interfere with Codeine Phosphate Tablets (Noumed). These

include:

- Medicines to help you sleep or relieve anxiety
- Anticholinergics, medicines to treat muscle spasms
- Medicines used to treat diarrhoea
- Medication for epilepsy
- Antihypertensive drugs (medicines used to treat high blood pressure)
- Diuretics or fluid tablets
- Other opioid analgesics used to block pain
- Antihistamines (medicines used to treat allergies such as hay fever, insect bites and some cold remedies)
- Monoamine oxidase inhibitors and Tricyclic antidepressants (medicines for treating depression) taken within the last 10 days
- Metoclopramide, a medicine used to relieve nausea and vomiting
- Antidepressant medicines used to treat depression
- Naloxone or Naltrexone, medicines used to counteract the effects of opioid analgesics

- Medicines used to relax muscles
- Quinidine (a medicine used to treat abnormal or irregular heart beat)
- Cimetidine (a medicine used to treat reflux or stomach ulcer)
- Alcohol
- Hypnotics and anxiolytics (Medicines to help you sleep or relieve anxiety)
- Metoclopramide and Domperidone (medicines used to relieve nausea and vomiting)
- Anaesthetics
- Antipsychotics (including phenothiazines)
- Other opioid analgesics used to block pain
- Ciprofloxacin (an antibiotic)
- Ritonavir (an antiviral)
- Mexiletine (a medicine used to treat arrhythmias within the heart, or serious irregular heart beats)
- Cimetidine (a medicine used to treat reflux or stomach ulcer)

The above medicines may reduce the effectiveness of Codeine Phosphate Tablets (Noumed), and/ or react with Codeine Phosphate Tablets (Noumed) resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Codeine Phosphate Tablets (Noumed).

How to use Codeine Phosphate Tablets (Noumed)

How much to take

The recommended dose of Codeine Phosphate Tablets (Noumed) is:

Adults:

Given orally in divided doses of 15 mg to 60 mg, as prescribed by your doctor. The maximum recommended daily dose should not exceed 300 mg.

Adolescents and paediatrics:

As prescribed by your doctor.

When to take it

Adults:

Every 4 to 6 hours, as prescribed by your doctor, up to a maximum recommended daily dose is 300 mg.

Adolescents and paediatrics:

As prescribed by your doctor.

How long to take it

Continue taking Codeine Phosphate Tablets (Noumed) for as long as your doctor tells you.

If symptoms persist, see your doctor.

For long term users, seek advice from the prescriber before stopping the medicine. Stopping the medicine may lead to withdrawal symptoms.

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.

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

Do not try to make up for a missed dose by taking more than one dose at a time. This may increase the chance of you getting an unwanted effect.

The medicine is only intended for the use of the person it has been prescribed for.

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

While you are using Codeine Phosphate Tablets (Noumed)

Things you must do

Use Codeine Phosphate Tablets (Noumed) exactly as directed or as prescribed by your doctor.

Contact a doctor immediately if you become pregnant while you are taking the medicine.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Codeine Phosphate Tablets (Noumed).

Tell your doctor if you feel Codeine Phosphate Tablets is not helping your condition.

Visit your doctor regularly, as your doctor needs to check your progress and see whether you need to keep taking Codeine Phosphate Tablets (Noumed).

Always discuss with your doctor any problems or difficulties during or after taking Codeine Phosphate Tablets (Noumed).

You should tell any other doctors or dentists treating you that you are taking Codeine Phosphate Tablets (Noumed).

Things you must not do

Do not take any other medicines while you are taking Codeine Phosphate Tablets (Noumed) without first telling your doctor.

Do not drive or operate machinery until you know how Codeine Phosphate Tablets (Noumed) affects you.

Codeine Phosphate may cause dizziness in some people and therefore may affect alertness.

Make sure you know how you react to Codeine Phosphate before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

You must not drink alcohol while using Codeine Phosphate Tablets (Noumed). Drinking alcohol could make some of the unwanted side effects of Codeine Phosphate worse and result in severe drowsiness, decreased awareness, breathing problems, coma and death.

Things to be careful of

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness, dizziness, which may further affect the risk when driving or using dangerous machinery.

Codeine Phosphate Tablets (Noumed) may be habit forming if used for extended periods of time.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too many Codeine Phosphate Tablets (Noumed).

Do this even if there are no signs of discomfort or poisoning.

The signs and symptoms of overdose may include weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and hypotension.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Codeine Phosphate Tablets (Noumed).

Codeine Phosphate Tablets (Noumed) helps most people in the treatment of mild to moderate pain. However, 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.

Ask your doctor or pharmacist any questions you may have. Common Side Effects:

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

- stomach cramps
- dry mouth
- loss of appetite
- constipation
- nausea (feeling sick)
- vomiting
- dizziness
- drowsiness
- feeling faint
- excitability
- skin rashes
- unable to sleep
- unusual dreams

Some side effects are potentially serious. Contact your doctor immediately if you notice any of the following less common side effects:

- itchy, raised or red skin rash
- swelling of face
- muscle stiffness
- breathing difficulties
- heartbeat irregularities
- blurred or double vision
- difficulty in urinating (passing water)

Other adverse effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Check with your doctor as soon as possible if you have any problems while taking Codeine Phosphate Tablets (Noumed) even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using Codeine Phosphate Tablets (Noumed)

Storage

Keep out of reach of children

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep Codeine Phosphate Tablets (Noumed) in a cool dry place where the temperature stays below 25°C and protect from light.

Do not store it, or any other medicines, in a bathroom or near a sink. Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

The tablets should not be taken if they show visible signs of deterioration. Do not take Codeine Phosphate if the tablets do not look quite right.

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

Disposal

If your doctor tells you to stop taking this medication OR it has passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Codeine Phosphate Tablets (Noumed) are white to cream, biconvex circular tablets.

Ingredients

These products contain sugars as lactose.

Codeine Phosphate Tablets (Noumed) 15 mg:

Each tablet contains: 15 mg of Codeine phosphate hemihydrate, plus Lactose monohydrate, Maize starch and Magnesium stearate.

Codeine Phosphate Tablets (Noumed) 30 mg:

Each tablet contains: 30 mg of Codeine phosphate hemihydrate, plus Lactose monohydrate, Maize starch, Acacia, Purified talc and Magnesium stearate.

Codeine Phosphate Tablets (Noumed) 60 mg:

Each tablet contains: 60 mg of Codeine phosphate hemihydrate, plus Lactose monohydrate, Maize starch and Magnesium stearate.

Sponsor Details

Codeine Phosphate Tablets (Noumed) are supplied in New Zealand by:

Noumed Pharmaceuticals Limited
Auckland, New Zealand

Freephone 0800 527 545

Date of Preparation

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