

Painstop Night-Time Pain Reliever®

Paracetamol, codeine phosphate hemihydrate, promethazine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Painstop Night-Time Pain Reliever®.

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 Painstop Night-Time Pain Reliever® against the benefits they expect 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 Painstop Night-Time Pain Reliever® is used for

Painstop Night-Time Pain Reliever® is an analgesic (pain reliever). It works to temporarily relieve acute moderate pain when paracetamol alone is not sufficient in adults and children 12 years and older and sedation is required.

It contains paracetamol, codeine phosphate hemihydrate and promethazine hydrochloride.

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

Codeine phosphate hemihydrate is an opioid pain reliever. Promethazine hydrochloride is antihistamine which in this instance is used for its sedative properties.

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

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

It is only available on a doctor's prescription.

Before you take/give Painstop Night-Time Pain Reliever®

When you must not take it

Do not take Painstop Night-Time Pain Reliever® if you:

- are under 12 years of age
- are breastfeeding
- are aged 18 years or younger and have had recent surgery on your tonsils or adenoids
- are known to be an ultra-rapid metaboliser of codeine.

Do not take Painstop Night-Time Pain Reliever® if you have an allergy to:

- any medicine containing paracetamol
- any medicine containing codeine
- any medicine containing promethazine

- 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 any of the following conditions:

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning
- narrow-angle glaucoma
- stenosing peptic ulcer
- symptomatic prostatic hypertrophy
- bladder neck obstruction
- pyloroduodenal obstruction.

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.

Do not take this medicine/it 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
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- a history of drug or alcohol dependence
- recent surgery on the throat, stomach or intestines
- head injury
- enlarged prostate
- low blood pressure
- underactive thyroid
- epilepsy with diabetes mellitus.

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant.

Codeine may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

If you have not told your pharmacist or doctor about any of the above, tell them before you start taking Painstop Night-Time Pain Reliever®.

Taking other medicines

Do not take with other medicines containing paracetamol.

It is important to check the labels of all other medicines you are taking to make sure they do not contain paracetamol. Taking too much paracetamol may cause serious liver damage.

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.

Painstop Night-Time Pain Reliever® and some other medicines 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
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- 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 heart beat
- 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 Painstop Night-Time Pain Reliever® 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 Painstop Night-Time Pain Reliever®

Follow all directions for use written on the medicine's label.

Do not take more than the recommended dose on the label or for a longer period of time.

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

How much to take

Adults and children 12 years and over: 20 mL to 35 mL as a single bed-time dose when needed to relieve pain and aid sleep.

Always use a metric medicine measure to ensure you give the correct dose

Do not take more than the recommended dose

How long to take it

Adults: Only take Painstop Night-Time Pain Reliever® for a few days at a time unless your doctor tells you to take it for longer.

Children and adolescents aged 12-17: Only take the medicine for 48 hours unless your doctor tells you to take it for longer.

If your symptoms persist, worsen or new symptoms develop, talk to your pharmacist.

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 Painstop Night-Time Pain Reliever®. Do this even if there are no signs of discomfort or poisoning.

Taking too much paracetamol can lead to delayed, serious liver damage. You may need urgent medical attention.

While you are using Painstop Night-Time Pain Reliever®

Things you must do

Only take the medicine as recommended on the label.

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.

Things you must not do

Do not take with other medicines containing paracetamol unless your doctor or pharmacist tells you to.

Adults: Do not take for more than a few days at a time unless your doctor tells you to.

Adolescents 12 to 18 years: Do not take for longer than 48 hours unless your doctor tells you to.

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

Things to be careful of

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

Codeine may be habit forming. Too much paracetamol may cause delayed, serious liver damage.

Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.

Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Be careful driving or operating machinery until you know how Painstop Night-Time Pain Reliever® affects you.

This medicine may cause drowsiness and/or dizziness in some people. If this happens, do not drive or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Painstop Night-Time Pain Reliever®.

This medicine helps most people who need a pain reliever, 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 lists 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
- dizziness
- constipation

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:

- 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 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.

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 using Painstop Night-Time Pain Reliever®

Storage

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

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

Do not store Painstop Night-Time Pain Reliever® 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

Painstop Night-Time Pain Reliever® is a maroon coloured liquid which comes in 100mL and 200mL amber glass bottles with a child-resistant cap.

Ingredients

Painstop Night-Time Pain Reliever® contains 24 mg of paracetamol, 1 mg of codeine phosphate hemihydrate and 1.3mg of promethazine hydrochloride per mL.

It also contains: Saccharin sodium, disodium edetate, sodium metabisulfite, sucrose, propylene glycol, sorbitol (880mg per 5mL), imitation toffee flavour, imitation strawberry flavour, brilliant blue CI 42090, amaranth CI 16185 and purified water. This medicine does not contain lactose or gluten.

Manufacturer/Distributor/Supplier

Painstop Night-Time Pain Reliever® is distributed and supplied in Australia by:

**Care Pharmaceuticals Pty Ltd
Suite 302, Level 3, 75 Grafton
Street**

**Bondi Junction NSW 2022
Australia**

Phone: 1800 788 870

Fax: (02) 9387 6654

E-mail:

info@carepharmaceuticals.com.au

Website:

www.carepharmaceuticals.com.au

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