

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

Consumer Medicine Information (CMI) summary

▼ The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets contains the active ingredient Paracetamol and Codeine Phosphate. Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets is used to temporarily relieve acute moderate pain fever when other analgesics have proven not to be effective.. For more information, see Section [1. Why am I using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#) in the full CMI.

2. What should I know before I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

Do not use if you have ever had an allergic reaction to paracetamol and codeine phosphate or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

- For adults and adolescents over 12 years take one to two tablets to be taken every four to six hours, when required, up to four times daily. DO NOT exceed 8 tablets in 24 hours. Do not give to children under 12 years of age. More instructions can be found in Section [4. How do I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#) in the full CMI.

5. What should I know while using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets.
Things you should not do	<ul style="list-style-type: none">• Do not take with other medicines containing paracetamol unless your doctor or pharmacist tells you to
Driving or using machines	<ul style="list-style-type: none">• This medicine may cause dizziness in some people. If this happens do not drive or use operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 30°C• Do not store in the bathroom or near a sink. Do not leave it on a window sill or in the car

For more information, see Section [5. What should I know while using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#) in the full CMI.

6. Are there any side effects?

Tell your pharmacist or doctor if you notice any of the following and they worry you such as nausea, vomiting, drowsiness, dizziness, constipation. These are common side effects of your medicine. They are usually mild.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:**Limitations of use**

Because of the risks associated with the use of opioids Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 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

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 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 Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 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 Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

Active ingredient(s): *Paracetamol and codeine phosphate hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets.**

Where to find information in this leaflet:

- [1. Why am I using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#)
- [2. What should I know before I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#)
- [5. What should I know while using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets contains the active ingredient **Paracetamol and Codeine Phosphate Hemihydrate**. Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets is analgesic (pain reliever).

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets is used to temporarily relieve acute moderate pain, fever when other analgesics have proven not to be effective.

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

Codeine phosphate is an opioid pain reliever.

2. What should I know before I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

Warnings

Do not use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets if:

- you are allergic to paracetamol and codeine phosphate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- a history of drug or alcohol dependence

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

Check with your doctor if you:

- have acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- have chronic constipation
- have diarrhoea caused by antibiotics or poisoning
- liver or kidney disease
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
- you drink large quantities of alcohol.
- recent surgery on the stomach or intestines
- head injury
- enlarged prostate
- low blood pressure
- underactive thyroid.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

This medicine passes into breastmilk and may affect the baby. It may cause breathing problems in newborn infants.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

Some medicines may interfere with Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets and affect how it works.

- Tranquilisers (medicines for anxiety and nerves)
- 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
- if you are an ultra-rapid metaboliser of CYP2D6
- if you are aged 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets.

4. How do I use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

How much to take

- Adults and adolescents over 12 years: One to two tablets to be taken every four to six hours, when required, up to four times daily. DO NOT exceed 8 tablets in 24 hours.

- Do not give Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets to children under 12 years of age.
- Adults (18 years and over): Keep to the recommended dose. Only take Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets for a few days at a time unless your doctor tells you to take it for longer.
- Children aged over 12 years: Keep to the recommended dose. Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.
- Do not take with other products containing paracetamol unless advised to do so by a doctor or pharmacist.
- If your symptoms persist, worsen or new symptoms develop, talk to your pharmacist.

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.

When to take

- Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets should be used when required, up to four times daily. DO NOT exceed 8 tablets in 24 hours.

How to take Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

- Swallow tablets whole with a glass of water.

If you forget to use Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

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 you missed.

If you use too much Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

If you think that you have used too much Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets?

Things you should 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.

Remind any doctor, dentist or pharmacist] you visit that you are using Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets.

Things you should not do

- Do not take with other medicines containing paracetamol unless your doctor or pharmacist tells you to.
- Adults (18 years and over): Do not take for more than a few days at a time unless your doctor tells you to.
- Children over 12 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.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets affects you.

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets may cause dizziness in some people. If this happens do not drive or use operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

- Keep your medicine in the original pack until it is time to take.
- Store below 30°C.
- Heat and dampness can destroy some medicines.

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • nausea or dyspepsia • vomiting • drowsiness • dizziness • constipation 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • cough suppression • unusual or extreme mood swings • flushing of the face • fast heart beat • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • Paracetamol • Codeine phosphate hemihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Potato starch • Lactose monohydrate • Povidone • Docusate Sodium • Colloidal anhydrous silica • Magnesium stearate • Erythrosine aluminium lake

Do not take this medicine if you are allergic to any of these ingredients.

What Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets look like

Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets are pink, circular, flat beveled tablets with central break line on one side and plain on other side. The products are presented in blister packs of 10, 12, 20, 24, 30, 36 or 40 tablets.

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Who distributes Cipla Pain Relief Paracetamol and Codeine Phosphate Hemihydrate 8 tablets

Medreich Australia Pty Ltd

Unit 8, Homebush Business Village

11-21 Underwood Road, Homebush, NSW 2140

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