

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15

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 + CODEINE 15?

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 contains the active ingredient Paracetamol and Codeine phosphate. CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 is used to relieve pain, when other analgesics have proven not to be effective.

For more information, see Section [1. Why am I using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#) in the full CMI.

2. What should I know before I use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?

Do not use if you have ever had an allergic reaction to CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 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 + CODEINE 15?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 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 + CODEINE 15?

The usual dose for adults and children over 12 years of age is one to two tablets every 4 to 6 hours with water as needed for relief of pain. Do not exceed 8 tablets in a 24 hour period. The usual dose for children 12 years is one tablet every 4 to 6 hours with water as needed up to a maximum of 4 tablets in 24 hours. CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 is not recommended for children under 12 years of age. More instructions can be found in Section [4. How do I use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#) in the full CMI.

5. What should I know while using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?

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 + CODEINE 15.Tell your doctor immediately if you become pregnant, have surgery including dental.
Things you should not do	<ul style="list-style-type: none">Do not give CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 to anyone else, even if they have the same condition as you or treat any other complaints.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Cipla Pain Relief Paracetamol + Codeine 15 affects you.
Drinking alcohol	<ul style="list-style-type: none">Do not drink alcohol.Drinking alcohol increases the likelihood of becoming drowsy.
Looking after your medicine	<ul style="list-style-type: none">Keep the tablets in a cool dry place where the temperature stays below 25°CDo not store the medicine in the bathroom or near a sink

For more information, see Section [5. What should I know while using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#) 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, Stomach pain, Constipation, Dizziness, Drowsiness, Skin rashes, 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, itching or hives on the skin.

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.

Limitations of use

Because of the risks associated with the use of opioids, CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 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 + CODEINE 15 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 + CODEINE 15. 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 + CODEINE 15.

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15

Active ingredient(s): Paracetamol and Codeine phosphate hemihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15. **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 + CODEINE 15.**

Where to find information in this leaflet:

- [1. Why am I using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#)
- [2. What should I know before I use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#)
- [5. What should I know while using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 is used for temporary relief of pain.

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 contains paracetamol and codeine. Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to reduce fever. When other analgesics have proven not to be effective.

Your doctor may recommend CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 for another reason. Ask your doctor if you have any questions about this medicine.

2. What should I know before I use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15

Warnings

Do not use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 if you have an allergy to:

- Paracetamol or codeine phosphate
- Other opioid analgesics such as morphine, pethidine or oxycodone
- Any of the ingredients listed at the end of this leaflet
- Some of the symptoms of an allergic reaction to CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 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
- acute breathing difficulties such as unstable asthma, bronchitis or emphysema
- chronic constipation
- diarrhoea caused by antibiotic use or other poisoning
- CYP2D6 ultra-rapid metaboliser
- Aged between 12 – 18 years in whom respiratory function might be compromised, including post tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, due to an increased risk of developing serious and life-threatening adverse reactions
- Pregnant or Breastfeeding or planning to breastfeed.
- 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

Do not take CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 after the expiry date printed on the pack or if the packaging appears to have been damaged or tampered with. If you take this medicine after its expiry date has passed, it may not work as well.

Do not give CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 to children under the age of 12 years.

If you are not sure whether you should be using CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15, contact your doctor.

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

Tell your doctor if you are 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.

Tell your doctor if you are breastfeeding.

A small amount of codeine passes into the breast milk. It may cause breathing problems in newborn infants.

If you have not told your pharmacist or doctor about any of the above, tell them before you start taking CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15.

Do not breast feed if you are taking CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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.

Some medicines may interfere with CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 and affect how it works.

Do not take with other medicines containing paracetamol unless advised to do so by your doctor or pharmacist.

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

Some medicines can interfere with CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15.

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 CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 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.

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 + CODEINE 15.

4. How do I use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15?

How much to take

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.

The usual dose for adults and children over 12 years of age is one to two tablets every 4 to 6 hours with water as

needed for relief of pain. Do not exceed 8 tablets in a 24 hour period.

The usual dose for children 12 years is one tablet every 4 to 6 hours with water as needed up to a maximum of 4 tablets in 24 hours.

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 is not recommended for children under 12 years of age.

Follow all directions given to you by your doctor and pharmacist carefully. Their directions may differ from the information contained in this leaflet.

How to take CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15

Swallow the prescribed dose of CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 with a glass of water. It can be taken before or after food. However, food intake delays the absorption of paracetamol.

How long to take it for

Adults: Only take CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 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.

- Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to use CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15

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 + CODEINE 15

If you think you or anyone else may have taken too much CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 tablets. The symptoms of overdose of CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 are nausea, vomiting, sweating, weakness, lowering of blood pressure, lethargy, dizziness and mental confusion.

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 + CODEINE 15?

Things you should do

Before starting any new medicine tell all of the doctors, dentists who are treating you for any condition that you are taking CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15.

Only take the medicine as recommended on the label.

Talk to your doctor if your symptoms do not improve.

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

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your 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
- low blood pressure
- head injury
- enlarged prostate
- underactive thyroid
- recent surgery on the stomach or intestines

Things you should not do

Do not give CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 to anyone else, even if they have the same condition as you.

Do not take CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 with any other product containing paracetamol and/or codeine, unless your doctor tells you to.

Do not use for any other complaints unless the 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.

Children and adolescents: 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.

Driving or using machines

Be careful driving a motor vehicle or operating machinery until you know how CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 affects you.

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 may cause drowsiness in some people. Make sure you know how you react to CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 before you drive a motor vehicle or operate machinery or do anything else that could be dangerous if you are drowsy. If drowsiness occurs do not drive a motor vehicle or 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. Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol drowsiness or dizziness may become worse while you are taking CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15.

Looking after your medicine

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

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C. DO not store CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 or any other medicine in the bathroom or near a sink. DO not leave it in the car on hot days or on window sills. Heat and dampness can destroy some medicines. Keep it where children cannot reach it.

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

When to discard your medicine

If you stop taking CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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

Serious side effects

Serious side effects	What to do
Allergy related <ul style="list-style-type: none">• flushing of the face• 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 Heart related <ul style="list-style-type: none">• fast heartbeat. Head and neurology related <ul style="list-style-type: none">• unusual or extreme mood swings	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.

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 + CODEINE 15 contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Paracetamals• Codeine phosphate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Maize starch• Sodium lauryl sulphate• Povidone• Pregelatinized starch

- | | |
|--|---|
| | <ul style="list-style-type: none">• Low substituted hydroxy propyl cellulose• Colloidal anhydrous silica• Purified talc• Magnesium stearate• Purified water |
|--|---|

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

What CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 looks like

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 are white to off white coloured, capsule shaped uncoated tablets with a centre break line on one side.

CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15 are available in a blister packs of 10, 12, 20, 24, 30 and 40 tablets.

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Who distributes CIPLA PAIN RELIEF PARACETAMOL + CODEINE 15

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