

AMCAL IBUPROFEN PLUS CODEINE

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 AMCAL IBUPROFEN PLUS CODEINE?

AMCAL IBUPROFEN PLUS CODEINE contains the active ingredients Ibuprofen and Codeine phosphate. AMCAL IBUPROFEN PLUS CODEINE is used to relieve pain, inflammation (swelling, redness, soreness) and fever when other analgesics have proven not to be effective.

For more information, see Section [1. Why am I using AMCAL IBUPROFEN PLUS CODEINE?](#) in the full CMI.

2. What should I know before I use AMCAL IBUPROFEN PLUS CODEINE?

Do not use if you have ever had an allergic reaction to AMCAL IBUPROFEN PLUS CODEINE 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.** Do not use at all during the last three months of pregnancy,

For more information, see Section [2. What should I know before I use AMCAL IBUPROFEN PLUS CODEINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AMCAL IBUPROFEN PLUS CODEINE 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 AMCAL IBUPROFEN PLUS CODEINE?

The usual dose of AMCAL IBUPROFEN PLUS CODEINE for adults and children over 12 years of age is 2 tablets followed by, if necessary 1 or 2 tablets every 4 hours. Do not take more AMCAL IBUPROFEN PLUS CODEINE than 6 tablets in 24 hours. More instructions can be found in Section [4. How do I use AMCAL IBUPROFEN PLUS CODEINE?](#) in the full CMI.

5. What should I know while using AMCAL IBUPROFEN PLUS CODEINE?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using AMCAL IBUPROFEN PLUS CODEINE.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 AMCAL IBUPROFEN PLUS CODEINE 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 before you drive or use any machines or tools until you know how AMCAL IBUPROFEN PLUS CODEINE affects you.AMCAL IBUPROFEN PLUS CODEINE may cause dizziness, lightheadedness or drowsiness in some people. If this occurs, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">If you drink alcohol, dizziness, lightheadedness or drowsiness may be worse.
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 AMCAL IBUPROFEN PLUS CODEINE?](#) in the full CMI.

6. Are there any side effects?

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following side effects; asthma, wheezing or shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash, fainting. These may be the sign of an allergic reaction. Speak to your doctor if you have any of the following common side effects and they worry you: nausea or vomiting, constipation or dizziness, light-headedness, drowsiness.

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**

AMCAL IBUPROFEN PLUS 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

AMCAL IBUPROFEN PLUS 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

AMCAL IBUPROFEN PLUS CODEINE 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 AMCAL IBUPROFEN PLUS 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.

Use of Other Medicines While Using AMCAL IBUPROFEN PLUS CODEINE

Using AMCAL IBUPROFEN PLUS 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 AMCAL IBUPROFEN PLUS CODEINE.

AMCAL IBUPROFEN PLUS CODEINE

Active ingredients: Ibuprofen and Codeine phosphate

Consumer Medicine Information (CMI)

This leaflet provides important information about using AMCAL IBUPROFEN PLUS CODEINE. **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 AMCAL IBUPROFEN PLUS CODEINE.**

Where to find information in this leaflet:

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

1. Why am I using AMCAL IBUPROFEN PLUS CODEINE?

AMCAL IBUPROFEN PLUS CODEINE contains the active ingredient **Ibuprofen and Codeine phosphate**. AMCAL IBUPROFEN PLUS CODEINE is a pain reliever. **Ibuprofen** belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines work by relieving pain, inflammation (swelling, redness, soreness) and fever. **Codeine phosphate** is an opioid

analgesic that works in the brain and spinal cord to relieve pain.

AMCAL IBUPROFEN PLUS CODEINE is used to relieve inflammation and strong pain associated with migraine headache, tension headache, headache, period pain, dental pain, back pain, neuralgia, rheumatic pain, arthritic pain and muscular pain when other analgesics have proven not to be effective.

AMCAL IBUPROFEN PLUS CODEINE is not recommended for children under 12 years of age.

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

2. What should I know before I use AMCAL IBUPROFEN PLUS CODEINE

Warnings

Do not use AMCAL IBUPROFEN PLUS CODEINE if:

- you are allergic to ibuprofen, codeine or other opioid analgesics such as morphine or pethidine or, aspirin, any other NSAID medicine or other anti-inflammatory medicines, or any of the ingredients listed at the end of this leaflet.
Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAIDs. If you are not sure if you are taking any of these medicines, ask your pharmacist.
Symptoms of an allergic reaction to these medicines may include:
 - asthma, wheezing or shortness of breath.

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- hives, itching or skin rash.
- fainting.

Always check the ingredients to make sure you can use this medicine.

If you are allergic to aspirin or NSAIDs and take AMCAL IBUPROFEN PLUS CODEINE these symptoms may be severe.

- you are in the third trimester of pregnancy (see Pregnancy and breastfeeding).
- you are vomiting blood or material that looks like coffee grounds
- you are bleeding from the rectum (back passage), have black sticky bowel motions (stool) or bloody diarrhoea
- you have peptic ulcer (i.e. stomach or duodenal ulcer) or have had one before.
- you are using other NSAIDS
- you have chronic constipation or shallow breathing, or severe diarrhoea.
- you consume regular and heavy amounts of alcohol.
- you are a CYP2D6 ultra- rapid metaboliser.
- you have severe liver impairment
- you have heart or kidney problems
- you are currently taking a Monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment with a MAOI.

Do not take AMCAL IBUPROFEN PLUS CODEINE if the packaging is torn or shows signs of tampering.

Do not give AMCAL IBUPROFEN PLUS CODEINE to children under 12 years or to those aged 12 -18 years in whom respiratory function may be compromised.

Check with your doctor if you:

- difficulty breathing, wheezing, chronic cough, allergies, asthma or other breathing conditions
- a history of drug dependence, including alcohol dependence
- skin rash (dermatitis)
- skin irritation
- a history of stomach ulcer.
- liver disease.
- kidney disease.
- heart problems/failure, including. swelling of ankles or feet.
- have thyroid problems or low blood pressure.
- a head injury or intracranial pressure.
- have prostatic problems.
- have stomach problems or recent stomach surgery.

Tell your doctor if you take sedatives (medicines used to help you relax or sleep).

Tell your doctor if you have allergies to:

- any other medicines including aspirin, or other NSAID medicines.

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

Not recommended for use in children under 12 years of age.

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.

Do not take AMCAL IBUPROFEN PLUS CODEINE at all during the last three months (third trimester) of pregnancy. Your doctor will decide if you should take AMCAL IBUPROFEN PLUS CODEINE during the first 6 months of pregnancy.

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

Small amounts of ibuprofen and codeine pass into the breast milk.

Codeine may also cause breathing problems in newborn infants.

AMCAL IBUPROFEN PLUS CODEINE is contraindicated during breastfeeding due to risk of respiratory depression in the infant.

Addiction

You can become addicted to AMCAL IBUPROFEN PLUS CODEINE even if you take it exactly as prescribed. AMCAL IBUPROFEN PLUS CODEINE may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking AMCAL IBUPROFEN PLUS CODEINE. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking AMCAL IBUPROFEN PLUS CODEINE suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to AMCAL IBUPROFEN PLUS CODEINE may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

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 AMCAL IBUPROFEN PLUS CODEINE and affect how it works.

- warfarin or other medicines used to prevent blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase inhibitors (MAOIs), medicines used to treat depression, if taken within the last 14 days
- medicines used to treat high blood pressure including diuretics (fluid tablets)
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines such as ciclosporin, tacrolimus, prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- medicines used to relieve stomach cramps, prevent travel sickness and to treat Parkinson's disease
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- metoclopramide, a medicine used to treat nausea and vomiting
- Medicines that affect serotonin levels (serotonergic medicines)
- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs)
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- mifepristone, quinolone antibiotics
- probenecid-medicines used to treat gout
- phenytoin – medicine used to treat epilepsy
- other opioid pain killers.

These medicines may be affected by AMCAL IBUPROFEN PLUS CODEINE or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AMCAL IBUPROFEN PLUS CODEINE.

4. How do I use AMCAL IBUPROFEN PLUS CODEINE?

How much to take

- The usual dose of AMCAL IBUPROFEN PLUS CODEINE for adults and children over 12 years of age is 2 tablets followed by, if necessary 1 or 2 tablets every 4 hours. **Do not take more than 6 tablets in 24 hours.**
- AMCAL IBUPROFEN PLUS CODEINE is not recommended for children under 12 years of age.

- Also, contraindicated in children 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.
- Follow the instructions provided and use AMCAL IBUPROFEN PLUS CODEINE until your doctor tells you to stop.

When to take AMCAL IBUPROFEN PLUS CODEINE

- AMCAL IBUPROFEN PLUS CODEINE should be used for not more than 3 days. If your symptoms persist, worsen or new symptoms develop, talk to your doctor.

How to take AMCAL IBUPROFEN PLUS CODEINE

Take AMCAL IBUPROFEN PLUS CODEINE by mouth with fluid. It may also be taken before, or after food.

If you forget to use AMCAL IBUPROFEN PLUS CODEINE

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 AMCAL IBUPROFEN PLUS CODEINE

If you think that you or someone else have used too much AMCAL IBUPROFEN PLUS CODEINE, you may need urgent medical attention. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used AMCAL IBUPROFEN PLUS CODEINE that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- nausea or upset stomach, vomiting and/or gastric irritation,
- drowsiness, dizziness or very slow,
- slow, unusual or difficult breathing.
- blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes.
- excitability,
- convulsions, fits or unconsciousness may be experienced in rare cases.

If you think you or someone else may have used too much AMCAL IBUPROFEN PLUS CODEINE, 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 AMCAL IBUPROFEN PLUS CODEINE?

Things you should do

Tell your doctor immediately:

- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking AMCAL IBUPROFEN PLUS CODEINE.
- if you become pregnant
- if you are about to be started on any new medicine that you are taking AMCAL IBUPROFEN PLUS CODEINE
- If you are going to have surgery, including dental, tell your service provider (doctor or dentist) that you are taking AMCAL IBUPROFEN PLUS CODEINE.

Talk to doctor if your symptoms do not improve.

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

Call your doctor straight away if you:

Become pregnant while taking AMCAL IBUPROFEN PLUS CODEINE

Remind any doctor, dentist or pharmacist you visit that you are using AMCAL IBUPROFEN PLUS CODEINE.

Things you should not do

- Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.
- Do not give AMCAL IBUPROFEN PLUS CODEINE to anyone else, even if they have the same condition as you
- Do not use AMCAL IBUPROFEN PLUS CODEINE to treat any other complaints unless your doctor tells you to.
- Do not exceed the recommended dose unless your doctor tells you to.
- Excessive use of ibuprofen can be harmful and increase the risk of heart attack, stroke or liver damage.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AMCAL IBUPROFEN PLUS CODEINE affects you.

AMCAL IBUPROFEN PLUS CODEINE may cause dizziness, light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, lightheadedness and/or drowsiness may be worse.

Drinking alcohol

Tell your doctor if you drink alcohol.

Using AMCAL IBUPROFEN PLUS CODEINE with alcohol may result in severe breathing difficulties, decreased awareness, drowsiness, coma and death.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

AMCAL IBUPROFEN PLUS CODEINE given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Looking after your medicine

- Keep the tablets in the pack until it is time to take the dose.
- If you take them out they will not keep well.
- Store where the temperature stays below 25°C.
- A locked cupboard at least one-and-a-half metres above the ground are 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

When you stop taking AMCAL IBUPROFEN PLUS CODEINE or it has passed its expiry date, ask your pharmacist what to do with any tablets 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
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> stomach upset including nausea, (feeling sick), heartburn, stomach pain or vomiting loss of appetite indigestion diarrhoea or constipation <p>Head and neurology related:</p> <ul style="list-style-type: none"> sleeplessness, nightmares change in mood e.g. depression, restlessness, irritability sore or dry mouth or tongue dizziness, light-headedness, drowsiness headache hearing disturbance central sleep apnoea <p>Respiratory related:</p> <ul style="list-style-type: none"> shallow breathing cough suppression 	<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
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> severe pain or tenderness in the stomach vomiting blood or material that looks like coffee grounds. bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea. <p>Allergy related:</p> <ul style="list-style-type: none"> shallow breathing or shortness of breath flushing of the face swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing. asthma, wheezing, shortness of breath, pain or tightness in the chest symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal <p>Heart related:</p> <ul style="list-style-type: none"> fast heart beat <p>Skin related</p> <ul style="list-style-type: none"> yellowing of the skin and eyes, also called jaundice 	<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>

<ul style="list-style-type: none"> sudden or severe itching, skin rash, hives, skin peeling swollen lymph glands <p>Urinary related</p> <ul style="list-style-type: none"> a change in the amount or frequency of urine passed, burning feeling when passing urine unusual weight gain, swelling of ankles or legs <p>Infection related:</p> <ul style="list-style-type: none"> signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers <p>Bleeding related:</p> <ul style="list-style-type: none"> bleeding or bruising more easily than normal, reddish or purplish blotches under the skin signs of anaemia, such as tiredness, being short of breath, and looking pale <p>Head and neurology related:</p> <ul style="list-style-type: none"> unusual or extreme mood swings dizziness, light-headedness severe dizziness, spinning sensation severe or persistent headache difficulty hearing, deafness tingling or numbness of the hands or feet <p>Eyes related:</p> <ul style="list-style-type: none"> eye problems such as blurred vision, sore red eyes, itching <p>Pregnancy related</p> <ul style="list-style-type: none"> not enough amniotic fluid in the womb during pregnancy newborns with kidney failure 	
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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 AMCAL IBUPROFEN PLUS CODEINE contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Ibuprofen• Codeine phosphate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Lactose monohydrate• Maize starch• Glyceryl behenate• Colloidal anhydrous silica• magnesium stearate• opadry white complete film coating system Y-1-7000

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

What AMCAL IBUPROFEN PLUS CODEINE looks like

AMCAL IBUPROFEN PLUS CODEINE is white to off-white capsule-shaped, biconvex, film-coated tablet. (Aust R 227475).

Who distributes AMCAL IBUPROFEN PLUS CODEINE

Cipla Australia Pty Ltd
Level 1, 132-136 Albert Road
South Melbourne, VIC 3205
drugsafety@Cipla.com
Phone: 1800-569-074

This leaflet was prepared in November 2022