ASPALGIN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking 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 taking ASPALGIN?

ASPALGIN contains the active ingredient aspirin and codeine phosphate hemihydrate. ASPALGIN is used for the temporary relief of acute moderate pain, inflammation and fever.

For more information, see Section 1. Why am I taking ASPALGIN? in the full CMI.

2. What should I know before I take ASPALGIN?

Do not take if you have ever had an allergic reaction to aspirin and codeine phosphate hemihydrate 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 take ASPALGIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ASPALGIN 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 take ASPALGIN?

- Your doctor will decide what dose you should receive.
- The usual dose for adults and children over 12 years of age is 2 tablets dissolved in water, every four hours or as directed.

More instructions can be found in Section 4. How do I take ASPALGIN? in the full CMI.

5. What should I know while taking ASPALGIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking ASPALGIN. • Tell your doctor immediately if you become pregnant or are breast-feeding while taking ASPALGIN. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking ASPALGIN.
Things you should not do	• Do not take ASPALGIN to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how ASPALGIN affects you.
Drinking alcohol	• You must not drink alcohol while taking ASPALGIN.
Looking after your medicine	• Keep the pack in a cool, dry place (below 25°C) in its original packaging. • Do not store ASPALGIN in the bathroom, near a sink, on a window sill or in the car. • Keep your tablets where children cannot reach it.

For more information, see Section 5. What should I know while taking ASPALGIN? in the full CMI.

6. Are there any side effects?

Common side effects: nausea (feeling sick), constipation, dizziness, lethargy, drowsiness, sweating, vomiting, skin rashes, runny nose, stomach pains, deafness, Reye's Syndrome. **Serious side effects:** fever, rash, swollen lymph nodes, facial swelling, low amniotic fluid during pregnancy.

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

ASPALGIN 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

ASPALGIN 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

ASPALGIN 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 ASPALGIN 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 Taking ASPALGIN

Taking ASPALGIN 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 taking ASPALGIN.

ASPALGIN®

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

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ASPALGIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ASPALGIN.**

Where to find information in this leaflet:

1. Why am I taking ASPALGIN?
2. What should I know before I take ASPALGIN?
3. What if I am taking other medicines?
4. How do I take ASPALGIN?
5. What should I know while taking ASPALGIN?
6. Are there any side effects?
7. Product details

1. Why am I taking ASPALGIN?

ASPALGIN contains the active ingredients aspirin and codeine phosphate hemihydrate. Aspirin belongs to a group of medicines called analgesics which are used to block pain. It is also an antipyretic. That means it helps reduce your body temperature if you have a fever. Codeine phosphate hemihydrate belongs to a group of medicines called opioid analgesics and it acts by blocking pain and your emotional response to pain.

ASPALGIN is used for the temporary relief of acute moderate pain, inflammation and fever.

Addiction

You can become addicted to ASPALGIN even if you take it exactly as prescribed. ASPALGIN 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 ASPALGIN. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking ASPALGIN suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I take ASPALGIN?

Warnings

Do not take ASPALGIN if:

- you are allergic to aspirin, codeine phosphate hemihydrate or 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

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

- **you have a stomach ulcer.**

  Elderly patients are more likely to have less effective kidney or liver function due to age. This may increase the risk of side effects. You should discuss how much ASPALGIN to take with your doctor or pharmacist.

- **you are in the third trimester of pregnancy.**
- the expiry date (EXP) printed on the pack has passed or 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 doctor.

Do not give this medicine to a child under the age of 12 years unless your doctor has prescribed it for them.

Do not give to children or teenagers suffering viral illness (such as influenza or chicken pox) or fever.

Do not give to 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.

Aspirin has been implicated in cases of Reye's Syndrome, a potentially fatal illness which results from brain inflammation.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- have had any of the following medical conditions:
  - liver disease, hepatitis
  - kidney disease
  - peptic ulcer
  - disorders of the gastrointestinal tract
  - asthma
  - bleeding disorders
  - inflammatory bowel disease
  - inflammation of the pancreas
  - bile duct disorders
  - adrenal gland disorders
  - sleep apnoea (breathing stops and starts while you sleep)
- are a heavy drinker or use drugs
- are about to have surgery under a general anaesthetic
- have recently had gastrointestinal tract or urinary tract surgery
- have had a recent head injury

Ask your doctor if you have a deficiency of liver enzymes that metabolise codeine or if your liver enzymes metabolise codeine too rapidly.

If you have not told your doctor about any of the above, tell them before you start taking ASPALGIN.

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.

Your doctor can discuss with you the risks and benefits involved.

Taking anti-inflammatory medicines (e.g. ASPALGIN) from 20 weeks of pregnancy may increase the risk of low amniotic fluid during pregnancy and kidney disease in the baby.

Do not take this medicine if you are in the third trimester of pregnancy.

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

Do not breast-feed if you are taking this medicine.

The active ingredients in ASPALGIN pass into the breast milk and there is a possibility that your baby may be affected.

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 and ASPALGIN may interfere with each other.

These include:

- medicines used to treat inflammation such as aspirin
- medicines used to treat epilepsy
- medicines used to treat gout
- diuretics
- hypnotics, sedatives or phenothiazines

These medicines may be affected by ASPALGIN 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 have more information on 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 ASPALGIN.

4. How do I take ASPALGIN?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Adults and children over 12 years of age:

- 2 tablets dissolved in water, to be taken every four hours or as directed.

DO NOT take more than 8 tablets in one day.

DO NOT give to children under 12 years of age unless on medical advice.

How to take it

Dissolve the tablets in a glass of water and then swallow the entire contents of the glass.

When to take ASPALGIN

- ASPALGIN should be taken at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

How long to take it

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop taking 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

ASPALGIN given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

If you forget to take ASPALGIN

ASPALGIN should be used regularly at the same time each day.

If it is less than 4 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much ASPALGIN

If you or someone else take too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. 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 has accidentally taken ASPALGIN that was prescribed for you.

If someone takes an overdose they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think you or someone else may have taken too much ASPALGIN, you should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take ASPALGIN as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while taking ASPALGIN?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ASPALGIN.**
- **Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

  It may affect other medicines used during surgery.
- **If you become pregnant while taking this medicine, tell your doctor immediately.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

  Your doctor needs to check your progress and to determine whether you need to continue taking ASPALGIN.
- Tell your doctor if you feel ASPALGIN is not helping your condition.

Things you should not do

- **Do not take ASPALGIN to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **Do not stop taking your medicine or lower the dosage without checking with your doctor.**

  If you stop taking it suddenly, your condition may worsen.

Driving or using machines

Be careful driving or operating machinery until you know how ASPALGIN affects you.

This medicine may cause nausea, vomiting, constipation, drowsiness, dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C. Keep the tablets in a dry place.

Do not store ASPALGIN 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.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Do not take 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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ASPALGIN.

This medicine helps most people with the temporary relief of acute moderate pain, inflammation and fever, but it may have unwanted side effects in some people. All medicines 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
• nausea (feeling sick) • vomiting • loss of appetite • indigestion • stomach pain • fever • constipation • dizziness • low blood pressure • lethargy • drowsiness • sweating • skin rash • runny nose • deafness • Reye's Syndrome (refer to previous comments on use in children and teenagers) • sleep apnoea (breathing stops and starts while you sleep) • sexual dysfunction • absence of menstrual period	**Speak to your doctor if you have any of these side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• fever, rash, swollen lymph nodes, facial swelling • low amniotic fluid during pregnancy • chest pain • difficulty swallowing • severe upper abdominal pain possibly radiating to the back, abdominal bloating and difficulty breathing	**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 ASPALGIN contains

Active ingredient (main ingredient)	ASPALGIN contains 300 mg of aspirin and 8 mg of codeine phosphate hemihydrate
Other ingredients (inactive ingredients)	• calcium carbonate • citric acid • disodium edetate • purified talc • saccharin sodium • sodium lauryl sulfate • wheat starch
Potential allergens	ASPALGIN contains gluten and saccharin.

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

What ASPALGIN looks like

ASPALGIN tablets are round, white and flat with bevelled edges with one side plain and one side engraved FM having a diameter of 17/32". They are available in blister packs of 40. (AUST R 13431).

Who distributes ASPALGIN

Viatris Pty Ltd

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30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in September 2025.

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