

ASPALGIN

Aspirin and Codeine phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about the ASPALGIN tablets.

It does not contain all of the available information about ASPALGIN.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ASPALGIN against the benefits he/she expects it will have.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is ASPALGIN

The name of your medicine is ASPALGIN.

The active ingredients are called aspirin and codeine phosphate.

Aspirin belongs to a group of medicines called analgesics which are used to block pain. It is also *antipyretic*; that means it helps reduce your body temperature if you have a fever.

Codeine phosphate belongs to a group of medicines called *opioid analgesics* and it acts by blocking pain and your emotional response to pain.

ASPALGIN is available as a tablet.

What ASPALGIN is used for

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

Use ASPALGIN only as directed and consult a health care professional if pain or symptoms persist.

Your doctor may have prescribed ASPALGIN for another purpose. Ask your doctor if you have any questions about why ASPALGIN has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

Before you take ASPALGIN

When you must not take it

Do not take ASPALGIN if you are allergic to:

- ASPALGIN or any of its ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to ASPALGIN may include red, itchy skin rashes, difficulty breathing, hay fever, swelling of the face or throat or faintness.

Do not use ASPALGIN after the expiry date (EXP.) printed on the pack.

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

Do **not** purchase or use ASPALGIN if the packaging is torn or shows signs of tampering.

Do **not** give it to children **under the age of 12** 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.

Do not take if you have a stomach ulcer. Aspirin is distributed to the breast milk so do not take if you are breastfeeding. However, if your doctor advises you require codeine therapy while breastfeeding, then breastfeeding should be suspended and alternative arrangements should be made for feeding the infant for any period during codeine treatment.

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.

Before you start to take it

You must tell your doctor if you are:

1. **allergic to any other medicines or any foods, dyes or preservatives.**
2. **you have any other medical conditions/ health problems, including:**
 - liver disease, hepatitis
 - kidney disease
 - peptic ulcer
 - disorders of the gastrointestinal tract
 - asthma
 - bleeding disorders
 - inflammatory bowel disease
3. **you are a heavy drinker or use drugs**
4. **you are about to have surgery under a general anaesthetic.**
5. **you have recently had gastrointestinal tract or urinary tract surgery**
6. **you have had a recent head injury**
7. **you are pregnant or breastfeeding**

ASPALGIN is rated in Australia as a Category C drug for use in pregnancy. This means that it is **not** recommended for use by pregnant women.

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 take any ASPALGIN

See your doctor before taking for thinning of the blood or for your heart.

Taking other medicines

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

Unless a doctor has said so, do not take with other medicines containing aspirin or other anti-inflammatory medicines.

Some medicines may interfere with ASPALGIN.

These include:

- medications for epilepsy
- anti-gout medications
- diuretics
- hypnotics, sedatives or phenothiazines

The above medicines may either reduce the effectiveness of ASPALGIN, reduce its own effectiveness and/ or react with ASPALGIN resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ASPALGIN.

How to take ASPALGIN

How much to take

The recommended doses of ASPALGIN are:

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

The tablets should be dissolved in a glass of water and the entire contents of that glass should be swallowed.

How long to take it

If pain persists, see your doctor.

Continue taking ASPALGIN for no more than a few days at a time unless your doctor has advised you to.

If you forget to take it

Take your dose as soon as you remember, and then go back to taking it as you would normally.

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

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

Do not try to make up missed doses by taking more than one dose at a time. This may increase the chance of you getting an unwanted effect.

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

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much ASPALGIN. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol (including any barbiturates or narcotics) which has been taken. You may need urgent medical attention. Keep telephone numbers for these places handy

If you take too much ASPALGIN you may have symptoms of weakness, dizziness, lethargy, drowsiness, nausea, vomiting, sweating, tinnitus (ringing in the ears), deafness, mental confusion and hypotension.

While you are using ASPALGIN

Things you must do

Use ASPALGIN exactly as directed or as your doctor has prescribed.

Tell your doctor if you feel ASPALGIN is not helping your condition.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking ASPALGIN. Always discuss with your doctor any problems or difficulties during or after taking ASPALGIN.

Things you must not do

Do not take any other medicines while you are taking ASPALGIN without first telling your doctor.

Do not drive or operate machinery until you know how ASPALGIN affects you.

ASPALGIN may cause dizziness in some people and therefore may affect alertness.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful drinking alcohol while taking ASPALGIN. If you drink alcohol, it could make some of the unwanted side effects of ASPALGIN worse.

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking ASPALGIN.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness, dizziness, which may further affect the risk when driving or using dangerous machinery.

Side effects

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

ASPALGIN helps most people with medical conditions listed in the beginning of this leaflet, but it may

have unwanted side effects in some people, especially in elderly patients or those with underlying disorders.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you.

Common Side Effects:

- nausea (feeling sick)
- constipation
- dizziness
- lethargy
- drowsiness
- sweating
- vomiting
- skin rashes
- runny nose
- stomach pains
- deafness
- Reye's Syndrome (refer to previous comments on use in children and teenagers)

Some people may get other side effects of ASPALGIN.

Check with your doctor as soon as possible if you have any problems while taking ASPALGIN even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After using ASPALGIN

Storage

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.

Keep ASPALGIN in a cool dry place where the temperature stays below 25°C and protect from light.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines. Do not take ASPALGIN if the tablets do not look quite right.

Keep your tablets in the blister pack they were provided in until it is time to take them.

Disposal

If your doctor tells you to stop taking this medication OR it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

ASPALGIN tablets are white tablets marked FM and come in blister packs of 20 and 40.

Ingredients

ASPALGIN tablets contain the following ingredients: aspirin, codeine phosphate, starch - wheat, calcium carbonate, citric acid – anhydrous, talc - purified, disodium edetate, sodium lauryl sulphate, saccharin sodium.

Sponsor

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Australia

The Australian Registration
Number for ASPALGIN is AUST R
13431.

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