

ASPALGIN

aspirin and codeine phosphate hemihydrate

Consumer Medicine Information

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 Using ASPALGIN

Using 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 using ASPALGIN.

What is in this leaflet

This leaflet answers some common questions about ASPALGIN. It does not contain all the available information. 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 they expect it will have for you.

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 ASPALGIN is used for

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

This medicine 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.

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.

Before you take ASPALGIN

When you must not take it

Do not take ASPALGIN if you have an allergy to:

- any medicine containing aspirin
- any medicine containing codeine phosphate hemihydrate
- 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

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.

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.

Do not take ASPALGIN if 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.

Do not take this medicine after the expiry date printed on the pack or if 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you 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

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

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

Tell your doctor if:

- you are a heavy drinker or use drugs

- you are about to have surgery under a general anaesthetic
- you have recently had gastrointestinal tract or urinary tract surgery
- you 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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.

How to 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 it

Take your medicine 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 it

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 (overdose)

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

If you think you or someone else may have taken too much ASPALGIN, 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.

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.

While you are using ASPALGIN

Things you must 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 must 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.

Things to be careful of

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.

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

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

Side effects

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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)

The above list includes the more common side effects of your medicine.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using ASPALGIN

Storage

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.

Disposal

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.

Product description

What it looks like

ASPALGIN tablets are round and white with bevelled edges and marked with FM on one side.

ASPALGIN is available in blister packs of 40.

Ingredients

ASPALGIN contains 300 mg of aspirin and 8 mg of codeine phosphate hemihydrate as the active ingredients.

The tablets also contain the following ingredients:

- calcium carbonate
- citric acid
- disodium edetate
- purified talc
- saccharin sodium
- sodium lauryl sulfate
- wheat starch

The tablets contain gluten and saccharin.

Distributor

ASPALGIN is distributed in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Phone: 1800 314 527

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