

Amcal Strong Pain Relief Plus

Paracetamol 500mg and Codeine Phosphate Hemihydrate 10mg and Doxylamine succinate 5.1mg Tablets

Consumer Medicine Information

Please read this information before you start taking this medicine

What is in this Leaflet?

This leaflet answers some common questions about Amcal Strong Pain Relief Plus Tablets. It does not contain all the available information. It does not take the place of talking to your doctor. All medicines have risks and benefits. Your doctor has weighed the risks of taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor.

Keep this leaflet with this medicine.

You may need to read it again.

What are Amcal Strong Pain Relief Plus Tablets used for

The name of your medicine is Amcal Strong Pain Relief Plus Tablets.

It contains the active ingredients paracetamol, codeine phosphate hemihydrate & doxylamine succinate.

Paracetamol, an analgesic with antipyretic action also reduces fever.

Doxylamine succinate is an antihistamine with pronounced sedative effects.

Codeine phosphate hemihydrate is an analgesic, and in combination with paracetamol and doxylamine produces greater analgesia than any of these drugs alone and avoids the side effects associated with large doses of these components.

Amcal Strong Pain Relief Plus Tablets are used to provide effective temporary relief from the pain and discomfort associated with

- neck and back pain,
- headache
- tension headache,
- toothache,
- backache,
- migraine headache,
- muscle pain,
- nerve pain,
- arthritis,
- rheumatics,
- osteoarthritis
- period pain
- symptoms of
 - cold,
 - sore throat,
 - flu
- trauma
- surgery
- dental procedures
- and other pain

where a combined calmatative and analgesic action is required.

It also reduces fever.

Your doctor may have prescribed this medicine for another reason.

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

Before you take Amcal Strong Pain Relief Plus Tablets

When you must not take it

Do not take this medicine if you have an allergy to:

- **any medicine containing paracetamol, codeine, doxylamine or other antihistamines or**
- **any of the inactive ingredients listed at the end of this leaflet.**

Signs of an allergic reaction may include:

- rash,
- itching of the skin,
- shortness of breath and
- swelling of the tongue or face.

Do not give this medicine to a child under 12 years.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn or shows signs of tampering. Do not take this medicine if you have or have had any of the following medical conditions:

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems

- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning
- if you are a Ultra-rapid metabolizer of CYP2D6
- if you are aged below 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea

Do not take this medicine if you have alcohol dependence.

Do not take this medicine during labour, especially if the baby is premature.

The medicine may produce withdrawal effects in the newborn baby. Do not take this medicine if you are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

If you are not sure whether you should be taking this medicine, talk to your doctor.

Before you start to take it

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 are pregnant, intend to become pregnant, or are breastfeeding or intend to breastfeed. Do not Amcal Strong Pain Relief Plus Tablets during labour, especially if the baby is premature.

This medicine may product withdrawal effects in the newborn baby.

Your doctor will discuss the possible risks and benefits of using this medicine during pregnancy and breastfeeding.

Do not use Amcal Strong Pain Relief Plus Tablets if you are breastfeeding or planning to breastfeed.

This medicine passes into breast milk and may affect the baby.

Tell your doctor if you suffer from or have had any medical conditions, especially the following:

- kidney or liver problems
- epilepsy
- difficulty breathing,
- wheezing,
- chronic cough,
- asthma
- other chronic breathing conditions
- glaucoma
- urinary retention
- chronic alcohol consumption
- a history of drug dependence, alcohol dependence
- recent surgery on the stomach or intestines
- head injury
- prostate problems
- low blood pressure underactive thyroid

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

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

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

Do not take with other medicines containing paracetamol, unless your doctor says you can. Some medicines may interact with this medicine.

These include:

- sleeping tablets or sedatives
- medicines to control fits or anti-epileptic drugs e.g. Dilantin or Tegretol
- anti-depressant tablets

- anti-coagulant tablets

These medicines may be affected by Amcal Strong Pain Relief Plus Tablets or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you. Your doctor has more information on medicines to be careful with or avoid while taking this medicine.

How to take Amcal Strong Pain Relief Plus Tablets

Follow all directions given to you by your doctor carefully and keep to the recommended dose.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor for help.

How much to take

The usual dose for adults and children over 12 years of age is one to two tablets every 4 to 6 hours, as needed for pain relief.

Do not take more than 8 tablets in a 24 hour period.

Do not give this medicine to a child under 12 years.

How to take it

Swallow the tablets with a full glass of water.

When to take it

It does not matter if you take this medicine before or after food.

How long to take it

This medicine is for short term use only.

Adults and children over 12 years:

The usual dose is one to two tablets to be taken every four to six hours, as needed for relief, up to four times daily. Do not exceed 8 tablets in a 24

hour period. Keep to the recommended dose.

Adults (18 years and over): Don't take this medicine for longer than a few days at a time unless advised by a doctor.

Adolescents (12-17 years): Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.

If pain persists for more than three days, please see your doctor.

If you forget to take it

There is no need to take extra doses if the pain has gone away.

If the pain is still present, take your next dose if required.

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

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

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 the Poisons Information Centre (13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage.

If you have taken too much of this medicine, you may feel drowsy, sick in the stomach, or restless and you may need urgent medical attention.

While you are taking Amcal Strong Pain Relief Plus Tablets

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are about to be started on a new medicine tell your doctor that you are taking this medicine.

If you plan to have surgery that needs a general anesthetic, tell your doctor or dentist that you are taking this medicine.

Tell your doctor if:

- you develop a skin rash or hives while taking this medicine
- you become pregnant while taking this medicine

Things you must NOT do

Do not give this medicine to anyone else, even if they have the same symptoms as you. Do not use this medicine to treat any other complaints unless your doctor tells you to.

Adults (18 years and over): Don't take this medicine for longer than a few days at a time unless advised by a doctor.

Adolescents (12-17 years): Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.

Things to be careful of

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

This medicine may cause drowsiness or lightheadedness in some people and affect mental alertness.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you get dizzy.

Do not drink alcohol.

Drinking alcohol increases the likelihood of becoming drowsy.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine.

This medicine helps most people with pain, but may have unwanted side effects in a few people. 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 any questions you may have.

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

- drowsiness
- depression
- dizziness
- feeling sick or stomach pains
- diarrhoea
- loss of appetite, weight loss
- constipation
- skin rashes

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Amcal Strong Pain Relief Plus Tablets

Storage

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

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

Keep your medicine in a cool, dry place where it stays below 30°C.

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

Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine where young 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

Return any unused medicines to your pharmacist.

Product Description

What it looks like

Tablets are white, capsule shaped, biconvex, bevel edged, uncoated tablets with a breakline on one side and plain on the other side. It is available in packs 20 and 40 tablets.

Active ingredients:

Each tablet contains:

Paracetamol 500mg

Codeine Phosphate Hemihydrate
10mg

Doxylamine Succinate 5.1mg

Other ingredients:

Lactose, Starch-Maize, Povidone, Ethanol, Crospovidone, Cellulose-microcrystalline, Stearic Acid, Magnesium Stearate.

Sponsor

Sigma Company Limited

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