

AMCAL Osteo Relief Modified Release Tablets

paracetamol 665 mg

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

AMCAL Osteo Relief Modified Release tablets are effective for the relief of persistent pain associated with:

- osteoarthritis
- muscle aches and pains such as backache

The active ingredient in this medicine is paracetamol, which is also used for effective temporary relief of pain and discomfort associated with:

- headache
- tension headache
- period pain
- toothache and pain after dental procedures
- colds and flu

Paracetamol also reduces fever.

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

Your pharmacist or doctor may have recommended it for another reason.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you are taking other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu or to aid sleep.

Do not take more than the recommended dose as it may cause serious harm to your liver.

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

- any medicine containing paracetamol
- 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 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 pharmacist or doctor.

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- liver or kidney disease
- are underweight or malnourished
- Regularly drink alcohol
You may need to avoid using this product altogether or limit the amount of paracetamol that you take.
- You have a severe infection, are severely malnourished or are a chronic heavy alcohol user as this may increase the risk of metabolic acidosis:
Signs of metabolic acidosis include:
 - Deep, rapid, difficult breathing
 - Feeling sick (nausea), being sick (vomiting)
 - Loss of appetite

Please see your doctor if your symptoms do not improve.

Ask your pharmacist or doctor if you are pregnant or plan to

become pregnant or are breastfeeding.

Paracetamol may be used during pregnancy and if you are breastfeeding but you should always consult your doctor first.

Consider taking the lowest effective dose for the shortest period of time.

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

If you have not told your pharmacist or doctor about any of the above, tell them before you start taking this medicine.

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 this one may interfere with each other. These include:

- warfarin, used to treat to prevent blood clots
- metoclopramide, used to control nausea and vomiting
- propantheline, used to treat urinary incontinence
- some antidepressants, used to treat mood disorders or narcotic analgesics, used for strong pain
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- alcohol
- probenecid, used to treat gout
- cholestyramine, used to treat high cholesterol levels in the blood

These medicines may be affected by paracetamol 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 this medicine

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 directions, ask your doctor or pharmacist for help.

How much to take

Adults and children aged 12 years and over:

Take 2 tablets swallowed whole three times a day, every six to eight hours as needed.

Do not take more than 6 tablets in 24 hours.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush or chew the tablets.

They can be taken with or without food.

When to take it

Take your medicine at about the same time each day, spacing the doses at equal intervals.

As this medication is a modified release tablet, taking it at the same time each day (at least 6-8 hours apart between doses) will have the best effect to prevent breakthrough pain. It will also help you remember when to take it.

How long to take it

Adults and children aged 12 years and over:

Do not take paracetamol for longer than a few days at a time, except on medical advice.

Children aged 12-17 years:

Do not use this medication for longer than 48 hours at a time, except on medical advice.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning because of the risk of liver failure.

You may need urgent medical attention.

Because AMCAL Osteo Relief contains a modified release formulation of paracetamol (slow-release), it is recommended that you seek help straight away even if you feel well because of the risk of delayed, serious liver damage.

While you are using this medicine

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

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 are about to have any blood tests, tell your doctor that you are taking this medicine.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use for more than a few days at a time unless your doctor or pharmacist tells you to.

Do not take more than the recommended dose unless your doctor tells you to.

Things to be careful of

Only drink small quantities of alcohol (beer, wine or spirits) while using paracetamol.

Drinking large quantities of alcohol whilst taking paracetamol may increase the risk of liver side effects.

Side effects

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

This medicine helps most people with various types of pain, but it may have unwanted side effects in a few people. All medicines can 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.

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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- unexplained bruising or bleeding
- bloody or dark urine or stools
- fever or body aches that may be accompanied by coughing, sensitivity to light or a sore throat

- blisters and sores on the skin and mucus membranes of the mouth, throat, eyes or genitals
- rash, peeling, itching or hives on the skin or mouth ulcers
- trouble breathing (often at night, in the morning or after you exercise), or chest tightness and pressure
- symptoms of liver problems including yellowing of the skin and eyes; dark urine; pale or bloody/tar-coloured stools; itchy skin; pain in the upper right abdomen; abdominal swelling; nausea and vomiting; disorientation or confusion; sleepiness
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Storage and Disposal

Storage

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

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

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

Do not store this medicine or any other medicine in the bathroom or

near a sink. Do not leave it on a windowsill 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

AMCAL Osteo Relief Modified Release Tablets

White to off-white caplet shaped coated tablets with 665 debossed on one side and plain on other side. AUST R 232216.

Ingredients

This medicine contains 665 mg of paracetamol as the active ingredient.

This medicine also contains the following:

- maize starch
- sodium starch glycollate type A
- colloidal anhydrous silica
- povidone
- magnesium stearate
- pregelatinised maize starch
- hypromellose
- microcrystalline cellulose
- macrogol 6000
- purified talc
- titanium dioxide

This medicine does not contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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This leaflet was prepared in
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