

ARCOXIA®

Etoricoxib

30 mg, 60 mg, 90 mg & 120 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using ARCOXIA.

This leaflet answers some common questions about ARCOXIA. 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 ARCOXIA 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 ARCOXIA is used for

ARCOXIA is used for the following:

- acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA)
- management of ankylosing spondylitis
- relief of chronic musculoskeletal pain
- relief of acute pain, including pain associated with minor dental procedures
- to treat acute gouty arthritis

Your doctor will prescribe ARCOXIA for you only after you have used other medicines, i.e paracetamol for your condition and it has not been suitable for you.

Your doctor will want to discuss your treatment with ARCOXIA from time to time. It is important that you use the lowest dose that controls your pain and you should not take ARCOXIA for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

Osteoarthritis

Osteoarthritis is a joint disease. It results from the gradual breakdown of the cartilage that covers the joints and cushions the ends of bones.

Symptoms of osteoarthritis include pain, tenderness, stiffness of one or more joints, and physical disability. The hips and knees are the most commonly affected joints, but other joints such as those of the hands and spine may also be affected.

Osteoarthritis is more common in women than in men. Many factors can lead to the development of osteoarthritis including obesity and joint injury (eg. from sport).

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic disease that causes pain, stiffness, swelling and loss of function in the joints and inflammation in other body organs.

Ankylosing Spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine and large joints.

Gout

Gout is a disorder characterised by sudden, recurring attacks of pain and inflammation in one or more joints.

How ARCOXIA works

ARCOXIA belongs to a group of medicines called cyclooxygenase-2 (COX-2) specific inhibitors (also known as Coxibs).

The body produces two similar enzymes called COX-1 and COX-2. COX-1, among other functions, is involved with protecting the stomach, while COX-2 plays a role in joint inflammation and pain.

ARCOXIA reduces pain and inflammation by blocking COX-2, an enzyme in the body. ARCOXIA does not block COX-1, the enzyme involved in protecting the stomach from ulcers.

Other anti-inflammatory medicines (NSAIDs) block both COX-1 and COX-2. ARCOXIA relieves pain and inflammation with less risk of stomach ulcers compared to NSAIDs. However taking aspirin with ARCOXIA may reverse this benefit (see Before you take ARCOXIA, *Taking Other Medicines*).

In clinical studies, the risk of developing ulcers on ARCOXIA was lower than with NSAIDs. Some people developed ulcers whether they were taking ARCOXIA or placebo in these studies; however the rate was higher on ARCOXIA when compared to patients taking placebo.

If any of the following symptoms: shortness of breath, chest pains or ankle swelling appear or worsen, stop your treatment with ARCOXIA and consult a doctor, as soon as is practical.

If you have kidney, liver or heart disease, your doctor will want to appropriately keep a check on you.

If you develop any symptoms that could indicate a severe allergic reaction such as an inability to breathe or a serious skin reaction you must consult a doctor on an urgent basis.

Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that controls your pain and you should not take ARCOXIA for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

ARCOXIA can increase blood pressure in some people, especially in high doses, and this could increase the risk of heart attacks and strokes. Your doctor will want to check your blood pressure from time to time, to make sure that it is safe to continue treatment.

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

ARCOXIA is not addictive.

Before you take ARCOXIA

When you must not take it

Do not take ARCOXIA if:

- **you have an allergy to ARCOXIA or any of the ingredients listed at the end of this leaflet**
- **you have taken aspirin or other anti-inflammatory medicines (commonly known as NSAIDs) before, which caused asthma, itchy swellings on the skin (hives), runny nose, or other allergic reactions**
- you have had heart failure, a heart attack, chest pain (angina), narrow or blocked arteries of the extremities (peripheral arterial disease), a stroke or mini stroke (TIA or transient ischaemic attack)
- you have high blood pressure that has not been controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is adequately controlled)
- you have had or are having major surgery on your heart or arteries
- you have serious liver disease
- you have a current stomach ulcer or bleeding in your stomach or intestines
- you have serious kidney disease
- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking ARCOXIA, talk to your doctor.

ARCOXIA has not been adequately studied in children. Therefore, ARCOXIA should not be given to children.

ARCOXIA works equally well in older and younger adult patients. Adverse experiences may occur at a higher incidence in older patients compared to younger patients. If you are elderly (ie. over 65 years of age), your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for older patients.

Before you start to take it

Tell your doctor if:

- **you are pregnant or intend to become pregnant.**
ARCOXIA is not recommended for use during late pregnancy. If there is a need to consider using ARCOXIA during your pregnancy, your doctor will discuss with you the benefits and risks of using it.
- **you are breast-feeding or plan to breast-feed.**
It is not known if ARCOXIA passes into breast milk. You and your doctor should discuss whether you should stop breast-feeding or not take ARCOXIA.
- **you have or have had any medical conditions, especially the following:**
 - **history of angina, heart attack or a blocked artery in your heart**
 - narrow or blocked arteries of the extremities
 - kidney disease
 - liver disease

- dehydration, for example by a prolonged bout of vomiting or diarrhoea
- **history of stomach bleeding or ulcers**
- **heart failure**
- **high blood pressure**
- swelling of the ankles, feet or legs due to fluid retention (also called oedema)
- **you have had an allergic reaction to aspirin or other anti-inflammatory medicines (commonly known as NSAIDs).**
Symptoms of an allergic reaction may include asthma, pinkish itchy swellings on the skin (hives), runny or blocked nose.
- **you have an infection.**
If you take ARCOXIA while you have an infection, it may hide fever and may make you think, mistakenly, that you are better or that your infection is less serious than it might be.
- **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**
- you have a history of stroke or mini stroke
- you have conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking.

If you have not told your doctor about any of the above, tell them before you take any ARCOXIA.

Taking other medicines

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

You should also tell any health professional.

Some medicines and ARCOXIA may interfere with each other. These include:

- warfarin, used to prevent blood clots
- rifampin (rifampicin), an antibiotic used to treat tuberculosis and other infections
- water/fluid pills (diuretics)
- ACE inhibitors and angiotensin receptor blockers, medicines used to lower high blood pressure or treat heart failure
- lithium, used to treat mood swings and some types of depression
- ethinyl oestradiol, used in some birth control pills
- conjugated estrogens used in some hormone replacement therapy
- methotrexate, used to treat arthritis and some types of cancer

These medicines may be affected by ARCOXIA or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Some medicines should not be taken with ARCOXIA. These include:

- non-steroidal anti-inflammatory medicines (NSAIDs), used to relieve pain, swelling, and other symptoms of inflammation
- aspirin when used regularly for conditions other than to prevent heart attack or stroke
ARCOXIA can be taken with low dose aspirin.

If you are currently taking low dose aspirin for the prevention of a heart attack or stroke, you should continue to do so unless specified by your Doctor. ARCOXIA cannot replace aspirin for this purpose.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ARCOXIA.

How to take ARCOXIA

How much to take

Take ARCOXIA only when prescribed by your doctor.

For osteoarthritis, the recommended dose is 30 mg or 60 mg once a day.

For rheumatoid arthritis the recommended dose is 60 mg or 90 mg once a day.

For ankylosing spondylitis the recommended dose is 60 mg or 90 mg once a day.

For the relief of gout attacks and acute pain, the recommended dose is 120 mg once a day, which should only be used for the acute painful period.

For relief of short term pain after dental procedures, the recommended dose is 90 mg once a day, which should only be used during the painful period, to a maximum of 8 days treatment.

For the relief of chronic musculoskeletal pain the recommended dose is 60 mg once a day.

Doses greater than those recommended for each condition have either not demonstrated additional efficacy or have not been studied. Therefore, the daily doses stated above for each condition should not be exceeded.

If you have mild liver disease, you should not take more than 60 mg a day. If you have moderate liver disease, you should not take more than 60 mg **every other day** or 30 mg a day.

Follow all directions given to you by your doctor 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 to take it

ARCOXIA comes as tablets.

When taking the tablets, swallow them with a glass of water. Do not halve the tablet.

When to take it

Take your ARCOXIA at about the same time each day.

Taking ARCOXIA at the same time each day will have the best effect. It will also help you remember when to take the dose.

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

How long to take it

Do not use ARCOXIA for longer than your doctor says.

Your doctor will want to discuss your treatment from time to time. It is important that you use the lowest dose that controls your pain and you should not take ARCOXIA for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

Depending on your condition, you may need to take ARCOXIA for a few days or for a longer period.

For arthritis ARCOXIA helps relieve your symptoms but it does not cure it. Continue taking ARCOXIA for as long as your doctor prescribes.

For the relief of gout attacks or other types of pain, ARCOXIA is usually only needed for a few days, limited to a maximum of 8 days treatment.

If you are not sure how long to take ARCOXIA, talk to your doctor.

If you forget to take it

If it is almost time for 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 tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

While you are using ARCOXIA

Things you must do

If you become pregnant while taking ARCOXIA, tell your doctor immediately.

If you get an infection while taking ARCOXIA, tell your doctor. ARCOXIA may hide fever and may make you think, mistakenly, that you are better or that your infection is less serious than it might be.

If you notice any of the following, tell your doctor immediately

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools), or bloody diarrhoea
- any symptoms that could indicate a severe allergic reaction such as inability to breathe, chest pains or ankle swelling or a serious skin reaction

These symptoms may occur without warning. Stop your treatment with ARCOXIA. You may need urgent medical attention.

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

Things you must not do

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

Things to be careful of

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

The effect of ARCOXIA on the ability to drive a car or operate machinery has not been studied, although it is thought to be unlikely to have any effect on these activities. However, as with many medicines, ARCOXIA may cause certain adverse effects in some people, including dizziness and tiredness. Make sure you know how you react to ARCOXIA before you drive a car or operate machinery.

Things that would be helpful for your osteoarthritis

Some self- help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Exercise - regular exercise can help reduce pain and disability from osteoarthritis by increasing muscle strength and reducing the load on joints, but it is important not to overdo it. Walking is good exercise, however, before starting any exercise, ask your doctor about the best kind of programme for you.
- Weight - your doctor may suggest losing some weight to help reduce the strain on your joints. Some people may need a dietician's help to lose weight.
- Hot and cold treatments- These can help to relieve pain from arthritis, including hot and cold packs, or exercising in a warm water pool (hydrotherapy). Talk to your doctor or physiotherapist about the types of hot and cold treatments available that would be helpful for your condition.
- Using support devices- These may assist in coping with everyday tasks at home or help to relieve pain in certain joints. Ask a physiotherapist or occupational therapist for advice about joint protection, aids and special equipment.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ARCOXIA.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

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

ARCOXIA helps most people with arthritis, or other types of pain, but it may have unwanted adverse effects in a few people.

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

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

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

- feeling sick (nausea), vomiting
- heartburn, uncomfortable feeling or pain in the stomach, indigestion
- mouth ulcers
- diarrhoea
- swelling of the legs, ankles or feet
- high/increase in blood pressure
- headache, dizziness
- unusual tiredness or weakness
- difficulty sleeping (insomnia)
- signs of urinary tract infection, including painful burning when passing urine
- wheezing
- signs of an infection of the breathing passages, including runny nose, sore throat, cough
- changes in taste
- high levels of potassium in the blood
- feeling anxious
- depression
- restlessness
- drowsiness
- confusion
- seeing, feeling or hearing things that are not there
- blurred vision

These are the more common adverse effects of ARCOXIA.

Tell your doctor immediately if you notice any of the following:

- skin rash or itchiness
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- redness of the skin
- severe stomach pain
- passing little or no urine
- yellowing of the skin and/or eyes, also called jaundice
- a feeling of pain, tightness, pressure or heaviness in the chest (angina)
- increased tendency to bleed/bruise, or tendency to bleed for a longer period of time – these may be symptoms of reduced platelets in your body
- severe pain and swelling following a dental extraction, “dry socket”

These may be serious adverse effects. Some of these may be symptoms of an allergic reaction to ARCOXIA. You may need urgent medical attention.

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

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing (hypersensitivity reactions, anaphylactic/anaphylactoid reactions including shock)
- shortness of breath, chest pain, and swelling of the feet or legs due to fluid build-up (which may be symptoms of heart failure)
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools), or bloody diarrhoea – these may be symptoms of bleeding stomach ulcers which may occur at any time during use and without warning
- shortness of breath, wheezing, or trouble breathing
- fast or irregular heart beats, also called palpitations (arrhythmia)
- rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- liver disease including liver failure with symptoms such as loss of appetite, yellowing of the skin and eyes, and dark coloured urine

These may be serious adverse effects. You may need urgent medical attention.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using ARCOXIA

Storage

Keep your tablets in the 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 ARCOXIA in a cool dry place where the temperature 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 or on window sills.

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 ARCOXIA, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ARCOXIA comes as four strengths of tablets:

- 30 mg tablet - a blue green apple shaped biconvex film coated tablet debossed 101 on one side and ACX 30 on the other (not currently marketed in New Zealand).
- 60 mg tablet - a dark green apple shaped biconvex film coated tablet debossed 200 on one side and ARCOXIA 60 on the other, and comes in boxes of 5 tablets (sample pack only not for sale) and 30 tablets.
- 90 mg tablet - a white apple shaped biconvex film coated tablet debossed 202 on one side and ARCOXIA 90 on the other, and comes in boxes of 30 tablets.
- 120 mg tablet - a pale green apple shaped biconvex film coated tablet debossed 204 on one side and ARCOXIA 120 on the other, and comes in boxes of 2 tablets (sample pack only not for sale) and 10 tablets.

Ingredients

Active ingredient:

ARCOXIA 30 mg tablet contains 30 mg etoricoxib.

ARCOXIA 60 mg tablet contains 60 mg etoricoxib.

ARCOXIA 90 mg tablet contains 90 mg etoricoxib.

ARCOXIA 120 mg tablet contains 120 mg etoricoxib.

Inactive ingredients:

- calcium hydrogen phosphate (anhydrous)
- microcrystalline cellulose
- lactose
- croscarmellose sodium
- hypromellose
- magnesium stearate
- carnauba wax
- titanium dioxide
- glycerol triacetate

The 30 mg, 60 mg and 120 mg tablets also contain yellow ferric oxide (iron oxide yellow CI77492) and indigo carmine lake (indigo carmine CI73015).

ARCOXIA does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor details

ARCOXIA is supplied in New Zealand by:

Organon New Zealand Limited

P O Box 99 851

Newmarket

Auckland
NEW ZEALAND
Telephone: 0800 111 700

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