

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARCOXIA?

ARCOXIA contains the active ingredient etoricoxib. ARCOXIA is used to relieve pain and inflammation in osteoarthritis, gout, menstrual cramps or period pain and minor dental procedures.

For more information, see Section [1. Why am I using ARCOXIA?](#) in the full CMI.

2. What should I know before I use ARCOXIA?

Do not use if you have ever had an allergic reaction to etoricoxib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ARCOXIA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARCOXIA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ARCOXIA?

- Take ARCOXIA as directed by your doctor
- Swallow ARCOXIA tablets with a glass of water

More instructions can be found in Section [4. How do I use ARCOXIA?](#) in the full CMI.

5. What should I know while using ARCOXIA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARCOXIA.• Tell your doctor immediately if you become pregnant while taking ARCOXIA or intend to become pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ARCOXIA affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them• Keep ARCOXIA in a cool dry place where the temperature stays below 30°C.• Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using ARCOXIA?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include indigestion, dizziness, stomach pain, diarrhoea, headache, fatigue, rash, high/ increased blood pressure, signs of an infection, swelling of the legs, ankles or feet. Serious side effects may include signs of an allergic reaction (such as fever, skin rash, swelling of the face), signs of bleeding stomach ulcers (such as vomiting blood, bleeding from the back passage, bloody diarrhoea, etc.), shortness of breath and chest pains.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARCOXIA

Active ingredient(s): *etoricoxib* (pronounced ee-TOR-ee-cox-ib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARCOXIA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARCOXIA. Keep this leaflet with the medicine, you may need to read it again.**

Where to find information in this leaflet:

1. [Why am I using ARCOXIA?](#)
2. [What should I know before I use ARCOXIA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use ARCOXIA?](#)
5. [What should I know while using ARCOXIA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using ARCOXIA?

ARCOXIA contains the active ingredient etoricoxib.

ARCOXIA is used for the following:

- to treat the symptoms of osteoarthritis
- to treat gout attacks
- to relieve short term pain, including cramp-like pain or discomfort before or during a menstrual period, and pain associated with minor dental procedures.

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 (e.g. from sport).

Gout

Gout is a disease that causes attacks of arthritis, usually in a single joint. The affected joint is red, swollen, painful and extremely tender. A gout attack usually lasts a few days and it may recur.

For more information about osteoarthritis or gout, speak to your doctor or pharmacist.

How ARCOXIA works

ARCOXIA belongs to a group of medicines called Coxibs. It works in a similar way to traditional anti-inflammatory medicines, known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), by blocking the production of substances

that cause pain and inflammation. In clinical trials, ARCOXIA has been shown to have a lower risk of serious side effects on the stomach (for example, bleeding stomach ulcers) than NSAIDs. However taking aspirin with ARCOXIA may reverse this benefit.

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.

2. What should I know before I use ARCOXIA?

Warnings

Do not use 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, pinkish 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 had or are having major surgery on your heart or arteries
 - 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 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.

Discuss the signs and/or symptoms of serious cardiovascular risks and steps to take if they occur with your doctor.

Check with your doctor if:

- you are pregnant or intend to become pregnant
- you are breast-feeding or plan to breast-feed
- you have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease
 - asthma, hives, itching, or skin rash
 - dehydration, for example by a prolonged bout of vomiting or diarrhoea
 - Inflammatory Bowel Disease

- heart failure
- high blood pressure
- heart attack, angina, or a blocked artery in your heart
- swelling of the ankles, feet or legs due to fluid retention (also called oedema)
- narrow or blocked arteries of the extremities
- stroke or mini stroke
- conditions which increase your risk of heart disease such as diabetes, high cholesterol, smoking or a first degree relative with heart disease
- you have a history of ulcers or bleeding in your stomach or intestines
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

ARCOXIA should not be used from 20 weeks of pregnancy onwards because it may harm the fetus. 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. 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.

Use in Children

The safety and effectiveness of ARCOXIA in children and teenagers under the age of 18 years have not been established.

Use in Elderly patients

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 (i.e., over 65 years of age), your doctor will want to keep a regular check on you. No dosage adjustment is necessary for older patients.

3. What if I am taking other medicines?

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

Some medicines and ARCOXIA may interfere with each other.

Medicines that should not be taken with ARCOXIA:

- 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.

If you are taking low-dose aspirin to help prevent a heart attack or stroke, do not stop taking it unless your doctor tells you to because ARCOXIA cannot replace the use of aspirin for this purpose.

Medicines that may increase the effect of ARCOXIA include:

- ketoconazole, used to treat fungal infections

Medicines that may reduce the effect of ARCOXIA include:

- rifampicin, an antibiotic used to treat tuberculosis and other infections

Medicines that may increase the risk of side effects if taken with AVANZA include:

- warfarin, used to prevent blood clots

Medicines that may be affected by ARCOXIA include:

- ACE inhibitor and angiotensin receptor blocker medicines used to lower high blood pressure or treat heart failure
- some fluid tablets (diuretics)
- lithium, used to treat mood swings and some types of depressions
- methotrexate, used to treat arthritis and some types of cancer
- ethinylestradiol, used in some oral contraceptives
- conjugated estrogens, used in some hormone replacement therapies

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARCOXIA.

4. How do I use ARCOXIA?

How much to take

- **Take ARCOXIA only when prescribed by your doctor.**
- Depending on your condition, you may need to take ARCOXIA for a few days or for a longer period.
- For osteoarthritis, the recommended dose is 30mg once a day, increased to a maximum of 60mg once a day if needed.
For arthritis ARCOXIA helps relieve your symptoms but it does not cure it. Continue taking ARCOXIA for as long as your doctor prescribes it.
- For the relief of gout attacks, the recommended dose is 120 mg taken once a day, which should only be used during the painful period, to a maximum of 8 days treatment.
- For the relief of cramp-like pain or discomfort before or during a menstrual period, the recommended dose is 120 mg taken once a day, which should only be used

during the painful period, to a maximum of 8 days treatment.

- For the relief of short-term pain after dental procedures, the recommended dose is 90 mg taken once a day, which should only be used during the painful period, to a maximum of 8 days treatment.
- Doses greater than those recommended for each condition stated above have either not been shown to improve the effectiveness of ARCOXIA or have not been studied. Therefore, the daily doses stated above for each condition should not be exceeded.
- If you have mild liver disease, do not take more than 60 mg once a day.
- If you have moderate liver disease, do not take more than 60 mg every second day or 30mg once a day.

How to take ARCOXIA

- Swallow ARCOXIA with a glass of water.

When to take ARCOXIA

- **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, with or after food.

If you forget to take ARCOXIA

ARCOXIA should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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.

If you take too much ARCOXIA (overdose)

If you think that you have used too much ARCOXIA, you may need urgent medical attention.

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.

5. What should I know while using ARCOXIA?

Things you should 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 have kidney, liver or heart disease, your doctor will want to keep a regular check on you.
- 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.

Call your doctor straight away if you notice any of the following:

- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools), or bloody diarrhoea. These symptoms may occur at any time during use and without warning.
- any symptoms that could indicate a severe allergic reaction such as inability to breath or a serious skin reaction which may occur without warning. You may need urgent medical attention.

Stop using ARCOXIA, and consult a doctor as soon as possible if any of the following symptoms appear or worsen:

- serious skin rash, shortness of breath, chest pains or ankle swelling.

Remind any doctor, dentist or pharmacist you visit that you are using ARCOXIA.

Things you should not do

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

Things that would be helpful for your arthritis

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 arthritis 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 program 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.

Support devices and aids

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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 side 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.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- Keep ARCOXIA in a cool dry place away from moisture, where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal-related: <ul style="list-style-type: none">• feeling sick (nausea), vomiting• heartburn, uncomfortable feeling in the stomach• mouth ulcers• diarrhoea Head and nervous system-related: <ul style="list-style-type: none">• changes in taste• headache, dizziness Heart and circulation-related: <ul style="list-style-type: none">• high/increase in blood pressure Mood-related: <ul style="list-style-type: none">• difficulty sleeping• depression• restlessness• feeling anxious• confusion• seeing, feeling or hearing things that are not there Kidney-related: <ul style="list-style-type: none">• signs of urinary tract infection, including painful burning when passing urine Infections: <ul style="list-style-type: none">• signs of an infection of the breathing passages, including runny nose, sore throat, cough Eye-related: <ul style="list-style-type: none">• blurred vision General conditions: <ul style="list-style-type: none">• swelling of the legs, ankles or feet• unusual tiredness or weakness• high levels of potassium in your blood	Speak to your doctor if you have any of these less serious side effects and they worry you. These are the more common side effects of ARCOXIA.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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" • gout pain not relieved by ARCOXIA 	<p>These may be serious side effects. Call your doctor straight away.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • fever, skin rash, swelling of the face • not enough amniotic fluid in the womb (diagnosed by a health care provider) • kidney injury in newborns (diagnosed by a health care provider) • swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing • 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 heartbeats, also called palpitations • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention.</p>

loss of appetite, yellowing of the skin and eyes, and dark coloured urine

- blood clots in the blood vessels of the lung and/or leg, and bleeding within the brain.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ARCOXIA contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • ARCOXIA 30 mg tablet contains 30 mg etoricoxib • ARCOXIA 60mg tablet contains 60 mg etoricoxib • ARCOXIA 90 mg tablet contains 90 mg etoricoxib • ARCOXIA 120 mg tablet contains 120 mg etoricoxib
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • calcium hydrogen phosphate • microcrystalline cellulose • lactose monohydrate • croscarmellose sodium • hypromellose • magnesium stearate • carnauba wax • titanium dioxide • triacetin • iron oxide yellow CI77492 (30mg, 60mg and 120mg tablets) • indigo carmine CI73015 (30mg, 60mg and 120mg tablets)
Potential allergens	lactose

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

Do not take this medicine if you are allergic to any of these ingredients.

What ARCOXIA looks like

- ARCOXIA 30 mg tablet - blue-green, apple-shaped biconvex film coated tablet with 101 marked on one side and ACX 30 on the other. Available in packs of 5 tablets*, 10 tablets (starter pack)*, and 30 tablets. (AUST R 131797)
- ARCOXIA 60 mg tablet - dark green, apple-shaped biconvex film coated tablet with 200 marked on one side and ARCOXIA 60 on the other. Available in packs of 5 tablets*, 10 tablets*, and 30 tablets. (AUST R 81456)
- ARCOXIA 90 mg tablet - white, apple-shaped biconvex film coated tablet debossed 202 marked on one side and ARCOXIA 90 on the other. Available in packs of 2 tablets (starter pack)*, 5 tablets*, and 10 tablets*. (AUST R 204147)
- ARCOXIA 120 mg tablet - pale green, apple-shaped biconvex film coated tablet with 204 marked on one side and ARCOXIA 120 on the other. Available in packs of 2 tablets (starter pack)*, 5 tablets*, and 10 tablets. (AUST R 81458)

*Presentation not currently marketed in Australia.

Who distributes ARCOXIA

Organon Pharma Pty Ltd
Level 5, 66 King St
Sydney NSW 2000
AUSTRALIA

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