Package leaflet: information for the user

ARCOXIA 30 mg film-coated tablets
ARCOXIA 60 mg film-coated tablets
ARCOXIA 90 mg film-coated tablets
ARCOXIA 120 mg film-coated tablets
etoricoxib

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Contact your doctor or pharmacist if your doctor or pharmacist.

Contents of this leaflet

1. What is ARCOXIA and what is this medicine used for?

What is ARCOXIA?
ARCOXIA contains the active substance etoricoxib. ARCOXIA belongs to a group of medicines called selective COX-2 inhibitors. These belong to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

What is this medicine used for?
ARCOXIA helps people aged 16 years and older with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and gout to reduce pain and swelling (inflammation) in the joints and muscles.

ARCOXIA is also used in people aged 16 years and older for short-term treatment of moderate pain after dental surgery.

What is osteoarthritis?
Osteoarthritis is a joint condition. It results from the gradual breakdown of cartilage that covers the ends of the bones. This causes swelling (inflammation), pain, tenderness, stiffness, and physical limitations.

What is rheumatoid arthritis?
Rheumatoid arthritis is a long-term inflammatory condition of the joints. It causes pain, stiffness, and swelling, with the affected joints becoming increasingly difficult to move. It can also cause inflammation in other parts of the body.

What is gout?
Gout is a disease with sudden, recurring attacks of very painful inflammation and redness of the joints. It is caused by the accumulation of mineral crystals in the joints.

What is ankylosing spondylitis?
Ankylosing spondylitis is an inflammatory condition of the spine and large joints. 2.When should you not take this medicine or be extra careful with it?

2. When should you not take this medicine or be extra careful with it?

When should you not take this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
You are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see section 4 'Possible side effects').
If you currently have an ulcer or bleeding in your stomach or intestines.
If you have a severe liver disease.
If you have a severe kidney disease.
If you are pregnant or may become pregnant or if you are breastfeeding (see 'Pregnancy, breastfeeding and fertility').
If you are under 16 years old.
If you have an inflammatory bowel disease, such as Crohn's disease. Crohn, bowel inflammations with ulcers (ulcerative colitis) or colon inflammation (colitis).
If you have high blood pressure that is not sufficiently controlled with treatment (consult your doctor or nurse if you are unsure whether your blood pressure is sufficiently controlled).
If your doctor has diagnosed heart problems, including heart failure (moderate or severe forms) or angina pectoris (chest pain).
If you have had a heart attack, bypass surgery or peripheral arterial disease (poor blood circulation in legs or feet due to narrow or blocked arteries).
If you have had a form of stroke (including a mini-stroke or TIA (transient ischemic attack)). Etoricoxib may slightly increase the risk of a heart attack or stroke and should therefore not be used by people who have already had heart problems or a stroke.

If you think any of the above points apply to you, do not take the tablets until you have consulted your doctor.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before taking this medicine if:

You have ever been diagnosed with stomach bleeding or stomach ulcers.
You are dehydrated, for example due to prolonged vomiting or diarrhea.
You have swelling due to fluid retention.
You have ever been diagnosed with heart failure or another heart condition.
If you have ever been diagnosed with high blood pressure. ARCOXIA can increase blood pressure in some people, especially at high doses, and your doctor will want to check your blood pressure from time to time.
If you have ever been diagnosed with liver or kidney disease.
If you are being treated for an infection. ARCOXIA can suppress fever, which is a symptom of infection.

If you have diabetes, high cholesterol, or if you smoke. This may increase your risk of heart disease.
If you are a woman trying to become pregnant.
If you are over 65 years old.

If you are not sure whether any of the above points apply to you, consult your doctor first to see if ARCOXIA is suitable for you before taking this medicine.

ARCOXIA works as well in older patients as it does in younger adult patients. If you are over 65 years old, your doctor will want to monitor you regularly. The dosage does not need to be adjusted for patients over 65 years old.

Children and adolescents under 16 years
Do not give this medicine to children and adolescents under 16 years.

Are you taking any other medicines?
Are you taking any other medicines besides ARCOXIA, have you done so recently or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

Especially if you are taking any of the following medicines, your doctor may want to monitor you to ensure that your medicines are still working well when you start taking ARCOXIA:

medicines that thin the blood (anticoagulants), such as warfarin
rifampicin (an antibiotic)
methotrexate (a medication to suppress the immune system often used in rheumatoid arthritis)
ciclosporin or tacrolimus (medications that suppress the immune system)
lithium (a medication for the treatment of certain types of depression)
medications for high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers , such as enalapril and ramipril, losartan and valsartan
diuretics (water tablets)
digoxin (a medicine for heart failure and irregular heartbeat)
minoxidil (a medicine for high blood pressure)
salbutamol, tablets or solution, to be taken orally (a medicine for asthma)
the pill (the combination can increase the risk of side effects)
hormonal replacement therapy (the combination can increase the risk of side effects)
aspirin; the risk of stomach ulcers is higher if you use ARCOXIA together with aspirin.
aspirin to prevent heart attacks or a stroke:
ARCOXIA can be used with a low dose of aspirin. If you are currently taking low doses of aspirin to prevent a heart attack or stroke, do not stop without consulting your doctor.
aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs):
Do not use high doses of aspirin or other anti-inflammatory drugs if you are using ARCOXIA.

What should you pay attention to with food and drink?
ARCOXIA may start to work faster if taken without food.

Pregnancy, breastfeeding, and fertility

Pregnancy
ARCOXIA tablets should not be used during pregnancy. If you are pregnant or think you might be, or if you want to become pregnant, do not use the tablets. If you become pregnant, stop taking the tablets and consult your doctor. Consult your doctor if you are unsure or want more advice.

Breastfeeding
It is not known whether ARCOXIA passes into breast milk. If you are breastfeeding or planning to breastfeed, consult your doctor before using ARCOXIA. If you use ARCOXIA, do not breastfeed.

Fertility
ARCOXIA is not recommended for women who want to become pregnant.

Driving and using machines
Dizziness and drowsiness have been reported by some patients using ARCOXIA.
Do not drive if you feel dizzy or drowsy.
Do not use tools or operate machines if you feel dizzy or drowsy.

ARCOXIA contains lactose
If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ARCOXIA contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, which means it is essentially 'sodium-free'.

3. How to take this medicine?

Always take this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Do not take more than the dose recommended for your condition. Your doctor will want to discuss your treatment with you from time to time. It is important that you use the lowest dose that controls your pain and you should not use ARCOXIA longer than necessary. This is because the risk of a heart attack or stroke may increase after long-term treatment, especially at high doses.

There are different strengths of this medicine available. Depending on your condition, your doctor will prescribe the strength that is most suitable for you.

The recommended dosage is:

Osteoarthritis
The recommended dose is 30 mg once a day, increased to a maximum of 60 mg once a day if necessary.

Rheumatoid arthritis

The recommended dose is 60 mg once a day, increased to a maximum of 90 mg once a day if necessary.

Ankylosing spondylitis
The recommended dose is 60 mg once daily, increase if necessary to a maximum of 90 mg once daily.

Conditions with acute pain
Etoricoxib should only be used during the period of acute pain.

Gout
The recommended dose is 120 mg once daily and should only be used during the period of acute pain, with a maximum of 8 days of treatment.

Pain after dental surgery
The recommended dose is 90 mg once daily, with a maximum of 3 days of treatment.

Patients with liver problems
If you have a mild form of liver disease, you should not take more than 60 mg once daily.
If you have a moderate form of liver disease, you should not take more than 30 mg once daily.

Children and adolescents under 16 years
ARCOXIA tablets should not be used by children or adolescents under 16 years.

Elderly
For elderly patients, the dosage does not need to be adjusted. As with other medications, this medicine should be used cautiously in elderly patients.

Method of administration
ARCOXIA tablets should be taken once a day by mouth. ARCOXIA can be taken with or without food.

Have you taken too much of this medicine?
You should never take more tablets than your doctor recommends. If you take too many ARCOXIA tablets, contact your doctor or pharmacist immediately.

Have you forgotten to take this medicine?
It is important to take ARCOXIA as prescribed by your doctor. If you miss a dose, just continue with your usual schedule the next day. Do not take a double dose to make up for a forgotten tablet.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone will experience them.

If you experience any of the following symptoms, you should stop taking ARCOXIA and consult your doctor immediately (see section 2 'When should you not take this medicine or be extra careful?'):

- you become short of breath, have chest pain or swollen ankles, or these worsen
- the skin and eyes turn yellow (jaundice) – this indicates liver problems
- severe or persistent stomach pain or your stools become black
- an allergic reaction, including possible skin problems such as ulcers or blisters, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing.

The following terms are used to indicate how often side effects have been reported:
Very common (occurs in more than 1 in 10 users)
Common (occurs in less than 1 in 10 users)
Sometimes (occurs in less than 1 in 100 users)
Rare (occurs in less than 1 in 1000 users)
Very rare (occurs in less than 1 in 10,000 users)

The following side effects may occur during treatment with ARCOXIA:

Very common:

- stomach pain

Common:

- dry socket (inflammation and pain after tooth extraction)
- swelling of the legs and/or feet due to fluid retention (edema)
- dizziness, headache
- palpitations (rapid or irregular heartbeat), stooirregularities in the heart rhythm (arrhythmia)
- increased blood pressure
- wheezing breathing or shortness of breath (bronchospasm)
- constipation, flatulence, inflammation of the stomach lining (gastritis), heartburn, diarrhea, digestive disorders (dyspepsia)/stomach complaints, nausea, vomiting, inflammation of the esophagus, mouth ulcers
- changes in the results of blood tests for your liver
- bruising spots
- weakness and fatigue, flu-like illness

Sometimes:

- gastro-enteritis (gastroenteritis/stomach flu), upper respiratory tract infection, urinary tract infection
- changes in laboratory test results (reduction of red and white blood cells, reduction of platelets)
- hypersensitivity reaction (an allergic reaction including hives, which can be so severe that you need immediate medical attention)
- increased or decreased appetite, weight gain
- anxiety, depression, reduced alertness, seeing, feeling, or hearing things that are not there (hallucinations)
- altered taste, inability to sleep, numbness or tingling, drowsiness
- blurred vision, eye irritation and redness
- tinnitus, dizziness

arrhythmias (atrial fibrillation), rapid heartbeat, heart failure, tight, painful heavy feeling in the chest (angina pectoris), heart attack
excessive flushing, stroke, minor stroke (TIA), severely increased blood pressure, inflammation of the blood vessels
coughing, shortness of breath, nosebleed
swollen stomach or abdomen, change in your bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become severe and bleed, irritable bowel syndrome, inflammation of the pancreas
swelling of the face, skin rash or itching, redness of the skin
muscle cramp/spasm, muscle pain/stiffness
elevated potassium level in your blood, changes in blood or urine test results for your kidneys, severe kidney problems
pain on the chest

Rare:

angio-edema (an allergic reaction with swelling of the face, lips, tongue, and/or throat that can cause difficulty breathing or swallowing and can be so severe that medical care is immediately needed)/anaphylactic/anaphylactoid reaction including shock (a severe allergic reaction requiring immediate medical care)
confusion, restlessness
liver problems (hepatitis)
decreased sodium level in the blood
liver failure, yellow discoloration of the skin or eyes (jaundice)
severe skin reactions

The reporting of side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Bottles: keep the bottle tightly closed to protect against moisture.
Blister packs: store in the original packaging to protect against moisture.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is etoricoxib. Each film-coated tablet contains 30, 60, 90, or 120 mg etoricoxib.

The other substances in this medicine are:
Core: calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose.
Tablet coating: carnauba wax, lactose monohydrate, hypromellose, titanium dioxide (E171), triacetin. The 30, 60, and 120 mg tablets also contain yellow iron oxide (E172, colorant) and indigotine (E132, colorant).

What does ARCOXIA look like and what is in a package?

ARCOXIA tablets are available in four strengths:
30 mg tablets: blue-green, apple-shaped, biconvex film-coated tablets with 'ACX 30' on one side and '101' on the other side.

60 mg tablets: dark green, apple-shaped, biconvex film-coated tablets with 'ARCOXIA 60' on one side and '200' on the other side.

90 mg tablets: white, apple-shaped, biconvex film-coated tablets with 'ARCOXIA 90' on one side and '202' on the other side.

120 mg tablets: pale green, apple-shaped, biconvex film-coated tablets with 'ARCOXIA 120' on one side and '204' on the other side.

Package sizes:
30 mg:
blister packs with 2, 7, 14, 20, 28, 49, 98 tablets or bulk packs of 98 (2 packs of 49) tablets.

60 mg
blister packs with 2, 5, 7, 10, 14, 20, 28, 30, 50, 84, 98, 100 tablets or bulk packs with 98 (2 packs of 49) tablets; or bottles with 30 and 90 tablets with desiccant capsules. The desiccant (one or two capsules) in the bottle is intended to keep the tablets dry and not to be ingested.

90 mg:
blister packs with 2, 5, 7, 10, 14, 20, 28, 30, 50, 84, 98, 100 tablets or bulk packs with 98 (2 packs of 49) tablets; or bottles with 30 and 90 tablets with desiccant capsules. The desiccant (one or two capsules) in the bottle is intended to keep the tablets dry and not to be ingested.
120 mg:
blister packs with 2, 5, 7, 10, 14, 20, 28, 30, 50, 84, 100 tablets or bulk packs with 98 (2 packs of 49) tablets; or bottles with 30 and 90 tablets with desiccant capsules. The desiccant (one or two capsules) in the bottle is intended to keep the tablets dry and not to be ingested.

60, 90 and 120 mg: aluminum/aluminum single-use blister packs of 5, 50 or 100 tablets. Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder: N.V. Organon
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Manufacturer:
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Attikis
Athens
Greece

Registered under RVG 34279 (30 mg), RVG 27705 (60 mg), RVG 27706 (90 mg) and RVG 27707 (120 mg).

This medicine is registered in EEA member states under the following names:

Belgium, Luxembourg	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg, tablets film-coated
Denmark, Estonia, Iceland, Norway	Arcoxia
Ireland, United Kingdom	ARCOXIA 30, 60, 90 or 120 mg film-coated tablets
Cyprus, Malta	ARCOXIA 60, 90, 120 mg film-coated tablets
Germany	ARCOXIA 30/60/90/120 mg film-coated tablets
Finland	Arcoxia 30, 60, 90 and 120 mg tablet, film-coated
France	ARCOXIA 30, 60 mg tablet film-coated
Greece	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg film-coated tablets
Hungary	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg film-coated tablet
Italy	ARCOXIA 30, 60, 90, 120 mg tablets coated with film
Latvia	Arcoxia 30 mg, 60 mg, 90 mg and 120 mg coated tablets
Lithuania	Arcoxia 30, 60, 90, 120 mg film coated tablets
Netherlands	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg, film-

	coated tablets
Austria	Arcoxia 30 mg, 60 mg, 90 mg, 120 mg-Film-coated tablets
Poland	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg tablets coated
Portugal	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg tablets coated with film
Slovenia	Arcoxia 30/60/90/120 mg film coated tablets
Slovakia	ARCOXIA 30 mg, 60 mg, 90 mg, 120 mg
Spain	ARCOXIA 30, 60, 90 and 120 mg tablets coated with film
Czech Republic	ARCOXIA 30 mg, 60 mg, 90 mg, coated tablets
Sweden	Arcoxia 30 mg, 60 mg, 90 mg and 120 mg film-coated tablets

This leaflet was last approved in November 2023.

Other sources of information

More information about this medicine can be found on the website of the Medicines Evaluation Board (www.cbg-meb.nl).