

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS
(PREPARATIONS) 1986**

This medicine can be sold under doctor's prescription only

ARCOXIA[®]
30 mg
Tablets

ARCOXIA[®]
60 mg
Tablets

ARCOXIA[®]
90 mg
Tablets

ARCOXIA[®]
120 mg
Tablets

Each film coated tablet contains:

Etoricoxib 30 mg

Etoricoxib 60 mg

Etoricoxib 90 mg

Etoricoxib 120 mg

For a list of inactive ingredients please refer to section 6.

Read all of this leaflet carefully before you start using this medicine.

- This leaflet contains concise information about **ARCOXIA**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their ailment seems similar to yours.
- This medicine is not intended for children and adolescents under 16 years of age.

1. WHAT ARCOXIA IS AND WHAT IT IS USED FOR?

1.1 What is ARCOXIA?

THERAPEUTIC GROUP: **ARCOXIA** is one of a group of medicines called selective COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

1.2 What is ARCOXIA used for?

ARCOXIA 30 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis.

ARCOXIA 60 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

ARCOXIA 90 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from rheumatoid arthritis and ankylosing spondylitis. **ARCOXIA 90 mg** is also used for the short term treatment of moderate pain after dental surgery.

ARCOXIA 120 mg helps to reduce the pain and swelling (inflammation) in the joints and muscles of people who suffer from gout.

What is osteoarthritis?

Osteoarthritis is a disease of the joints. It results from the gradual breakdown of cartilage that cushions the ends of the bones. This causes swelling (inflammation), pain, tenderness, stiffness and disability.

What is rheumatoid arthritis?

Rheumatoid arthritis is a long term inflammatory disease of the joints. It causes pain, stiffness, swelling, and increasing loss of movement in the joints it affects. It may also cause inflammation in other areas of the body.

What is gout?

Gout is a disease of sudden, recurring attacks of very painful inflammation and redness of the joints. It is caused by deposits of mineral crystals in the joints.

What is ankylosing spondylitis?

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

2. BEFORE YOU TAKE ARCOXIA

2.1 Do not take ARCOXIA if you:

- are allergic (hypersensitive) to etoricoxib or any of the other ingredients of this medicine (detailed in section 6)
- are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see "Side Effects", section 4)
- have a current stomach ulcer or bleeding in your stomach or intestines
- have serious liver disease
- have serious kidney disease
- are or could be pregnant or if you are breast-feeding (see "Pregnancy, breast feeding, and fertility", section 2.5)
- are under 16 years of age
- have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis
- 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 suffer from heart problems including heart failure (moderate or severe), angina (chest pain)
- you suffer from ischemic heart disease, have had a heart attack or bypass surgery or peripheral vascular disease (poor circulation in the legs or feet due to narrowing or blocked arteries)
- you have had any kind of stroke (including mini-stroke, transient ischaemic attack or TIA). Etoricoxib may slightly increase the risk of heart attack and stroke and this is why it should not be used in patients who have already had heart problems or stroke.

If you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

2.2 Special warnings concerning use of ARCOXIA

Talk to your doctor or pharmacist before taking **ARCOXIA** if:

- You have a history of stomach bleeding or ulcers.
- You are dehydrated, for example by a prolonged bout of vomiting or diarrhoea.
- You have swelling due to fluid retention.
- You have a history of heart failure, or any other form of heart disease.
- You have a history of high blood pressure. **ARCOXIA** can increase blood pressure in some people, especially in high doses, and your doctor will want to check your blood pressure from time to time.
- You have a history of liver or kidney disease.
- You are being treated for an infection. **ARCOXIA** can mask or hide a fever which is a sign of infection.
- You have diabetes, high cholesterol or are a smoker. These can increase your risk of heart disease.
- You are a woman trying to become pregnant.
- You are over 65 years of age.

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

ARCOXIA works equally well in older and younger adult patients. If you are over 65 years of age, your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for patients over 65 years of age.

2.3 Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.

In particular if you are taking any of the following medicines, your doctor may want to monitor you to check that your medicines are working properly, after starting the treatment with **ARCOXIA**:

- medicines that thin your blood (anticoagulants), such as warfarin
- rifampicin (an antibiotic)
- methotrexate (a drug used for suppressing the immune system, and often used in rheumatoid arthritis)
- ciclosporin or tacrolimus (drugs used for suppressing the immune system)

- lithium (a medicine used to treat some types of depression)
- medicines used to help treat high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include enalapril, ramipril, losartan and valsartan
- diuretics (water tablets)
- digoxin (a medicine for heart failure and irregular heart rhythm)
- minoxidil (a drug used to treat high blood pressure)
- salbutamol tablets or oral solution (a medicine for asthma)
- birth control pills (the combination may increase your risk of side effects)
- hormone replacement therapy (the combination may increase your risk of side effects)
- aspirin, the risk of stomach ulcers is greater if you take **ARCOXIA** with aspirin.
 - aspirin for prevention of heart attacks or stroke:
ARCOXIA can be taken with **low-dosages** of aspirin. If you are currently taking a low-dose of aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor.
 - aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs):
do not take **high dose** aspirin or other anti-inflammatory medicines while taking **ARCOXIA**.

2.4 Taking ARCOXIA with food and drink

ARCOXIA tablets may be taken with or without food. The onset of the effect of **ARCOXIA** may be faster when taken without food.

2.5 Pregnancy, breast-feeding and fertility

Pregnancy

ARCOXIA tablets must not be taken during pregnancy. If you are pregnant or think you could be pregnant, or if you are planning to become pregnant, do not take the tablets. If you become pregnant, stop taking them and consult your doctor. Consult your doctor if you are unsure or need more advice.

Breast-feeding

It is not known if **ARCOXIA** is excreted in human milk. If you are breast-feeding, or planning to breast-feed, consult your doctor before taking **ARCOXIA**. If you are using **ARCOXIA**, you must not breast-feed.

Fertility

ARCOXIA is not recommended in women attempting to become pregnant.

2.6 Driving and using machines

Dizziness and sleepiness have been reported in some patients taking **ARCOXIA**.

Do not drive if you experience dizziness or sleepiness.

Do not use any tools or machines if you experience dizziness or sleepiness.

2.7 Important information about some of the ingredients of ARCOXIA

ARCOXIA contains lactose.

If you have been told by your doctor 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, that is to say essentially 'sodium-free'.

2.8 Children and adolescents

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

3. HOW DO YOU USE ARCOXIA?

Always take **ARCOXIA** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dosage and treatment will only be determined by the physician.

Do not take more than the recommended dose for your condition. 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.

There are different strengths available for this medicinal product and depending on your disease your doctor will prescribe the tablet strength that is appropriate for you.

The usually recommended dosage is:

Osteoarthritis

The recommended dosage is 30 mg once a day, may be increased to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis

The recommended dosage is 60 mg once a day, may be increased to a maximum of 90 mg once a day if needed.

Ankylosing spondylitis

The recommended dosage is 60 mg once a day, may be increased to a maximum of 90 mg once a day if needed.

For acute gouty arthritis and postoperative dental surgery pain, etoricoxib should be used only for the acute symptomatic period.

Gout

The recommended dosage is 120 mg once a day, which should only be used in the acute period of the pain, limited to a maximum of 8 days treatment.

Postoperative dental surgery pain

The recommended dosage is 90 mg once daily, limited to a maximum of 3 days treatment.

People with liver problems

- 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 30 mg a day.

Do not exceed the recommended dose.

Use in children and adolescents

ARCOXIA should not be given to children or adolescents under 16 years of age.

Elderly

No dosage adjustment is necessary for elderly patients. As with other medicines, caution should be exercised in elderly patients.

Method of administration

ARCOXIA is for oral use. Take the tablets once a day. **ARCOXIA** can be taken with or without food. Swallow the medicine with a small amount of water.

No information is available with regards to crushing/splitting/chewing the coated tablets.

If you take more ARCOXIA than you should

You should never take more tablets than the doctor has recommended. If you do take too many **ARCOXIA** tablets, you should seek medical attention immediately.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take ARCOXIA

It is important to take **ARCOXIA** as your doctor has prescribed. **If you missed a dose**, take the next tablet at the regular time the following day. Do not take a double dose to make up for the forgotten dose.

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, **ARCOXIA** can cause side effects, in some of the users.

Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

If you develop any of these signs you should stop ARCOXIA and talk to your doctor immediately (see “Before you take ARCOXIA”, section 2):

- shortness of breath, chest pains, or ankle swelling appear or if they get worse
- yellowing of the skin and eyes (jaundice) - these are signs of liver problems
- severe or continual stomach pain or your stools become black
- an allergic reaction - which can include skin problems such as ulcers or blistering, or swelling of the face, lips, tongue, or throat which may cause difficulty in breathing

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

The following side effects can occur during treatment with **ARCOXIA**:

Very Common

- stomach pain

Common:

- dry socket (inflammation and pain after a tooth extraction)
- swelling of the legs and/or feet due to fluid retention (oedema)
- dizziness, headache
- palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia)
- increased blood pressure
- wheezing or shortness of breath (bronchospasms)
- constipation, wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhoea, indigestion (dyspepsia)/stomach discomfort, nausea, being sick (vomiting), inflammation of the oesophagus, mouth ulcers
- changes in blood tests related to your liver
- bruising
- weakness and fatigue, flu-like illness

Uncommon:

- gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection
- changes in laboratory values (decreased number of red blood cells, decreased number of white blood cells, platelets decreased)
- hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention)
- appetite increases or decreases, weight gain
- anxiety, depression, decreases in mental sharpness; seeing, feeling or hearing things that are not there (hallucinations)
- taste alteration, inability to sleep, numbness or tingling, sleepiness
- blurred vision, eye irritation and redness
- ringing in the ears, vertigo (sensation of spinning while remaining still)
- abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack
- flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure. inflammation of the blood vessels
- cough, breathlessness, nose bleed
- stomach or bowel bloating, changes in your bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, irritable bowel syndrome, inflammation of the pancreas
- swelling of the face, skin rash or itchy skin, redness of the skin
- muscle cramp/spasm, muscle pain/stiffness
- high levels of potassium in your blood, changes in blood or urine tests relating to your kidneys, serious kidney problems
- chest pain

Rare:

- angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, and may be serious enough to require immediate medical attention)/anaphylactic/anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention)
- confusion, restlessness
- liver problems (hepatitis)
- low blood levels of sodium
- liver failure, yellowing of the skin and/or eyes (jaundice)
- severe skin reactions

If a side effect appears, if any of the side effects gets serious or if you notice a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE ARCOXIA?

Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not use **ARCOXIA** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.

Store below 30°C.

Store in the original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

6.1 What ARCOXIA contains

- The active substance is etoricoxib. Each film coated tablet contains 30, 60, 90 or 120 mg of etoricoxib.
- The other ingredients are:
Core: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate.
Tablet coating: carnauba wax, lactose monohydrate, hypromellose, titanium dioxide, glycerol triacetate.
ARCOXIA 30, 60 and 120 mg tablets also contain:
Iron oxide yellow and indigo carmine lake (E132 colouring agent).
- **ARCOXIA** tablets contain lactose:
ARCOXIA 30 mg tablets contain 1.3 mg of lactose (as lactose monohydrate).
ARCOXIA 60 mg tablets contain 2.7 mg of lactose (as lactose monohydrate).
ARCOXIA 90 mg tablets contain 4.0 mg of lactose (as lactose monohydrate).
ARCOXIA 120 mg tablets contain 5.3 mg of lactose (as lactose monohydrate).

6.2 What ARCOXIA looks like and contents of the pack

ARCOXIA tablets are available in four strengths:

ARCOXIA 30 mg blue-green, apple-shaped, biconvex film coated tablets marked 'ACX 30' on one side and '101' on the other.

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

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

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

Pack sizes:

30 mg: Pack sizes of 2, 7, 28 tablets in blisters.

60, 90, 120 mg: Pack sizes of 2, 5, 7, 10, 14, 30 tablets in blisters.

Not all pack sizes may be marketed.

Manufacturer:

Organon LLC, NJ USA

License holder and address:

Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

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Drug registration no. listed in the official registry of the Ministry of Health:

ARCOXIA 30 mg Tablets: 141.86.31986

ARCOXIA 60 mg Tablets: 129.42.30786

ARCOXIA 90 mg Tablets: 129.43.30787

ARCOXIA 120 mg Tablets: 129.44.30788