APPROVED PATIENT INFORMATION LEAFLET

INFORMATION FOR THE PATIENT ABOUT ARCOXIA

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ARCOXIA® 30 mg tablet (30 mg etoricoxib)

ARCOXIA® 60 mg tablet (60 mg etoricoxib)

ARCOXIA® 90 mg tablet (90 mg etoricoxib)

ARCOXIA® 120 mg tablet (120 mg etoricoxib)

Read all of this leaflet carefully before you start taking ARCOXIA

• Keep this leaflet. You may need to read it again.

• If you have further questions, please ask your doctor or your pharmacist.

• ARCOXIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ARCOXIA CONTAINS

ARCOXIA (etoricoxib, MSD) is a tablet that contains 30 mg, 60 mg, 90 mg or 120 mg of etoricoxib as the active ingredient.

In addition, all ARCOXIA tablets contain the following inactive ingredients:

Calcium hydrogen phosphate anhydrous USP, carnauba wax NF, croscarmellose sodium NF, lactose monohydrate, magnesium stearate NF and microcrystalline cellulose NF

In addition:

30 mg tablets contain Opadry II Blue-green 39K11526.

60 mg tablets contain Opadry II Green 39K11520.

90 mg tablets contain Opadry II White 39K18305.

120 mg tablets contain Opadry II Green 39K11529.

All ARCOXIA tablets contain sugar (lactose).

2. WHAT ARCOXIA IS USED FOR

ARCOXIA is a member of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDS) that are used to reduce pain and inflammation. ARCOXIA is a selective COX-2 inhibitor.

Your doctor has prescribed ARCOXIA for one of the following conditions:

- relief of symptoms of osteoarthritis
- relief of symptoms of rheumatoid arthritis
- treatment of ankylosing spondylitis
- short term relief of acute pain, treatment limited to a maximum period of 8 days
- treatment of moderate to severe acute pain after dental surgery
- treatment of menstrual pain
- treatment of acute gout attacks

3. BEFORE YOU TAKE ARCOXIA

Do not take ARCOXIA:

- if you are hypersensitive (allergic) to etoricoxib or any of the other ingredients of ARCOXIA
- if you have previously experienced any of the following after taking aspirin (acetylsalicylic acid) or other non-steroidal anti-inflammatory medications, including ARCOXIA or other COX-2 inhibitors: asthma (wheezing or inability to breathe easily), nasal irritation, nasal polyps, or allergic symptoms such as swelling of the face, lips, tongue or throat and/or itching skin rash
- if you have an active stomach ulcer or bleeding in the stomach or intestines
- if you have serious liver disease
- if you have serious kidney disease
- if you have high blood pressure which is not adequately controlled by treatment
- if you are pregnant or breastfeeding
- if you are under 16 years of age
- if you have inflammatory bowel disease
- if you are taking lithium (used to treat a certain type of depression)
- if you are taking digoxin (a heart medication)

- if your doctor has diagnosed heart problems including heart failure (moderate or severe types), chest pain (angina) or if you have had a heart attack, bypass surgery, narrow or blocked arteries of the extremities (peripheral arterial disease), or any kind of stroke (including mini-stroke, transient ischaemic attack or TIA).

ARCOXIA may increase your risk of heart attack and stroke and that is why it should not be used in those who have already had heart problems or stroke.

Take special care with ARCOXIA:

Tell your doctor about any medical conditions or allergies you have now or have had, including:

- If you have a history of stomach bleeding or ulcers
- If you are dehydrated, for example by a prolonged period of vomiting or diarrhoea
- if you have a history of kidney disease; long term administration may affect kidney function
- if you have or have had liver disease; your physician should monitor your liver enzymes
- if you have a history of heart failure, heart attack, or any other form of heart disease
- if you have narrow or blocked arteries of the extremities
- if you have a history of high blood pressure
- if you have swelling due to fluid retention
- if you have a history of stroke or mini-stroke
- if you are lactose intolerant
- if you are elderly since you may be more likely to develop certain side effects
- if you are trying to become pregnant
- if you have conditions which increase your risk of coronary artery disease or atherosclerosis such as high blood pressure, diabetes, high cholesterol or smoking.

There may be a higher risk of cardiovascular events such as heart attack and strokes with higher doses and longer duration of treatment.

ARCOXIA can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue it without consulting your doctor because ARCOXIA cannot substitute for aspirin for this purpose. Aspirin increases the risk of gastrointestinal events.

Serious skin reactions, which may be fatal, may occur. Signs and symptoms may include fever, rash, peeling of the skin, and/or blisters and sores.

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.

Use in children

Safety and efficacy in children have not been established. Therefore, ARCOXIA should not be given to children.

Use in the elderly

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 appropriately keep a check on you.

Taking ARCOXIA with food and drink

ARCOXIA may be taken with or without food.

Pregnancy and Breastfeeding

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

  It is not known if ARCOXIA is excreted in human milk. If you are breastfeeding, or planning to breastfeed, consult your doctor before taking ARCOXIA.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery

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.

Important information about some of the ingredients of ARCOXIA

ARCOXIA contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ARCOXIA.

Taking other medicines with ARCOXIA

Your doctor may want to check that your medicines are working properly if you are taking:

- warfarin (a blood thinner)
- rifampicin (an antibiotic)
- diuretics (water tablets)
- ACE inhibitors and angiotensin receptor blockers (medicines used for high blood pressure and heart failure)
- lithium (a medicine used to treat a certain type of depression)
- digoxin (a heart medication)
- birth control pills
- methotrexate (a medicine used for suppressing the immune system)
- ciclosporin and tacrolimus (medicines used for suppressing the immune system)
- furosemide (a water tablet)
- hormone replacement therapy
- aspirin: ARCOXIA can be taken with low-dose aspirin. If you are currently taking low-dose aspirin for prevention of heart attack or stroke, you should not discontinue it without consulting your doctor, because ARCOXIA cannot substitute aspirin for this purpose. It is unknown whether the concurrent use of aspirin lessens the increased risk of serious heart problems such as heart attack or stroke that may be associated with ARCOXIA.

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of ARCOXIA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE ARCOXIA

Do not share ARCOXIA with anyone else; it was prescribed only for you.

Always take ARCOXIA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

ARCOXIA should be taken once a day. You may take ARCOXIA with or without food.

Your doctor will decide what dose of ARCOXIA you should take and how long you should take it. Use the lowest effective dose for the shortest possible duration of treatment.

For relief of symptoms of osteoarthritis:

- The recommended dose is 30 mg once daily. In some patients with insufficient relief from symptoms, the dose may be increased to 60 mg once daily.

For relief of symptoms of rheumatoid arthritis:

- The recommended dose is 90 mg once a day. In some patients, 60 mg once daily may provide adequate therapeutic effect.

For the treatment of ankylosing spondylitis:

- The recommended dose is 90 mg once a day. In some patients, 60 mg once daily may provide adequate therapeutic effect.

Acute pain conditions:

- The recommended dose is 90 or 120 mg once daily, limited to a maximum of 8 days treatment.

For the relief of gout attacks:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.

For the treatment of menstrual pain:

- The recommended dose is 120 mg once a day which should only be used for the acute painful period.

For the relief of pain after dental surgery

- The recommended dose is 90 mg once daily.

If you have the impression that the effect of ARCOXIA is too strong or too weak, talk to your doctor or pharmacist.

Doses greater than those recommended for each condition did not provide additional benefit or have not been studied. Therefore, do not exceed the dose stated above for each condition.

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. You should not use ARCOXIA if you have severe liver disease.

If you take more ARCOXIA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ARCOXIA

Try to take ARCOXIA as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule the following day.

Do not take a double dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

ARCOXIA can have side effects.

Not all side effects reported for ARCOXIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ARCOXIA, please consult your doctor, pharmacist or other healthcare professional for advice.

The following serious side effects have been reported in association with the use of ARCOXIA. If any of the following happen, stop taking ARCOXIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if shortness of breath, chest pains or ankle swelling appear, or if these 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

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

The following side effects can occur during treatment with ARCOXIA:

Body System Class		**Frequency**
Infections and infestations	dry socket (inflammation and pain after a tooth extraction)	Frequent

	mild to severe nausea, vomiting, cramps and diarrhoea, upper respiratory infection, urinary tract infection	Less frequent
Metabolism and nutrition disorders	swelling of the legs and/or feet due to fluid retention (oedema)	Frequent
	appetite increase or decrease, weight gain	Less frequent
Psychiatric disorders	nervousness, anxiety, depression, decrease in mental alertness	Less frequent
Nervous system disorders	dizziness, headache	Frequent
	inability to sleep, pins and needles/increased feeling or sensitivity, especially in the skin	Less frequent
Eye disorders	eye irritation and redness	Less frequent
Ear and labyrinth disorders	buzzing, hissing, whistling, ringing, or other persistent noise in the ears, vertigo	Less frequent
Cardiac disorders	palpitations	Frequent
	abnormal heart rhythm (atrial fibrillation), disease of the heart with shortness of breath and swelling of the feet or legs due to fluid build-up, non-specific ECG changes, heart attack	Less frequent
	feeling of tightness, pressure or heaviness in the chest (angina)	Less frequent
	high blood pressure that became worse, irregular heart rhythm (dysrhythmia)	Unknown
Vascular Disorders	high blood pressure	Frequent

	flushing, stroke, mini-stroke (transient ischaemic attack)	Less frequent
Respiratory, thoracic and mediastinal disorders	cough, difficulty in breathing, nose bleeds	Less frequent
Gastro intestinal disorders	stomach pain, wind, heartburn, diarrhoea, indigestion, stomach discomfort, nausea	Frequent
	stomach distention, acid reflux, bowel movement pattern change, constipation, dry mouth, stomach ulcer, irritable bowel syndrome, inflammation of the food pipe, mouth ulcer, vomiting, stomach inflammation	Less frequent
Skin and subcutan-eous tissue disorders	bruising	Frequent
	facial swelling, redness of the skin, itching, rash	Less frequent
Musculo-skeletal and connective tissue disorders	muscle cramp/spasm, muscle pain/stiffness	Less frequent
Renal and urinary disorders	changes in blood or urine tests relating to your kidney	Less frequent
General disorders and administration site	unusual tiredness or weakness/tiredness, flu-like disease	Frequent

conditions		
	chest pain	Less Frequent
Investigations	changes in blood tests related to your liver	Frequent
	decreased haematocrit, decreased haemoglobin, decreased blood cells which help blood to clot, increased serum creatinine, increased uric acid, decrease in raised potassium levels in the blood	Less Frequent
	Low blood levels of sodium	Less Frequent

Additionally, the following have been reported after the product has been on the market. Frequency of these side effects is unknown.

Blood and lymphatic system disorders	decreased white blood cells
Immune system disorders	swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, allergic reactions, (which may be serious enough to require immediate medical attention) including shock and hives
Psychiatric disorders	confusion, hallucinations, depression, restlessness
Nervous system disorders	taste alteration, sleepiness
Eye disorders	blurred vision
Cardiac disorders	heart failure, palpitations, irregular heart rhythm (dysrhythmia), angina
Vascular disorders	severe increase in blood pressure (hypertensive crisis)
Respiratory, thoracic and mediastinal disorders	wheezing or shortness of breath

Gastrointestinal disorders	inflammation of the stomach lining or stomach ulcers that can become serious and may lead to bleeding (especially in the elderly), vomiting, diarrhoea and abdominal pain
Hepatobiliary disorders	yellowing of the skin and eyes (jaundice), liver problems
	liver failure
Skin and subcutaneous tissue disorders	severe skin reactions which may occur without warning (rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, detachment of the top layer of skin from the lower layers of the skin all over the body)
	rash, itching, redness of the skin
Renal and urinary disorders	serious kidney problems.

6. STORING AND DISPOSING OF ARCOXIA

Do not use this medicine after the month and year shown by the four numbers following EXPIRES/VERVAL on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

Store ARCOXIA at or below 30 °C. Store in the original packaging.

Keep all medicines out of reach of children.

7. PRESENTATION OF ARCOXIA

ARCOXIA 30 mg and 60 mg tablets are available in aluminium blister packs of 28.

ARCOXIA 90 mg and 120 mg tablets are available in aluminium blister packs of 7 and 28.

8. IDENTIFICATION OF ARCOXIA

ARCOXIA 30 mg: A blue-green, apple-shape, biconvex, film-coated tablet with '101' debossed on one side and ‘ACX 30’ on the other side.

ARCOXIA 60 mg: A dark green, apple shape, biconvex, film-coated tablet with '200' debossed on one side and 'ARCOXIA 60' on the other side.

ARCOXIA 90 mg: A white, apple shape, biconvex, film-coated tablet with '202' debossed on one side and 'ARCOXIA 90' on the other side.

ARCOXIA 120 mg: A pale green, apple shape, biconvex, film-coated tablet with '204' debossed on one side and 'ARCOXIA 120' on the other side.

9. REGISTRATION NUMBERS

ARCOXIA 30 mg: 44/3.1/0063

ARCOXIA 60 mg: 37/3.1/0399

ARCOXIA 90 mg: 37/3.1/0400

ARCOXIA 120 mg: 37/3.1/0401

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Organon South Africa (Pty) Ltd

Spaces, 1st Floor

22 Magwa Crescent, Gateway West

Waterfall City, Midrand, 2090

South Africa

Telephone no.: +27 (0) 87 106 9655

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date on the registration certificate: 11 October 2013

Date of the most recently revised Patient Information Leaflet: 31 March 2020

WPPI-MK0663-T-062015