

Read all this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to the others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What ARCOXIA 60 mg film-coated tablets is and what it is used for
2. Before you take ARCOXIA 60 mg film-coated tablets
3. How to take ARCOXIA 60 mg film-coated tablets
4. Possible side effects
5. Storing ARCOXIA 60 mg film-coated tablets

ARCOXIA[®] 60 mg film-coated tablets
(etoricoxib)

Each tablet contains as active ingredient 60 mg of etoricoxib.

The other ingredients (excipients) are: calcium hydrogen phosphate (anhydrous), carnauba wax, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, glycerol triacetate, yellow ferric oxide (E-172) and indigo carmine lake (E-132).

License holder:

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1. WHAT ARCOXIA 60 mg film-coated tablets IS AND WHAT IT IS USED FOR

ARCOXIA 60 mg film-coated tablets are supplied in packages of 28 tablets. The tablets are dark green, modified apple-shaped, biconvex film coated tablets marked 'ARCOXIA 60' on one side and '200' on the other.

ARCOXIA is a member of a class of non-steroidal anti-inflammatory drugs (NSAIDs) known as cyclo-oxygenase-2 (COX-2) selective inhibitors, which act by reducing pain and inflammation.

ARCOXIA is indicated to relieve the symptoms of your osteoarthritis, rheumatoid arthritis or gout.

2. BEFORE YOU TAKE ARCOXIA 60 mg film-coated tablets

Do not take ARCOXIA 60 mg film-coated tablets if:

- You are allergic to etoricoxib or to any of the excipients of Arcoxia.
- You have an active stomach ulcer or bleeding in the stomach or intestines.

- You have previously experienced any of the following after taking aspirin (acetylsalicylic acid) or other anti-inflammatory medications: 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.
- You are or could be pregnant or are breast-feeding.
- You are under 16 years of age.
- You have serious liver or kidney disease.
- You have inflammatory bowel disease (i. e. ulcerative colitis or Crohn disease).
- Your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain) or if you have had a heart attack, bypass surgery, any kind of stroke (including mini-stroke, transient ischaemic attack or TIA). Etoricoxib may slightly increase your risk of heart attack and stroke and this is why it should not be used in those who have already had heart problems or stroke.
- 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).

Take special care with ARCOXIA 60 mg film-coated tablets in the following situations:

- You have had gastric or duodenal ulcer, bleeding or perforation.
- You could be dehydrated, for example, as a consequence of a disease accompanied by vomiting or diarrhea or because of the use of diuretics.
- You have fluid retention (swollen feet or ankles).
- You have a history of heart attack, heart, liver or kidney disease, especially if you are elderly.
- You have a history of stroke or mini stroke.
- You have raised blood pressure.
- You develop any symptoms that could indicate liver problems, such as yellowing of the skin and eyes.
- You develop severe or persistent abdominal pain and/or your stools become black.
- 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.
- You develop any symptoms that could indicate a severe allergic reaction such as 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.
- You have an infection, since taking ARCOXIA can mask a fever or other signs of inflammation.
- You have conditions such as high blood pressure, diabetes, high cholesterol or smoking. These may increase your risk of a heart disease and you should talk to your doctor if this medicine is appropriate for you.
- You are taking acetyl salicylic acid or other anti-inflammatory medications. If you are currently taking low dose acetyl salicylic acid (less than or equal to 81 mg daily) for prevention of heart attack or stroke, you should not discontinue without consulting your doctor because ARCOXIA cannot substitute for acetyl salicylic acid for this purpose. You should be aware that the risk of stomach ulcers is greater if you are taking acetyl salicylic acid with ARCOXIA.
- You are receiving medicines to reduce blood coagulation, i. e. warfarin.

Consult your doctor, even if any of the above mentioned circumstances have ever happened to you.

Taking ARCOXIA 60 mg film-coated tablets with food and drink:

ARCOXIA can be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding, ARCOXIA is contraindicated. If you think you could be pregnant or if you are planning to become pregnant, do not take ARCOXIA. If you become pregnant during the treatment with ARCOXIA, you must discontinue the treatment immediately.

Driving and using machines

If you experience dizziness, vertigo or somnolence after taking ARCOXIA, try not to perform tasks which may require special attention (driving vehicles or operating machinery) until you know how you tolerate the medicine.

Important information about some of the ingredients of ARCOXIA 60 mg film-coated tablets:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Using other medicines:

Inform your doctor or pharmacist if you are using or have recently used any other medicines - even those not prescribed.

Certain medicines can interact with ARCOXIA; in these cases, dosage adjustment or discontinue the treatment with any of the medicines can be necessary.

It is important that you inform your doctor if you are taking or have recently taken some of the following medicines:

- Warfarin or other oral anticoagulants (used to prevent blood clotting).
- ACE inhibitors and angiotensin receptor blockers (medicines to treat high blood pressure and heart failure).
- Diuretics (used to increase urine elimination).
- Acetyl salicylic acid or other anti-inflammatory drugs.
- Cyclosporin or tacrolimus (drugs used for transplant patients).
- Lithium (used to treat bipolar depression).
- Methotrexate (used in rheumatoid arthritis and to treat some kind of cancer).
- Birth control pills.
- Digoxin (a medicine for heart failure and irregular heart rhythm).
- Minoxidil (lotion used to treat hair loss and high blood pressure).
- Oral salbutamol (a medicine for asthma).
- Rifampicin (used to treat bacterial infections and tuberculosis).
- Hormone replacement therapy.

3. HOW TO TAKE ARCOXIA 60 mg film-coated tablets

Follow these instructions unless your doctor gave you different advice.

Remember to take your medicine.

Your doctor will tell you the duration of your treatment with ARCOXIA. Do not discontinue the treatment before.

Take ARCOXIA by mouth once a day. ARCOXIA can be taken with or without food.

Do not exceed the recommended dose for treatment of your condition.

Adults:

Osteoarthritis

The recommended dose is 60 mg once a day.

Rheumatoid arthritis

The recommended dose is 90 mg once a day.

Gout

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.

Doses greater than those recommended for each condition have either not demonstrated additional efficacy or have not been studied. Therefore, the dose stated above for each condition is the maximum recommended dose.

Patients older than 65 years old:

No dosage reduction is necessary for patients older than 65 years old.

Children and adolescents:

Etoricoxib is contra-indicated in children and adolescents under 16 years of age.

Hepatic insufficiency:

- Severe: ARCOXIA is contraindicated in patients with severe hepatic insufficiency.
- Mild or moderate: if you have mild hepatic insufficiency, you should not take more than 60 mg a day. If you have moderate hepatic insufficiency, you should not take more than 60 mg every other day.

Renal insufficiency:

- Severe: ARCOXIA is contraindicated in patients with severe renal insufficiency.
- Mild or moderate: it is not necessary to reduce the dosage of ARCOXIA for patients with mild renal insufficiency.

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

If you take more ARCOXIA 60 mg film-coated tablets than you should:

If you have taken more ARCOXIA than you should, consult immediately your doctor or pharmacist.

In case of overdose or accidental intake contact the Information Service of Toxicology, tel.: 91 562 04 20.

If you forget to take ARCOXIA 60 mg film-coated tablets:

Do not take a double dose to make up for forgotten individual doses. Take the following dose when it is scheduled.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ARCOXIA 60 mg may have side effects. The estimated frequency of occurrence of the side effects is the following:

The common side effects that can affect more than 1 person in every 100, are the following:

Weakness and fatigue, dizziness, flu-like illness, diarrhoea, indigestion (dyspepsia), stomach pain or discomfort, heartburn, nausea, headache, swelling of the legs and/or feet due to fluid retention (oedema) and raised blood pressure.

The uncommon side effects that can affect more than 1 person in every 1,000, are the following:

Abdominal bloating, chest pain, swelling of the face, flushing, upper respiratory infection, heart failure, bruising, bowel movement pattern change, constipation, dry mouth, taste alteration, gastroenteritis, wind, stomach ulcer, irritable bowel syndrome, mouth ulcers, vomiting, blurred vision, nose bleed, ringing in the ears, appetite increase or decrease, weight gain, muscle cramp/spasm, muscle pain/stiffness, inability to sleep, numbness or tingling, sleepiness, anxiety, depression, decrease in mental acuity, breathlessness, cough, skin rash or itchy skin, urinary tract infection.

The very rare side effects that can affect up to 1 person in every 10,000, are the following:

Allergic reactions (which may be serious enough to require immediate medical attention) including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, heart attack, inflammation of the stomach lining or stomach ulcers that may become serious and may bleed, stroke, serious kidney problems.

If you notice these effects or any other not mentioned in this leaflet, inform your doctor or pharmacist.

5. STORING ARCOXIA 60 mg film-coated tablets

Keep ARCOXIA out of the reach and sight of children.

No special storage conditions are required.

Expiration:

Do not use ARCOXIA 60 mg after the expiry date on the carton.

This leaflet was approved on October 2005.

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