

- 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 kidney, 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, which 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

5. How to store Etoricoxib tablet

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Bottles: Keep the container tightly closed in order to protect from moisture.

Blisters: Store in the original package in order to protect from moisture.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Etoricoxib Tablets contains

- The active substance is Etoricoxib. Each film coated tablet contains 30, 60, 90 or 120mg of etoricoxib.
- The other ingredients are:
- Core: Sodium Lauryl sulphate, Micro crystalline cellulose, Low substituted Hydroxy propyl cellulose, Calcium Hydrogen Phosphate anhydrous, Croscarmellose Sodium, Silica Colloidal anhydrous., Magnesium stearate, Tablet coating: Instacoat Universal A05E00627 GREEN, Instacoat Universal A05E20670 GREEN, Instacoat Universal A05E00041 WHITE, Lactose Monohydrate, Triacetin.

What Etoricoxib Tablets looks like and contents of the pack

Etoricoxib tablets are available in three strengths:

- **Etoricoxib Tablets 30mg** are Light green to bluish-green, round, biconvex, film-coated tablets debossed '30' on one side and plain on other side.
- **Etoricoxib Tablets 60mg** are Green, round, biconvex, film-coated tablets debossed '60' on one side and plain on the other side.
- **Etoricoxib Tablets 90mg** are White to off-white, round, biconvex, film-coated tablets debossed '90' on one side and plain on the other side.
- **Etoricoxib Tablets 120mg** are Green, round, biconvex, film-coated tablets debossed '120' on one side and plain on the other side.

Pack Size: Blister Pack of 10 Tablets.

Zydus Cadila

Marketing Authorization Holder and Manufacturer

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PATIENT INFORMATION LEAFLET (PIL)

NUCOXIA 30, 60, 90 & 120mg, FILM COATED TABLETS (Etoricoxib)

Read all of this 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.
- This medicine has been prescribed for you only. Do not pass it 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.

What is in this leaflet:

1. What Etoricoxib Tablets is and what it is used for
2. What you need to know before you take Etoricoxib Tablets
3. How to take Etoricoxib Tablets
4. Possible side effects
5. How to store Etoricoxib Tablets
6. Contents of the pack and other information

1. What Etoricoxib Tablet is and what it is used for

What is Etoricoxib Tablets ?

- Etoricoxib Tablets contains the active substance etoricoxib. NUCOXIA 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).

What is Etoricoxib Tablets used for?

- Etoricoxib Tablets helps to reduce the pain and swelling (inflammation) in the joints and muscles of people 16 years of age and older with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and gout.
- Etoricoxib Tablets is also used for the short term treatment of moderate pain after dental surgery in people 16 years of age and older.

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 in the joints. It is caused by deposits of mineral crystals in the joint.

What is ankylosing spondylitis?

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

2. What you need to know before you take Etoricoxib Tablets

Do not take Etoricoxib Tablets:

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of this medicine.
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors
- if you have a current stomach ulcer or bleeding in your stomach or intestines
- if you have serious liver disease
- if you have serious kidney disease
- if you are or could be pregnant or are breast-feeding (see 'Pregnancy, breast feeding, and fertility')
- if you are under 16 years of age
- if you have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis
- if 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)
- if your doctor has diagnosed heart problems including heart failure (moderate or severe types), angina (chest pain)
- if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)
- if you have had any kind of stroke (including mini-stroke, transient ischemic 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.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Etoricoxib Tablets 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.