

Arcoxia® 60mg Tablets
Arcoxia® 90mg Tablets
Arcoxia® 120mg Tablets
(etoricoxib)

1151, 1152, 1168
05.03.13[14]

PATIENT INFORMATION LEAFLET

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

- Keep this leaflet. You may want to read it again.
- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This medicine is available using any of the above names but will be referred to as Arcoxia throughout the following.

Arcoxia tablets are also available in other strengths.

In this leaflet:

1. What Arcoxia is and what it is used for
2. Before you take Arcoxia
3. How to take Arcoxia
4. Possible side effects
5. How to store Arcoxia
6. Further information

1. WHAT ARCOXIA IS AND WHAT IT IS USED FOR

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

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. BEFORE YOU TAKE ARCOXIA

Do not take Arcoxia:

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of Arcoxia (see Further information, section 6)
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see Possible Side Effects, section 4)
- 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 and breast feeding')
- if you are under 16 years of age
- if you have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis
- if 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, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries), or 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
- 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 you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Take special care with Arcoxia

Arcoxia may not be suitable for you, or you may need to be monitored regularly while taking it if any of the following apply to you:

- 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 any 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 are a woman trying to become pregnant.
- You are elderly (i.e., over 65 years of age).
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.

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 elderly (i.e., over 65 years of age), your doctor will want to appropriately keep a check on you. No dosage adjustment is necessary for elderly patients.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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, once you start taking 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)
- medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include enalapril and ramipril, and losartan and valsartan
- lithium (a medicine used to treat some types of depression)
- diuretics (water tablets)
- ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- 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
- hormone replacement therapy
- aspirin, the risk of stomach ulcers is greater if you take Arcoxia with aspirin.
 - o Arcoxia can be taken with low-dose aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor
 - o do not take high dose aspirin or other anti-inflammatory medicines while taking Arcoxia

Pregnancy and breast-feeding

Arcoxia 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 the tablets and consult your doctor. Consult your doctor if you are unsure or need more advice.

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.

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.

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.

Important information about some of the ingredients of Arcoxia

Arcoxia contains lactose. If you have been told by your doctor that you are unable to tolerate some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ARCOXIA

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

Arcoxia Tablets should not be taken by children or adolescents under 16 years of age.

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

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.

Osteoarthritis

The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis

The recommended dose is 90 mg once a day.

Ankylosing spondylitis

The recommended dose is 90 mg once a day.

Acute pain conditions

Etoricoxib should be used only for the acute painful period.

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.

Postoperative dental surgery pain

The recommended dose 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.

If you take more Arcoxia than you should

You should never take more tablets than the doctor recommends. If you do take too many Arcoxia Tablets, you should seek medical attention immediately.

If you forget to take Arcoxia

It is important to take Arcoxia as your doctor has prescribed. If you miss a dose, just resume your usual schedule the following day. Do not take a double dose to make up for the forgotten tablet.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Arcoxia can cause side effects, although not everybody gets them.

If you develop any of these signs you should stop Arcoxia and talk to your doctor immediately:

- 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)

Not known (frequency cannot be estimated from the available data).

The following side effects can occur during treatment with Arcoxia:

Common

Weakness and fatigue, dizziness, headache, flu-like illness, diarrhoea, wind, nausea, indigestion (dyspepsia), stomach pain or discomfort, heartburn, changes in blood tests related to your liver, swelling of the legs and/or feet due to fluid retention (oedema), increased blood pressure, palpitations, bruising, dry socket (inflammation and pain after a tooth extraction).

Uncommon

Stomach or bowel bloating, chest pain, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack, stroke, mini-stroke (transient ischaemic attack), abnormal heart rhythm (atrial fibrillation), upper respiratory infection, high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, changes in your bowel habits including constipation, dry mouth, mouth ulcers, taste alteration, gastroenteritis, gastritis, stomach ulcer, being sick (vomiting), irritable bowel syndrome, inflammation of the oesophagus, blurred vision, eye irritation and redness, nose bleed, ringing in the ears, vertigo, appetite increases or decreases, weight gain, muscle cramp/spasm, muscle pain/stiffness, inability to sleep, sleepiness, numbness or tingling, anxiety, depression, decreases in mental sharpness, breathlessness, cough, swelling of the face, flushing, skin rash or itchy skin, urinary tract infection, platelets decreased, decreased number of red blood cells, decreased number of white blood cells.

Rare

Low blood levels of sodium, redness of the skin.

Very Rare

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, bronchospasm (wheezing or shortness of breath), severe skin reactions, inflammation of the stomach lining or stomach ulcers that can become serious and may lead to bleeding, liver problems, serious kidney problems, severe increase in blood pressure, confusion, seeing, feeling or hearing things that are not there (hallucinations).

Not known

Yellowing of the skin and eyes (jaundice), liver failure, inflammation of the pancreas, fast heart rate, irregular heart rhythm (arrhythmia), restlessness, inflammation of the blood vessels.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ARCOXIA

Keep your tablets out of the sight and reach of children.

Do not put the tablets into another container, as they might get mixed up.

Store in the original blister pack and do not remove the tablet from its blister until you are ready to take it, as the tablets are moisture sensitive.

There are no other special storage conditions required for this medicine.

Do not take the tablets if they are past the expiry date, which is clearly marked on the pack.

If your doctor tells you to stop taking this medicine, return any unused tablets to your doctor for safe disposal. Only keep the tablets if your doctor tells you to. If your tablets become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

6. FURTHER INFORMATION

What Arcoxia contains

The active ingredient in Arcoxia Tablets is etoricoxib.

Arcoxia 60mg tablets: Green, apple-shaped, biconvex film-coated tablets marked '200' on one side and plain on the other side, containing 60mg of etoricoxib.

Arcoxia 90mg tablets: White, apple-shaped, biconvex film-coated tablets marked '202' on one side and plain on the other side, containing 90mg of etoricoxib.

Arcoxia 120mg tablets: Pale-green, apple-shaped, biconvex film-coated tablets marked '204' on one side and plain on the other side, containing 120mg of etoricoxib.

Other ingredients: calcium hydrogen phosphate (anhydrous), carnauba wax, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, and glycerol triacetate. The 60mg and 120mg tablets also contain yellow iron oxide (E172) and indigo carmine lake (E132).

Pack sizes: 60mg and 90mg strengths: 20 or 30 tablets per pack
120mg strength: 5 or 30 tablets per pack.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Arcoxia is manufactured by Merck Sharp & Dohme B.V., Waarderweg 39, Haarlem, The Netherlands. Procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharma Ltd.

POM

Arcoxia 60mg Tablets PL No: 20636/1151
Arcoxia 90mg Tablets PL No: 20636/1152
Arcoxia 120mg Tablets PL No: 20636/1168

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Etoricoxib 60mg Tablets

Etoricoxib 90mg Tablets

Etoricoxib 120mg Tablets

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- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This medicine is available using any of the above names but will be referred to as Etoricoxib throughout the following.

Etoricoxib tablets are also available in other strengths.

In this leaflet:

1. What Etoricoxib is and what it is used for
2. Before you take Etoricoxib
3. How to take Etoricoxib
4. Possible side effects
5. How to store Etoricoxib
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1. WHAT ETORICOXIB IS AND WHAT IT IS USED FOR

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

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. BEFORE YOU TAKE ETORICOXIB

Do not take Etoricoxib:

- if you are allergic (hypersensitive) to etoricoxib or any of the other ingredients of Etoricoxib (see Further information, section 6)
- if you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors (see Possible Side Effects, section 4)
- 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 and breast feeding')
- if you are under 16 years of age
- if you have inflammatory bowel disease, such as Crohn's Disease, Ulcerative Colitis, or Colitis
- if 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, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries), or 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
- 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 you think any of these are relevant to you, do not take the tablets until you have consulted your doctor.

Take special care with Etoricoxib

Etoricoxib may not be suitable for you, or you may need to be monitored regularly while taking it if any of the following apply to you:

- 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. Etoricoxib 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 any history of liver or kidney disease.
- You are being treated for an infection. Etoricoxib can mask or hide a fever, which is a sign of infection.
- You are a woman trying to become pregnant.
- You are elderly (i.e., over 65 years of age).
- You have diabetes, high cholesterol, or are a smoker. These can increase your risk of heart disease.

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

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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, once you start taking Etoricoxib:

- 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)
- medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include enalapril and ramipril, and losartan and valsartan
- lithium (a medicine used to treat some types of depression)
- diuretics (water tablets)
- ciclosporin or tacrolimus (drugs used for suppressing the immune system)
- 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
- hormone replacement therapy
- aspirin, the risk of stomach ulcers is greater if you take Etoricoxib with aspirin.
 - o Etoricoxib can be taken with low-dose aspirin. If you are currently taking low-dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor
 - o do not take high dose aspirin or other anti-inflammatory medicines while taking Etoricoxib

Pregnancy and breast-feeding

Etoricoxib 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 the tablets and consult your doctor. Consult your doctor if you are unsure or need more advice.

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

Taking Etoricoxib with food and drink

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

Driving and using machines

Dizziness and sleepiness have been reported in some patients taking Etoricoxib. 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 Etoricoxib

Etoricoxib contains lactose. If you have been told by your doctor that you are unable to tolerate some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ETORICOXIB

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

Etoricoxib Tablets should not be taken by children or adolescents under 16 years of age.

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

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 Etoricoxib for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.

Osteoarthritis

The recommended dose is 30 mg once a day, increase to a maximum of 60 mg once a day if needed.

Rheumatoid arthritis

The recommended dose is 90 mg once a day.

Ankylosing spondylitis

The recommended dose is 90 mg once a day.

Acute pain conditions

Etoricoxib should be used only for the acute painful period.

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.

Postoperative dental surgery pain

The recommended dose 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.

If you take more Etoricoxib than you should

You should never take more tablets than the doctor recommends. If you do take too many Etoricoxib Tablets, you should seek medical attention immediately.

If you forget to take Etoricoxib

It is important to take Etoricoxib as your doctor has prescribed. If you miss a dose, just resume your usual schedule the following day. Do not take a double dose to make up for the forgotten tablet.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Etoricoxib can cause side effects, although not everybody gets them.

If you develop any of these signs you should stop Etoricoxib and talk to your doctor immediately:

- 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)

Not known (frequency cannot be estimated from the available data).

The following side effects can occur during treatment with Etoricoxib:

Common

Weakness and fatigue, dizziness, headache, flu-like illness, diarrhoea, wind, nausea, indigestion (dyspepsia), stomach pain or discomfort, heartburn, changes in blood tests related to your liver, swelling of the legs and/or feet due to fluid retention (oedema), increased blood pressure, palpitations, bruising, dry socket (inflammation and pain after a tooth extraction).

Uncommon

Stomach or bowel bloating, chest pain, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack, stroke, mini-stroke (transient ischaemic attack), abnormal heart rhythm (atrial fibrillation), upper respiratory infection, high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, changes in your bowel habits including constipation, dry mouth, mouth ulcers, taste alteration, gastroenteritis, gastritis, stomach ulcer, being sick (vomiting), irritable bowel syndrome, inflammation of the oesophagus, blurred vision, eye irritation and redness, nose bleed, ringing in the ears, vertigo, appetite increases or decreases, weight gain, muscle cramp/spasm, muscle pain/stiffness, inability to sleep, sleepiness, numbness or tingling, anxiety, depression, decreases in mental sharpness, breathlessness, cough, swelling of the face, flushing, skin rash or itchy skin, urinary tract infection, platelets decreased, decreased number of red blood cells, decreased number of white blood cells.

Rare

Low blood levels of sodium, redness of the skin.

Very Rare

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, bronchospasm (wheezing or shortness of breath), severe skin reactions, inflammation of the stomach lining or stomach ulcers that can become serious and may lead to bleeding, liver problems, serious kidney problems, severe increase in blood pressure, confusion, seeing, feeling or hearing things that are not there (hallucinations).

Not known

Yellowing of the skin and eyes (jaundice), liver failure, inflammation of the pancreas, fast heart rate, irregular heart rhythm (arrhythmia), restlessness, inflammation of the blood vessels.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ETORICOXIB

Keep your tablets out of the sight and reach of children.

Do not put the tablets into another container, as they might get mixed up.

Store in the original blister pack and do not remove the tablet from its blister until you are ready to take it, as the tablets are moisture sensitive.

There are no other special storage conditions required for this medicine.

Do not take the tablets if they are past the expiry date, which is clearly marked on the pack.

If your doctor tells you to stop taking this medicine, return any unused tablets to your doctor for safe disposal. Only keep the tablets if your doctor tells you to. If your tablets become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

6. FURTHER INFORMATION

What Etoricoxib contains

The active ingredient in Etoricoxib Tablets is etoricoxib.

Etoricoxib 60mg tablets: Green, apple-shaped, biconvex film-coated tablets marked '200' on one side and plain on the other side, containing 60mg of etoricoxib.

Etoricoxib 90mg tablets: White, apple-shaped, biconvex film-coated tablets marked '202' on one side and plain on the other side, containing 90mg of etoricoxib.

Etoricoxib 120mg tablets: Pale-green, apple-shaped, biconvex film-coated tablets marked '204' on one side and plain on the other side, containing 120mg of etoricoxib.

Other ingredients: calcium hydrogen phosphate (anhydrous), carnauba wax, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, and glycerol triacetate. The 60mg and 120mg tablets also contain yellow iron oxide (E172) and indigo carmine lake (E132).

Pack sizes: 60mg and 90mg strengths: 20 or 30 tablets per pack
120mg strength: 5 or 30 tablets per pack.

MANUFACTURER AND PRODUCT LICENCE HOLDER

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POM

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Etoricoxib 90mg Tablets PL No: 20636/1152
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