

VIOXX[®]

rofecoxib

12.5mg, 25mg & 50mg tablets

12.5mg, 25mg Oral Suspension

What is in this leaflet

This leaflet answers some common questions about VIOXX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking VIOXX against the benefits they expect it will have for you or your child.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What VIOXX is used for

VIOXX is used for the following:

- to treat the signs and symptoms of osteoarthritis, including pain, stiffness, and tenderness of the joints
- to treat the signs and symptoms of rheumatoid arthritis
- to treat juvenile rheumatoid arthritis in patients 2 years and older
- to treat cramp-like pain or discomfort before or during a menstrual period
- to relieve other types of pain.
- to treat migraine attacks.

Osteoarthritis

Osteoarthritis is a joint disease. It results from the gradual breakdown of the cartilage that covers the joints and cushions the ends of bones.

Symptoms of osteoarthritis include pain, tenderness, stiffness of one or more joints, and physical disability. The hips and knees are the most commonly affected joints, but other joints such as those of the hands and spine may also be affected.

Osteoarthritis is more common in women than in men. Many factors can lead to the development of osteoarthritis including obesity and joint injury (eg. from sport).

Rheumatoid Arthritis

Rheumatoid arthritis is a chronic disease that causes pain, stiffness, swelling and loss of function in the joints and inflammation in other body organs.

Juvenile Rheumatoid Arthritis

Juvenile rheumatoid arthritis is a chronic disease that causes joint pain, inflammation and stiffness.

Migraine

Migraine is an intense, throbbing, typically one-sided headache that often includes nausea, vomiting, sensitivity to light and sensitivity to sound. Some people may have visual symptoms before the headache, such as flashing lights or wavy lines, called an aura.

How VIOXX works

VIOXX belongs to a group of medicines called cyclooxxygenase-2 (COX-2) specific inhibitors (also known as Coxibs).

The body produces two similar enzymes called COX-1 and COX-2. COX-1 amongst other functions, is involved with protecting the stomach, while COX-2 plays a role in joint inflammation and arthritis pain.

VIOXX reduces pain and inflammation by blocking COX-2, an enzyme in the body.

VIOXX does not block COX-1, the enzyme involved in protecting the stomach from ulcers.

Other anti-inflammatory medicines (NSAIDS) block both COX-1 and COX-2.

VIOXX relieves pain and inflammation with less risk of stomach ulcers compared to NSAIDS.

Your doctor may have prescribed VIOXX for another reason. Ask your doctor if you have any questions about why VIOXX has been prescribed for you.

VIOXX is not addictive.

Before you take VIOXX

When you or your child must not take it

Do not take VIOXX if:

- you have an allergy to VIOXX or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you or your child should start taking VIOXX, talk to your doctor.

VIOXX has not been studied in patients under the age of 2 years.

Safety and efficacy have been studied in 2-17 year old JRA patients (see How much to take)

Before you start to take it

Tell your doctor if you or your child:

- are pregnant or intend to become pregnant
VIOXX is not recommended for use during late pregnancy. If there is a need to consider using VIOXX during your pregnancy, your doctor will discuss with you the benefits and risks of using it.
- are breast-feeding or plan to breast-feed
It is not known if VIOXX passes into breast milk. You and your doctor should discuss whether you should stop breast-feeding or not take VIOXX.

- have or have had any medical conditions, especially the following:
history of angina, heart attack or a blocked artery in your heart
kidney disease
liver disease
heart failure
high blood pressure
- have had an allergic reaction to aspirin or other anti-inflammatory medicines (commonly known as NSAIDs)
Symptoms of an allergic reaction may include asthma, pinkish itchy swellings on the skin (hives), runny or blocked nose.
- have an infection
If you take VIOXX while you have an infection, it may hide fever and may make you think, mistakenly, that you are better or that your infection is less serious than it might be.
- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before taking any VIOXX.

Taking other medicines

Tell your doctor if you or your child are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and VIOXX may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots
- theophylline, a medicine used to treat asthma
- rifampicin, an antibiotic used to treat tuberculosis and other infections
- ACE inhibitor medicines used to lower high blood pressure or treat heart failure
- lithium, a medicine used to treat a certain type of depression

These medicines may be affected by VIOXX or may affect how well it works. You ~~or your child~~ may need different amounts of your medicine, or may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking VIOXX.

VIOXX can be taken with low dose aspirin (less than or equal to 325mg daily). If you or your child take both aspirin and VIOXX, you may have a greater chance of serious stomach problems than if VIOXX was taken alone. If you are currently taking low dose aspirin for the prevention of a heart attack or stroke, you should continue to do so unless specified by your Doctor. VIOXX cannot replace aspirin for this purpose.

How to take VIOXX

How much to take

Take VIOXX only when prescribed by your doctor.

For osteoarthritis, the usual starting dose is 12.5 mg taken once a day. The dose may

need to be increased, depending on your response, to a maximum of 25 mg once a day.

For rheumatoid arthritis, the recommended dose is 25 mg once a day. The maximum recommended daily dose is 25 mg.

For juvenile rheumatoid arthritis, the recommended dose for pediatric patients 2 to 11 years of age is 0.6 mg/kg once a day. The recommended dose for adolescent patients 12 to 17 years of age is 25 mg once a day. The maximum recommended dose is 25 mg.

For the relief of menstrual pain or other types of pain, the recommended dose is 50 mg taken once a day on the first day. On the second day and after that, the dose is 25 or 50 mg once a day, as prescribed by your doctor. The maximum recommended daily dose is 50 mg.

For the treatment of migraine attacks, the recommended starting dose is 25mg taken once a day. Your doctor may increase the dose to 50mg. The maximum recommended daily dose is 50mg.

If you have moderate liver disease, you should not take more than 12.5 mg a day in long-term use.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

VIOXX comes as tablets and oral suspension.

When taking the tablets, swallow them with a glass of water.

When you are taking the suspension, shake the bottle well and accurately measure the dose with a measuring device.

This will make sure that you get the correct dose.

When to take it

Take your VIOXX at about the same time each day.

Taking VIOXX at the same time each day will have the best effect. It will also help you remember when to take the dose.

It does not matter if you take VIOXX before or after food.

How long to take it

Do not use VIOXX for longer than your doctor says.

Depending on your condition, you may need to take VIOXX for a few days or for a longer period.

For osteoarthritis, rheumatoid arthritis and JRA, VIOXX helps relieve your symptoms but it does not cure it. Continue taking VIOXX for as long as your doctor prescribes.

For the relief of menstrual pain, migraine or other types of pain, VIOXX is usually only

needed for a few days.

If you are not sure how long to take VIOXX, talk to your doctor. Your doctor will decide what dose of VIOXX you should take and how long you should take it.

If you or your child forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you or your child take too much (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much VIOXX. Do this even if there are no signs of discomfort or poisoning.

While you are using VIOXX

Things you or your child must do

If you become pregnant while taking VIOXX, tell your doctor immediately.

If you get an infection while taking VIOXX, tell your doctor. VIOXX may hide fever and may make you think, mistakenly, that you are better or that your infection is less serious than it might be.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking VIOXX.

Things you or your child must not do

Do not give VIOXX to anyone else, even if they have the same condition as you.

Things that would be helpful for arthritis

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Exercise - regular exercise can help reduce pain and disability from osteoarthritis by increasing muscle strength and reducing the load on joints, but it is important not to overdo it. Walking is good exercise, however, before starting any exercise, ask your doctor about the best kind of programme for you.
- Weight - your doctor may suggest losing some weight to help reduce the strain on your joints. Some people may need a dietician's help to lose weight.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while you are taking VIOXX.

VIOXX helps most people with osteoarthritis, rheumatoid arthritis, menstrual pain or other types of pain, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice or have any of the following and they worry you:

- feeling sick (nausea), vomiting
- heartburn, indigestion, uncomfortable feeling or pain in the stomach,
- diarrhoea
- constipation
- swelling of the legs, ankles or feet
- high blood pressure
- mouth ulcers
- dizziness
- headache
- drowsiness
- tiredness
- dry mouth
- hair loss
- difficulty concentrating
- anxiety
- blurred vision
- colitis
- confusion
- depression
- wheezing
- rash, itching
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- skin reactions caused by sunlight
- severe skin reactions
- tingling sensation
- palpitations
- pancreatitis
- ringing in the ears
- hallucinations
- increased levels of potassium in the blood
- low blood cell count
- menstrual disorder
- vertigo
- insomnia
- worsening of epilepsy

These are usually the mild adverse effects of VIOXX.

If any of the following happen, stop taking VIOXX and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- stomach ulcers that may become serious and may bleed
- fluid in the lungs
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- severe increase in blood pressure

- heart failure
- serious kidney problems
- serious liver problems
- unusual headache with a stiff neck

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using VIOXX

Storage

Keep your tablets in the blister pack and the suspension in the bottle until it is time to take them.

If you take the tablets out of the blister pack or the suspension out of the bottle the medication may not keep well.

Keep VIOXX in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking VIOXX, or the tablets or the suspension have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

VIOXX comes as three strengths of tablets and two strengths of oral suspension:

- 12.5 mg tablet - cream/off-white, round tablet with VIOXX marked on one side and MSD 74 on the other and comes in boxes of 30 tablets.
- 25 mg tablet - yellow, round tablet with VIOXX marked on one side and MSD 110 on the other and comes in boxes of 10 and 30 tablets.
- 50 mg tablet – orange, round tablet with VIOXX marked on one side and MSD 114 on the other and comes in boxes of 5 tablets.

A bottle of VIOXX oral suspension contains 150 mL.

- 12.5 mg/5 mL suspension - white to faint yellow
- 25 mg/5 mL suspension – white to faint yellow

Ingredients

Active ingredient:

VIOXX - 12.5 mg tablet contains 12.5 mg rofecoxib

VIOXX - 25 mg tablet contains 25 mg rofecoxib

VIOXX - 50 mg tablet contains 50 mg rofecoxib.

VIOXX - 12.5 mg/5 mL suspension contains 12.5 mg rofecoxib per 5 mL.

VIOXX - 25 mg/5 mL suspension contains 25 mg rofecoxib per 5 mL

Inactive ingredients:

12.5 mg, 25 mg and 50 mg tablets

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- hydroxypropyl cellulose
- magnesium stearate
- yellow ferric oxide
- The 50 mg tablets also contain red ferric oxide.

12.5 mg/5 mL and 25 mg/5 mL oral suspensions

- xanthan gum
- sorbitol solution
- sodium citrate (dihydrate)
- citric acid (monohydrate)
- strawberry flavour
- purified water
- sodium methylparaben as preservative
- sodium propylparaben as preservative

VIOXX does not contain gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Supplier

VIOXX is marketed in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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