

RABIROX CAPSULE

Celecoxib 200mg & 400mg

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What Rabirox Capsule is used for

Rabirox Capsule is a capsule that contains celecoxib as the active ingredient.

Rabirox is used for pain relief and to alleviate swelling of tissue in the degenerative joint disorder (osteoarthritis), inflammatory rheumatic joint disease (rheumatoid arthritis) and in certain types of inflammation of intervertebral joints (ankylosing spondylitis).

It is also used for the low back pain (for the 200mg strength).

How Rabirox Capsule works

Rabirox is a nonsteroidal anti-inflammatory drug (NSAID). It belongs to a group of medicines called cyclo-oxygenase-2 (COX-2) inhibitors. These work by lowering the amount of prostaglandins. Prostaglandins are substances made by your body. Some prostaglandins cause pain and swelling, but others help protect the stomach lining. *Rabirox* reduces the production of prostaglandins that cause pain and swelling prostaglandins that cause pain and swelling and not the ones that protect the stomach.

Before you use Rabirox Capsule

-When you must not use it

Do not take *Rabirox* if you have an allergy to:

- any medicine containing celecoxib

- any of the ingredients listed at the end of this leaflet.
- have an allergic reaction to 'sulphonamide'.
- have had asthma or breathing difficulties or wheezing as a result of taking in acetylsalicylic acid (aspirin) or any other anti-inflammatory and pain relieving medicine.
- have heart failure, established ischaemic heart disease or cerebrovascular disease, e.g. you have been diagnosed with a heart attack, stroke, or transient ischaemic attack (temporary reduction of blood flow to the brain; also known as "mini-stroke"), angina or blockages of blood vessels to the heart or brain.

-Before you start to use it

Talk to your doctor or pharmacist before taking *Rabirox* if you:

- have heart, liver or kidney problems, your doctor may want to keep a regular check on you.
- have previously had a stomach or duodenal (intestinal) ulcer or bleeding in the stomach or intestines.
- smoke, have diabetes, raised blood pressure or raised levels of cholesterol in your blood.
- have had a serious allergic reaction or a serious skin reaction to any medicines.

As with other NSAIDs (e.g. ibuprofen or diclofenac) this medicine may lead to an increase in blood pressure, and so your doctor may ask to monitor your blood pressure on a regular basis.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking *Rabirox*.

-Taking other medicines

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

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

- Dextromethorphan (used to treat coughs).
- carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression).
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure)
- Fluconazole, ketoconazole and rifampicin (used to treat fungal and bacterial infections).
- Warfarin or other warfarin like medicines ("blood-thinning" agents that reduce blood clotting).
- Lithium (used to treat some types of depression).
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia).
- Ciclosporin (used for immune system suppression e.g. after transplants).
- Acetylsalicylic acid (even at low dose for heart protective purposes) or other nonsteroidal anti-inflammatory medicines (e.g. ibuprofen or diclofenac). Ask your doctor advice before taking both medicines together".

If you are not sure, please talk to your doctor or pharmacist before use *Rabirox*.

How to use Rabirox Capsule

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

As the risk of side effects associated with heart problems may increase with dose and duration of use, it is important that you use the lowest dose that control your pain and you should not take this medicine for longer than necessary to control symptoms.

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For treatment of osteoarthritis: The recommended dosage is 200mg each day.

For treatment of rheumatoid arthritis: The recommended dosage is 200mg twice a day.

For treatment of ankylosing spondylitis:

The recommended dosage is 200 mg each day. Some patients might be given 400mg each day but this will depend on your doctor.

For acute treatment of pain and dysmenorrhea:

The recommended dosage is 400mg initially, followed by 200mg if needed on the first day.

On the subsequent day, the usual dose is 200mg twice a day when needed.

For treatment of lower back pain:

The recommended dosage is 200mg daily.

Older people

If you are over 65 years of age and especially if you weigh less than 50 kg, your doctor may want to monitor you more closely.

Kidney or liver problems

Make sure your doctor knows if you have liver or kidney problems as you may need a lower dose.

-When to use it

You should take your medicine at the same time each day with a drink of water. *Rabirox* can be given with or without food.

Take as directed by your doctor or pharmacist.

-How long to use it

Continue taking *Rabirox* for as long as your doctor recommends.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

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

-If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Rabirox Capsule

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Rabirox*.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Rabirox* to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Pregnancy and breast-feeding

If you are pregnant, trying to get pregnant or are breast-feeding you should not take *Rabirox* without discussing it with your doctor first.

Be careful driving or operating machinery until you know how *Rabirox* affects you.

Side effects

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

Very common side-effects

High blood pressure, including worsening of existing high blood pressure.

Common side-effects

- inflammation of the sinuses (sinusitis)
- upper respiratory tract infection
- urinary infection
- worsening of existing allergies
- difficulty sleeping, dizziness
- muscle stiffness
- headache
- heart attack
- cough
- breathing difficulty
- sore throat
- runny or stuffy nose, sneezing
- stomach ache
- diarrhea
- indigestion
- wind
- nausea (feeling sick)
- vomiting
- difficulty swallowing
- rash, itching of the skin
- painful joints
- fluid buildup with swollen ankles, legs and/or hands
- flu-like symptoms
- accidental injury

Uncommon side-effects

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- high level of blood potassium which can cause abnormal heart rhythm
- anxiety, depression, tiredness
- stroke
- tingling or numbness (paraesthesia), sleepiness
- blurred vision, eye inflammation (conjunctivitis)
- ringing in the ears, difficulty hearing
- heart failure

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- faster heart beat or feeling your heartbeat
- difficulty breathing (bronchospasm)
- constipation, burping, stomach inflammation, worsening of inflammation of the stomach or intestine
- mouth pain and sores
- changed liver function, increased levels of liver enzymes in the blood
- raised itchy rash (hives)
- skin discolouration (bruising)
- leg cramps
- changes in kidney-related blood tests: increased levels of creatinine and blood urea nitrogen
- face swelling
- chest pain (generalised pain not related to the heart)

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Public Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of Rabirox Capsule

-Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not take the capsule after the expiry date shown on the pack and blisters.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Rabirox Capsule 200mg

White to off-white granules in white opaque hard gelatin capsule size '2'.

Rabirox Capsule 400mg

White to off-white granules in white opaque hard gelatin capsule size '0'.

-Ingredients

-Active ingredient:

Celecoxib 200mg and 400mg

-Inactive ingredient:

Lactose Monohydrate, Povidone K30, Sodium Lauryl Sulphate, Croscarmellose Sodium, Magnesium Stearate and Purified Water.

-MAL number

Rabirox Capsule 200mg

MALXXXXXXXXXX.

Rabirox Capsule 400mg

MALXXXXXXXXXX.

Manufacturer:

Pharmaniaga Manufacturing Berhad
198001006232 (60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing Berhad
198001006232 (60016-D),
11A, Jalan P/1, Kawasan Perusahaan
Bangi, 43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

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