

RITOVID TABLET 120 MG

Etoricoxib (120 mg)

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What Ritovid Tablet is used for:

Ritovid Tablet is used:

- As acute and chronic treatment of signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA)
- To treat ankylosing spondylitis (AS) (an inflammatory disease causes some of the vertebrae in your spine to fuse together)
- To treat acute gouty arthritis (an extremely painful attack with a rapid onset of joint inflammation)
- To treat acute pain, including related to primary dysmenorrhoea (painful menstruation) and minor dental procedures.

How Ritovid Tablet works

Ritovid Tablet contains the active substance etoricoxib. Ritovid Tablet 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).

Before you use Ritovid Tablet

- When you must not use it

Do not take this medicine if:

- you are allergic (hypersensitive) to etoricoxib or any other ingredients of this medicine listed in this leaflet
- you are allergic to non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors
- your doctor has diagnosed heart problems including heart failure (moderate or severe types)
- you have had any kind of stroke

- you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries)
- you are or could be pregnant or are breast-feeding
- you have high blood pressure that has not been controlled by treatment
- you have serious kidney disease
- you have a current stomach ulcer or bleeding in your stomach or intestines
- you have inflammatory bowel disease
- 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 serious liver disease
- you are under 16 years of age
- you are taking aspirin or NSAIDs (e.g. Celecoxib, Diclofenac, Ibuprofen, Indomethacin, etc), experience tightening of muscles in the airways in your lungs, common cold symptoms (runny nose, sneezing or congestion), swellings of the nose lining in the shape of teardrop, skin redness and itching bumps or other allergic-like reactions.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

- Before you start to use it

Tell your doctor if:

- you have a history of heart failure, or any other form of heart disease.
- you have a history of high blood pressure, hyperlipidemia, diabetes, smoking and with peripheral arterial disease.
- you are taking acetylsalicylic acid.
- you have any history of liver or kidney disease
- you are dehydrated
- you have swelling due to fluid retention
- you have a history of high blood pressure. Ritovid Tablet can increase blood pressure in some people especially in high doses.

These can increase your risk of heart disease

- you have a history of stomach bleeding or ulcers
- you are being treated for an infection. Ritovid Tablet can mask or hide a fever, which is a sign of infection
- you have history of hypersensitive reaction related taking non-steroidal anti-inflammatory drugs (NSAIDs)
- you are pregnant or plan to get pregnant
- you are breastfeeding or plan to breastfeed.

- Taking other medicines

Ritovid Tablet may affect or be affected by other medicines you are taking. Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

They include:

- 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 (diuretics) that help reduce the amount of water in the body and reduces the effect of water build up like bumetanide, frusemide, hydrochlorothiazide, amiloride and spironolactone
- medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers, examples include captopril, enalapril, perindopril, losartan, telmisartan, vasartan
- medicines used to help control high blood pressure and heart failure called beta-blockers include atenolol, bisoprolol and carvedilol
- lithium (a medicine used to treat mental disorder)
- aspirin (for the relief of mild to moderate pain)
- birth control pills (the combination may increase risk of side effects associated with oral contraceptives)

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- hormone replacement therapy (HRT) (the combination may increase risk of side effects associated with HRT)
- abciximab (for the prevention of platelet aggregation), dipyridamole (a drug used to prevent blood coagulation), fondaparinux (for the prevention of blood clot formation), heparin (used as blood thinner) and tirofiban (for the prevention of blood clot formation) as this will increase the risk of bleeding
- citalopram (for the treatment of depressive illness), clopidogrel (for the prevention of platelet clumping together), dabigatran etexilate (for the prevention of blood clot formation by blocking a substance in the body), duloxetine (for the treatment of psychiatric disorder), enoxaparin (for the prevention of blood from coagulating), escitalopram (antidepressant), fluoxetine (antidepressant), ginkgo (improve cognitive function), paroxetine (for the treatment of major depressive episodes), pentoxifylline (antidepressant), prasugrel (to prevent formation of blood clot), rivaroxaban (prevent blood coagulation), tinzaparin (prevent blood coagulation), and venlafaxine (antidepressant), which may result in increased risk of bleeding
- diltiazem (for the treatment of high blood pressure and prevent angina), felodipine, (for the treatment of hypertension), flunarizine (for the prevention of migraine), nifedipine (for the treatment of high blood pressure and prevent angina), nifedipine (for the treatment of high blood pressure and prevent angina), and nimodipine (for the treatment of high blood pressure and prevent angina) which may result in an increased risk of gastrointestinal hemorrhage and/or antagonism of hypotensive effect
- levofloxacin (for the treatment of bacterial infections), ofloxacin (for the treatment of bacterial infections) and norfloxacin (for the treatment of bacterial infections) which may result in an increased risk of seizures
- gliclazide (for the treatment of Type 2 diabetes mellitus), glimepiride (for the treatment of Type 2 diabetes mellitus) and glipizide (for the control of blood sugar levels) which may result in an increased risk of hypoglycemia
- cyclosporin (for suppressing the immune system)
- ketorolac (prevent and relieve inflammation)
- minoxidil (a drug used to treat high blood pressure)
- tacrolimus (for suppressing the immune system)

Interactions which are not listed at here might happen as well. Please discuss with your doctors or pharmacists if there is any concerns.

How to use Ritovid Tablet

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Arthritis

- 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 60 mg once a day, increased to a maximum of 90 mg once a day if needed
- Ankylosing Spondylitis**
The recommended dose is 60 mg once a day, increased to a maximum of 90 mg once a day if needed
- Acute painful conditions**
Ritovid Tablet 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.

Use in children and adolescents

Ritovid Tablet should not be taken by children or adolescents under 16 years of age.

Elderly

No dose adjustment is necessary for elderly patients. As with other medicines, caution should be exercised in elderly patients.

- When to use it

Ritovid Tablet is for oral use. Take the tablets once a day. Ritovid Tablet can be taken with or without food.

- How long to use it

It is important continue to take Ritovid Tablet until your doctor tells you otherwise.

- If you forget to use it

It is important to take Ritovid Tablet 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 medicine, ask your doctor or pharmacist.

- If you use too much (overdose)

You should never take more tablets than the doctor recommends. 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.

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While you are using Ritovid Tablet

- Things you must do

Tell your doctor:

- If you experience allergic reactions/ any of the unwanted side effects while using this medicine.
- If you become pregnant while using this medication

Tell all the doctors and pharmacists treating you that you are using Ritovid Tablet.

Use this medicine exactly as your doctor has told you.

- Things you must not do

Do not:

- stop taking the medicines unless advised by your doctor
- give Ritovid Tablet to anyone else even if they have the same symptoms or condition as you
- take any new medicines without consulting your doctor
- use Ritovid Tablet after the expiry date

- Things to be careful of

Driving and using machines

Patients who experience dizziness, vertigo or somnolence while taking etoricoxib should refrain from driving or operating machinery.

Side effects

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

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine. They include:

- 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.
- muscle weakness, tingling sensation, high levels of potassium in your blood, changes in blood or

urine tests relating to your kidney (hyperkalemia)

- serious kidney problems
- palpitations (fast or irregular heartbeat), irregular heart rhythm (arrhythmia), chest pain
- severe increase in blood pressure that can lead to stroke (hypertensive crisis)
- difficulty in breathing, feeling of tightness in chest (bronchospasm)
- abdominal pain, oral ulcers, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, vomiting, diarrhea.
- yellowing of the skin and eyes (jaundice), inflammation of liver (hepatitis)
- anxiety, difficulty in sleeping, confusion, seeing, feeling or hearing things that are not there (hallucinations), confusion, depression, restlessness
- inability to taste, sleepiness
- blurred vision
- swelling of the face, skin rash or itchy skin, redness of the skin

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Ritovid Tablet

- Storage

Keep out of reach of children. Store below 30°C. Protect from light and moisture.

- 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

Round, 10.0 mm in diameter, red film-coated tablet, bevel-edged, shallow convex faces.

- Ingredients

- Active ingredients
Ritovid Tablet 120 mg contains 120 mg of etoricoxib.
- Inactive ingredients
 - Dicalcium Phosphate Dihydrate
 - Croscarmellose Sodium
 - Polyvinylpyrrolidone
 - Magnesium Stearate
 - Microcrystalline Cellulose
 - Propylene glycol
 - Talc
 - Titanium dioxide
 - Iron oxide red
 - Hydroxypropyl methylcellulose E-5
 - Hydroxypropyl methylcellulose E-15
 - Purified water

- MAL Number:

MAL18086136AZ

Manufacturer

HOVID Bhd.
Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.
121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar),
30010 Ipoh, Malaysia.

Date of revision

21/10/2024