

TORCOXIB CAPSULES

Celecoxib 200 mg

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What TORCOXIB is used for

- For the management of acute pain in adult for the treatment of menstrual pain.
- Relief of acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis.
- Relief of signs and symptoms of ankylosing spondylitis.
- For the management of low back pain.

How TORCOXIB works

TORCOXIB belongs to a group of medicinal products called nonsteroidal anti-inflammatory drugs (NSAID), and specifically a sub-group known as (COX-2) inhibitors. Your body makes prostaglandins that may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. TORCOXIB acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

You should expect your medicine to start working within hours of taking the first dose, but you may not experience a full effect for several days.

Before you use TORCOXIB

- When you must not use it

Do not take TORCOXIB unless you have been prescribed TORCOXIB by your doctor.

The following information will help you get the best results with TORCOXIB. If you have any further questions, please ask your doctor or pharmacist.

Do not take TORCOXIB:

- If you are allergic to celecoxib or any of the other ingredients of this medicine.
- If you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections).
- If you currently have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines.
- If as a result of taking acetylsalicylic acid or any other anti-inflammatory and pain-relieving medicine (NSAID) you have had asthma, nose polyps, severe nose congestion, or an allergic reaction such as an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing.
- If you have severe liver disease.
- If you have severe kidney disease.
- If you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn’s disease.
- Do not take TORCOXIB if you who have increased risk of cardiovascular disease (ischemic heart disease and stroke) i.e. if you have heart failure, or you have been diagnosed with a heart attack, stroke, or mini-stroke (temporary reduction of blood flow to the brain, blockages of blood vessels to the heart or brain).
- If you have or have had problems with your blood circulation (peripheral arterial disease) or if you have had surgery on the arteries of your legs.
- This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Pregnancy and lactation

Do not take TORCOXIB if you are pregnant or plan to become pregnant or think you might be pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor.

Do not take TORCOXIB if you are breast-feeding. Ask your doctor or

pharmacist for advice before taking any medicine.

- Before you start use it

Talk to your doctor or pharmacist before taking TORCOXIB:

- If you have previously had an ulcer or bleeding in your stomach or intestines (do not take TORCOXIB if you currently have an ulcer or bleeding in your stomach or intestine).
- If you are taking acetylsalicylic acid (even at low dose for heart protective purposes).
- If you use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban).
- If you use medicines called corticosteroids (e.g. prednisone).
- If you are using TORCOXIB at the same time as other non-acetylsalicylic NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided.
- If you smoke, have diabetes, raised blood pressure or raised cholesterol
- If your heart, liver or kidneys are not working well your doctor may want to keep a regular check on you.
- If you have fluid retention (such as swollen ankles and feet).
- If you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (used to treat excess fluid in the body).
- If you have had a serious allergic reaction or a serious skin reaction to any medicines.
- If you feel ill due to an infection or think you have an infection, as TORCOXIB may mask a fever or other signs of infection and inflammation.
- If you are over 65 years of age your doctor will want to monitor you regularly.
- The consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems. 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.

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- Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib.
- Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.
- TORCOXIB may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.
- Neuroleptics (used to treat some mental disorders).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia).
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression).
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders).
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants).

How to use TORCOXIB

- Taking other medicines

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

Tell your doctor if you:

- Are taking acetylsalicylic acid (even at low dose for heart protective purposes).
- Use medicines called corticosteroids (e.g. prednisone).
- Are using TORCOXIB at the same time as other non-acetylsalicylic NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Dextromethorphan (used to treat coughs).
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure).
- Fluconazole and rifampicin (used to treat fungal and bacterial infections).
- Warfarin or other warfarin like medicines ("blood-thinning" agents that reduce blood clotting) including newer medicines like apixaban.
- Lithium (used to treat some types of depression).
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat.

- How much to use

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

Symptomatic Treatment of Osteoarthritis (joint disease): The recommended dose of celecoxib is 200 mg administered as a single dose or as 100 mg twice per day.

Symptomatic Treatment of Rheumatoid Arthritis: The recommended dose of celecoxib is 100 mg or 200 mg twice per day.

Ankylosing Spondylitis (long-term (chronic) condition in which the spine and other areas of the body become inflamed): The recommended dose of celecoxib is 200 mg administered as a single dose or 100 mg twice per day. Some patients may benefit from a total daily dose of 400 mg.

Management of Acute Pain: The recommended dose of celecoxib is 400 mg, initially, followed by an additional 200 mg dose, if needed on the first day. On subsequent days, the recommended dose is 200 mg twice daily, as needed.

Treatment of Primary Dysmenorrhea (painful menstrual cramps): The recommended dose of celecoxib is 400 mg, initially, followed by an additional 200 mg dose, if needed on the first day. On subsequent days, the recommended dose is 200 mg twice daily, as needed.

Low Back Pain: Usual dosage for adults is 100 mg of celecoxib orally twice daily, morning and evening after

meal, or 200 mg once daily (100 mg and 200 mg only).

Elderly: No dosage adjustment is generally necessary. However, for elderly patients with a lower than average body weight (<50 kg), it is advisable to initiate therapy at the lowest recommended dose.

Liver impairment: No dosage adjustment is necessary in patients with mild liver impairment (Child-Pugh Class A). Introduce celecoxib at half the recommended dose in arthritis or pain patients with moderate liver impairment (Child-Pugh Class B).

Patients with severe liver impairment (Child-Pugh Class C) have not been studied.

Kidney impairment: No dosage adjustment is necessary in patients with mild or moderate kidney impairment. There is no clinical experience in patients with severe kidney impairment.

Children: Celecoxib is not indicated for use in children.

- When to use it

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

Given the association between cardiovascular risk and exposure to COX-2 Inhibitors (TORCOXIB), doctors are advised to use the lowest effective dose for the shortest possible duration of treatment. If you think or feel that the effect of TORCOXIB is too strong or too weak, talk to your doctor or pharmacist. Your doctor will tell you what dose you should take. 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 controls your pain and you should not take TORCOXIB for longer than necessary to control symptoms.

- How long to use it

Continue taking TORCOXIB for as long as your doctor recommends. If you have any further questions on the use of this product, ask your doctor or pharmacist.

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- 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 use too much (overdose)

You should not take more capsules than your doctor tells you to. If you take too many capsules contact your doctor, pharmacist or hospital and take your medicine with you.

While you are using it

- 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 TORCOXIB.
- Celecoxib is for adults only. It is not for use in children.
- You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant.

- 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 TORCOXIB to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the capsule make you feel dizzy or drowsy, do not drive or use machines and contact your doctor immediately.

Side effects

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

If any of the following happen, stop taking TORCOXIB and inform your doctor immediately:

- If you have an allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing.

- If you have heart problems such as pain in the chest.
- If you have severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood.
- If you have a skin reaction such as rash, blistering or peeling of the skin.
- If you have liver failure (symptoms may include nausea (feeling sick), diarrhea, jaundice (your skin or the whites of your eyes look yellow).

Very common:

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

Common:

- Heart attack.
- Fluid buildup with swollen ankles, legs and/or hands.
- Urinary infections.
- Shortness of breath, sinusitis (sinus inflammation, sinus infection, blocked or painful sinuses), blocked or runny nose, sore throat, coughs, colds, flu-like symptoms.
- Dizziness, difficulty sleeping.
- Vomiting, stomach ache, diarrhea, indigestion, wind.
- Rash, itching.
- Muscle stiffness.
- Difficulty swallowing.
- Headache.
- Nausea (feeling sick).
- Painful joints.
- Worsening of existing allergies.
- Accidental injury

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 nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TORCOXIB

- Storage

- Store below 30°C.

- 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

TORCOXIB 200mg CAPSULES

An opaque yellow colored, size '1' hard gelatin capsule, '1309' imprinting with black ink on cap and '200' imprinting with black ink on body, containing white to off white granular powder.

Ingredients

Active ingredient:

- Celecoxib

In-active ingredients:

- Crosscarmellose Sodium.
- Povidone K-30.
- Lactose Monohydrate.
- Magnesium Stearate.
- Sodium Lauryl Sulphate.
- Empty Hard Gelatin Capsule Shells. *Source of gelatin capsule: Bovine*
- Iron oxide yellow (E172)
- Titanium Dioxide

- MAL number:

MAL19086002AZ

Manufacturer

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Product Registration Holder

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Date of revision

11/02/2022

Serial Number

NPRA(R2)19/70