

CELEBREX[®] CAPSULES

Celecoxib (100 mg, 200 mg, 400 mg)

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What Celebrex is used for

Celebrex is used for:

- Menstrual cramps or period pains.
- Relief symptoms of joint pain, tenderness, swelling and stiffness in rheumatoid arthritis and osteoarthritis.
- Relief of signs and symptoms of ankylosing spondylitis (a chronic inflammatory rheumatic disorder that primarily affects, but is not limited to, the spine).
- The management of low back pain (100 mg and 200 mg only).

How Celebrex works

Celebrex 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.

Celebrex acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

Before you use Celebrex

- When you must not use it

Tell your doctor if any of the following are true for you as patients with these conditions should not take Celebrex.

- If you are allergic (hypersensitive) to celecoxib or any of the other ingredients of Celebrex

- If you have had an allergic reaction to a group of medicines called “sulfonamides” (e.g. Some antibiotics used to treat infections)
- If as a result of taking acetylsalicylic acid or any other anti-inflammatory and pain-relieving medicine (NSAID) you have had asthma, , 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 been diagnosed with a heart attack, heart disease, stroke, mini stroke (temporary reduction or blockage of blood flow to the brain), chest pain, or blockage of blood vessels to the heart or brain
- If you have or have had problems with your blood circulation or if you have had surgery on the arteries of your legs
- Allergic reactions such as DRESS syndrome that can cause fever and skin rash, disease of the lymph nodes and blood disorders like increase in eosinophil count (eosinophilia).

Pregnancy and lactation

Do not take celecoxib if you are pregnant or can become pregnant (i.e. if you are of child bearing potential and not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with Celecoxib you should discontinue the treatment and contact your doctor for alternative treatment.

Celecoxib can pass into breast milk and may harm a nursing baby. Celecoxib must not be used during breast-feeding. Tell your doctor if you are breast-feeding.

- Before you start to use it

Talk to your doctor or pharmacist before taking Celecoxib:

- If you currently have or previously had an ulcer or bleeding in your stomach or intestines
- If you have severe liver or kidney disease

- If you have any heart disease
- If you smoke, drink alcohol, have diabetes, raised blood pressure or raised cholesterol
- If you have fluid retention (such as swollen ankles and feet)
- If you are over 65 years of age
- If you are taking acetylsalicylic acid
- If you are dehydrated, due to sickness, diarrhea or the use of diuretics (used to treat excess fluid in the body)
- If you feel ill due to an infection or think you have an infection, as Celecoxib may mask a fever or other signs of infection and inflammation
- If you are planning to become pregnant or if you have problems to become pregnant
- If you are in second or third trimester of pregnancy.

- Taking other medicines

Some medicines can affect the way other medicines work. 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, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Dextromethorphan (used to treat cough)
- ACE inhibitors, like lisinopril, or angiotensin II antagonists (used for high blood pressure and heart failure)
- Diuretics (used to treat excess fluid in the body)
- Fluconazole, ketoconazole and rifampicin (used to treat fungal and bacterial infections)
- Warfarin or other oral anticoagulants (“blood thinning” agents that reduce blood clotting)
- Lithium (used to treat some types of depression)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)

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- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Cyclosporin (used for immune system suppression e.g. after transplants)
- Metoprolol (used to treat high blood pressure)
- Non-aspirin NSAIDs (used to treat pain and fever)
- Aspirin or acetylsalicylic acid (used to prevent blood clots)

How to use Celebrex

- How much to use

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 Celebrex for longer than necessary to control symptoms.

For osteoarthritis the recommended dose is 200 mg each day. It can be given as a single dose or as 100 mg twice per day.

For rheumatoid arthritis the recommended dose is 100 mg or 200 mg twice per day.

For ankylosing spondylitis, the recommended dose is 200 mg each day, given as a single dose or as 100 mg twice per day. Some patients may benefit from a total daily dose of 400 mg.

For management of acute pain and primary dysmenorrhea, the recommended dose 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.

For low back pain recommended dose is 100 mg twice daily or 200 mg once daily.

- When to use it

Celebrex should be swallowed whole with a drink of water. The capsules can be taken at any time of the day, with or without food. However, try to take each dose of Celebrex at the same time each day.

Contact your doctor within two weeks of starting treatment if you do not experience any benefit

- How long to use it

Suddenly stopping your treatment with Celebrex may lead to your symptoms getting worse. Do not stop taking Celebrex unless your doctor tells you to.

Your doctor may tell you to reduce the dose over a few days before stopping completely. If you have any further questions on the use of this product, ask your doctor or pharmacist

- If you forget to use it

If you forget to take a capsule, take it as soon as you remember. Do not take a double dose to make up for forgotten doses.

- 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

Always take Celebrex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. If you think or feel that the effect of Celebrex is too strong or too weak, talk to your doctor or pharmacist.

- 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 or pharmacist.

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

- Things to be careful of

Driving and using machines

You should be aware of how you react to Celebrex before you drive or operate machinery. If you feel dizzy or drowsy after taking Celebrex, do not drive or operate machinery until these effects wear off.

Side effects

Like all medicines, Celebrex can have side-effects, although not everybody gets them.

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

If any of the following happen, stop taking Celebrex and tell your doctor immediately:

- An allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
- Heart problems
- Severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools or vomiting blood
- A skin reaction such as rash, blistering or peeling of the skin
- Liver failure (symptoms may include nausea (feeling sick), diarrhea, jaundice (your skin or the whites of your eyes look yellow)).

The side effects listed below were observed in patients treated with Celebrex.

Very common (affects more than 1 user in 10)

- High blood pressure
- Diarrhea

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Common (affects 1 to 10 users in 100)

- Heart problems: heart attack, angina (chest pain)
- Fluid build-up 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, difficult or laboured breathing
- Dizziness, difficulty sleeping
- High blood pressure, including worsening of existing high blood pressure
- Cough
- Stomach problems: irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind), vomiting, nausea
- Rash, itching
- Kidney stones (which may lead to stomach or back pain, blood in urine), difficulty passing urine
- Weight gain
- Ear infection
- Fungal infection
- Difficulty in swallowing
- Stomach reflux disease (symptoms like heartburn, chest pain, regurgitation, and nausea)
- Diverticulum (small bulging sac pushing outward from the colon wall)
- Uncontrollable muscle contractions
- Vaginal bleeding
- Swelling, inflammation or enlargement of prostate gland
- Increase in liver enzyme levels

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, 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 npa.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Celebrex

- Storage

Store at or below 30°C. Keep out of the reach and sight of children. Do not use Celebrex after the expiry date stated on the blister and carton.

- 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

100 mg Capsules: Opaque, white to off-white, hard gelatin capsule with identifying markings, 100 mg marked with blue ink.

200 mg Capsules: Opaque, white to off-white, hard gelatin capsule with identifying markings, 200 mg marked with gold ink.

400 mg Capsules: Hard Gelatin Capsule (containing white to off white granulation), White opaque body with green ink band containing in white "400". White opaque cap with green band containing in white "7767".

- Ingredients

- Active ingredient

The active substance is celecoxib.
1 capsule contains 100 mg, 200 mg or 400 mg celecoxib.

- Inactive ingredients

100 mg, 200 mg and 400 mg capsules contain

- lactose monohydrate
- sodium lauryl sulphate
- polyvidone K30
- croscarmellose sodium
- magnesium stearate.

Capsule shells contain

- gelatin
- titanium dioxide
- ink gold SB-3002 (200 mg capsule)

- ink blue SB-6018 (100 mg capsule)
- ink green SB-4027 (400 mg capsule)

- MAL number(s):

Celebrex Capsule 100 mg-
MAL20000004ARZ
Celebrex Capsule 200 mg-
MAL20000005ARZ
Celebrex Capsule 400 mg-
MAL08051748ARZ

Manufacturer

Manufactured By:
Viatris Pharmaceuticals LLC
KM 1.9 Road 689, Vega Baja,
Puerto Rico 00693, USA.

Product Registration Holder

Viatris Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

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