

Celebib 100/200

Celecoxib Capsules 100 mg / 200 mg

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1. What Celebib 100 / 200 is used for:

Celebib 100 / 200 is used in acute pain in adults and for the treatment of primary dysmenorrhoea. Relief of acute and chronic pain and inflammation of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis.

2. How Celebib 100 / 200 works:

Celecoxib 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. Celecoxib 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.

3. Before you use Celebib 100 / 200 :

- 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 Celecoxib:

- 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 are pregnant.
- if you are breast-feeding
- 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
- if you 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
- 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

- Before you start to use it

Talk to your doctor or pharmacist before taking Celecoxib:

- if you have previously had an ulcer or bleeding in your stomach or intestines.
- 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 Celecoxib 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 Celecoxib 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

- Taking other medicines

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
 - 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)
- Celecoxib can be taken with low dose acetylsalicylic acid (75 mg or less daily). Ask your doctor for advice before taking both medicines together.

4. How to use Celebib 100 / 200 :

How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you think or feel that the effect of Celecoxib is too strong or too weak, talk to your doctor or pharmacist.

Celecoxib is for oral use. If you have difficulty swallowing capsules: The entire capsule contents can be sprinkled onto a level teaspoon of semi-solid food (such as cool or room temperature applesauce, rice gruel, yogurt or mashed banana) and swallowed immediately with a drink approximately 240 ml of water.

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To open the capsule, hold upright to contain the granules at the bottom then gently squeeze the top and twist to remove, taking care not to spill the contents. Do not chew or crush the granules.

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

The recommended dose is:

For osteoarthritis : The recommended dose is usually:

- one 200 mg capsule once a day; or
- one 100 mg capsule twice a day.

For Primary Dysmenorrhea: The recommended dose is usually: one 400 mg followed by 200 mg once a day followed by 200mg capsule twice a day.

For Acute Pain : The recommended dose is usually: one 400 mg followed by 200 mg once a day followed by 200mg capsule twice a day.

For rheumatoid arthritis : The recommended dose is usually: one 100 mg or 200 mg capsule twice a day.

For ankylosing spondylitis : The recommended dose is usually:

- one 200 mg capsule once a day; or
- one 100 mg capsule twice a day.

The elderly, especially those with a weight less than 50 kg; 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.

You should not take more than 400 mg per day.

Use in children: Celecoxib is for adults only; it is not for use in children.

- When to use it

Celebib 100 / 200 can be taken at any time of the day, with or without food. However, try to take each dose of Celecoxib at the same time each day

- How long to use it

Your doctor will tell you, at what time and for how long to 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 Celecoxib for longer than necessary to control symptoms.

- If you forget to use it

If you forgot to take a dose, take it as soon as you remember .Do not double-up the next dose to make up for the missed dose.

- If you use too much (overdose)

If you accidentally take too many Celebib 100 / 200 capsules, contact your doctor or nearest emergency department for advice. Take the medicine with you so that you can easily describe what you have taken.

- If you use stop taking

Do not stop taking Celebib 100 / 200 just because you feel better. Suddenly stopping your treatment with Celecoxib may lead to your symptoms getting worse. Do not stop taking Celecoxib unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

5. While you are using it:

- Things you must do

- If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor

- Celecoxib 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.

- If you become pregnant during treatment with Celecoxib you should discontinue the treatment and contact your doctor for alternative treatment.

- Things you must not do

- Do not take Celecoxib if you currently have an ulcer or bleeding in your stomach or intestine.

- Celecoxib must not be used during breast-feeding.

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

- Things to be careful of

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.

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.

6. Side Effects

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

The side effects listed below were observed in arthritis patients who took Celecoxib. If any of the following happen, stop taking Celecoxib and tell your doctor immediately:

If you have:

- an allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
- heart problems such as pain in the chest
- 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), diarrhoea, 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, diarrhoea, indigestion, wind
- Rash, itching
- Muscle stiffness
- Difficulty swallowing
- Headache
- Nausea (feeling sick)
- Painful joints
- Worsening of existing allergies
- Accidental injury
- Heart problems: angina (chest pain)
- Stomach problems: irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind)
- Kidney stones (which may lead to stomach or back pain, blood in urine), difficulty passing urine
- Weight gain

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Reporting of side effects:

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.moh.gov.my (Consumers - > Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

7. Storage and disposal Of Celebib 100 / 200 :

Storage

Keep out of the reach and sight of children. This medicinal product needs to Store below 30° C in a dry place. Protect from light.

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.

8. Product Description

What it looks like and contents of the pack

Celebib 100 : Size '4' Capsule, containing white to off-white powder, having white opaque cap, white opaque body with 'C5' imprinted on a blue band on the cap and '100 mg' imprinted on a blue band on the body.

Celebib 200 : Size '2' Capsule, containing white to off-white powder, having white opaque cap, white opaque body with 'C6' imprinted on a yellow band on the cap and '200 mg' imprinted on a yellow band on the body.

Available as Alu-PVC/PVdC Blister of 10's and such 3 & 10 blisters packed in a carton along with pack insert.

What Celebib 100 / 200 contains

Active ingredient: Celecoxib

Excipients : Lactose Monohydrate, Hydroxypropyl Cellulose, Crospovidone Type A, Povidone (PVPK-30), Sodium Lauryl Sulfate, Purified Water & Magnesium Stearate.

- MAL number(s):

Celebib 100: MAL19036012AZ

Celebib 200: MAL19036008AZ

9. Manufacturer

Macleods Pharmaceuticals Limited

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10. Product Registration Holder

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