

CELECOXIB 100 mg and 200 mg CAPSULES, HARD

Package leaflet: Information for the patient

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Celecoxib is and what it is used for
2. What you need to know before you take Celecoxib
3. How to take Celecoxib
4. Possible side effects
5. How to store Celecoxib
6. Contents of the pack and other information

1 What Celecoxib is and what it is used for

Celecoxib Capsules is used for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis in adults.

Celecoxib Capsules, with the active substance celecoxib, belong to a group of medicinal products called nonsteroidal anti-inflammatory drugs (NSAIDs) and specifically a sub-group known as COX-2 inhibitors.

Your body produces substances, so-called 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 these substances, thereby reducing the pain and inflammation.

2 What you need to know before you take Celecoxib

Do not take Celecoxib:

- if you are allergic to celecoxib or any of the other ingredients of this medicine (listed in section 6)
- if you have had an allergic reaction to a group of medicines called "sulfonamides" (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 (NSAIDs) 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 can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor
- 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
- if you have 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 pectoris, 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Celecoxib

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

Do not take Celecoxib 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 smoke
- if you have diabetes (diabetes mellitus)
- if you have high blood pressure
- if you have 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

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.


Children

Celecoxib is not for use in children.

Other medicines and Celecoxib

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

- some medicines to treat coughs (dextrometorphan)
- medicines used for high blood pressure and heart failure (e.g. ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics)
- some medicines used to treat fungal and bacterial infections (fluconazole and rifampicin)
- "blood-thinning" agents that reduce blood clotting (warfarin or other warfarin like medicines including newer medicines like apixaban);
- medicines to treat depression (e.g. lithium)
- medicines to treat sleep disorders or an irregular heartbeat
- medicines to treat some mental disorders (neuroleptics)
- some medicines to treat rheumatoid arthritis, psoriasis and leukaemia (methotrexate)
- some medicines to treat epilepsy/seizures and some forms of pain or depression (carbamazepine)

Peel Here To Open 

- some medicines to treat epilepsy/seizures and some sleep disorders (barbiturates)
- some medicines used for immune system suppression e.g. after transplants (ciclosporin and tacrolimus)
- acetylsalicylic acid. Celecoxib Capsules can be taken together with acetylsalicylic acid but only in low daily doses of acetylsalicylic acid. Talk to your doctor or pharmacist before taking both medicines together.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Celecoxib must **not** be used by women who are pregnant or can become pregnant (i.e. women of child-bearing potential who are 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..

Breast-feeding

Celecoxib must **not** be used during breast-feeding.

Fertility

NSAIDs, including Celecoxib, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

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.

3 How to take Celecoxib

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage Celecoxib 100 mg Capsules, Hard:

For osteoarthritis

the recommended daily dose is 200 mg (**100 mg twice a day or 200 mg once a day**), increased by your doctor to a maximum of 400 mg (**200 mg twice a day**), if needed.

For rheumatoid arthritis

the initial recommended daily dose is 200 mg (**100 mg twice a day**), increased by your doctor to a maximum of 400 mg (**200 mg twice a day**), if needed.

For ankylosing spondylitis

the recommended daily dose is 200 mg (**100 mg twice a day or 200 mg once a day**), increased by your doctor to a maximum of 400 mg (**400 mg once a day or 200 mg twice a day**), if needed.

Dosage Celecoxib 200 mg Capsules, Hard:

For osteoarthritis

the recommended daily dose is 200 mg (**200 mg once a day**), increased by your doctor to a maximum of 400 mg (**200 mg twice a day**), if needed.

For rheumatoid arthritis

the initial recommended daily dose is 200 mg (**200 mg once a day**), increased by your doctor to a maximum of 400 mg (**200 mg twice a day**), if needed.

For ankylosing spondylitis

the recommended daily dose is 200 mg (**200 mg once a day**), increased by your doctor to a maximum of 400 mg (**400 mg once a day or 200 mg twice a day**), if needed.

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 Celecoxib for longer than necessary to control symptoms. If you think that the effect of Celecoxib is too strong or too weak, talk to your doctor or pharmacist.

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

Maximum daily dose:

Celecoxib 100 mg Capsules, Hard: You should not take more than 400 mg (4 capsules, hard of 100 mg) of Celecoxib per day.

Celecoxib 200 mg Capsules, Hard: You should not take more than 400 mg (2 capsules, hard) of Celecoxib per day.

Kidney or liver problems

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

Elderly, especially those with a weight less than 50 kg

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

Use in children

Celecoxib is for adults only and **not** for use in children.

How to take Celecoxib

The capsules 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.

Celecoxib Capsules should be swallowed with a sufficient amount of water (e.g. one glass [200 ml]).

If you have difficulty swallowing capsules: The entire capsule contents can be sprinkled onto a spoonful of semi-solid food (such as cool or room temperature applesauce, rice gruel, yogurt or mashed banana) and swallowed immediately with a drink approximately one glass of water.

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

If you take more Celecoxib Capsules than you should

You should not take more hard capsules than your doctor tells you to. If you take too many hard capsules contact your doctor, pharmacist or hospital and take your medicines with you so that your doctor can see what you are taking.

If you forget to take Celecoxib

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

If you stop taking Celecoxib

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 Celecoxib completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible 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. Side effects marked with an asterisk (*) are listed below at the higher frequencies that occurred in patients who took celecoxib to prevent colon polyps. Patients in these studies took celecoxib at high doses and for a long duration.

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
- skin reactions such as rash, blistering or peeling of the skin
- 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
- liver failure (symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow)).

Very common (may affect more than 1 in 10 people):

- high blood pressure including worsening of existing high blood pressure *

Common (may affect up to 1 in 10 people):

- Heart attack*
- 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
- 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

Uncommon (may affect up to 1 in 100 people):

- Stroke*
- Heart failure, palpitations (awareness of heart beat), fast heart rate
- Abnormalities in liver-related blood tests
- Abnormalities in kidney-related blood tests
- Anaemia (changes in red blood cells that can cause fatigue and breathlessness)
- Anxiety, depression, tiredness, drowsiness, tingling sensations (pins and needles)
- High levels of potassium in blood test results (can cause nausea (feeling sick), fatigue, muscle weakness or palpitations)
- Impaired or blurred vision, ringing in the ears, mouth pain and sores, difficulty hearing*
- Constipation, burping, stomach inflammation (indigestion, stomach ache or vomiting), worsening of inflammation of the stomach or intestine.
- Leg cramps
- Raised itchy rash (hives)
- Eye inflammation
- Difficulty breathing
- Skin discolouration (bruising)
- Chest pain (generalised pain not related to the heart)
- Face swelling

Rare (may affect up to 1 in 1,000 people):

- Ulcers (bleeding) in the stomach, gullet or intestines; or rupture of the intestine (can cause stomach ache, fever, nausea, vomiting, intestinal blockage), dark or black stools, inflammation of the pancreas (can lead to stomach pain), inflammation of the gullet (oesophagus)
- Low levels of sodium in the blood (a condition known as hyponatraemia)
- Reduced number of white blood cells (which help to protect the body from infection) or blood platelets (increased chance of bleeding or bruising)
- Difficulty coordinating muscular movements
- Feeling confused, changes in the way things taste
- Increased sensitivity to light
- Loss of hair

- Hallucinations
- Bleeding in the eye
- Acute reaction that may lead to lung inflammation
- Irregular heartbeat
- Flushing
- Blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse
- Bleeding of the stomach or intestines (can lead to bloody stools or vomiting), inflammation of the intestine or colon
- Severe liver inflammation (hepatitis). Symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellow discolouration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills
- Acute kidney failure
- Menstrual disturbances
- Swelling of the face, lips, mouth, tongue or throat, or difficulty swallowing

Very rare (may affect up to 1 in 10,000 people):

- Serious allergic reactions (including potentially fatal anaphylactic shock)
- Serious skin conditions such as Stevens-Johnson syndrome, exfoliative dermatitis and toxic epidermal necrolysis (can cause rash, blistering or peeling of the skin) and acute generalised exanthematous pustulosis (symptoms include the skin becoming red with swollen areas covered in numerous small pustules)
- A delayed allergic reaction with possible symptoms such as rash, swelling of the face, fever, swollen glands, and abnormal test results (e.g., liver, blood cell (eosinophilia, a type of raised white blood cell count))
- Bleeding within the brain causing death
- Meningitis (inflammation of the membrane around the brain and spinal cord)
- Liver failure, liver damage and severe liver inflammation (fulminant hepatitis) (sometimes fatal or requiring liver transplant). Symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellow discolouration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills
- Liver problems (such as cholestasis and cholestatic hepatitis, which may be accompanied by symptoms such as discoloured stools, nausea and yellowing of the skin or eyes)
- Inflammation of the kidneys and other kidney problems (such as nephrotic syndrome and minimal change disease, which may be accompanied by symptoms such as water retention (oedema), foamy urine, fatigue and a loss of appetite)
- Worsening of epilepsy (possible more frequent and/or severe seizures)
- Blockage of an artery or vein in the eye leading to partial or complete loss of vision
- Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
- A reduction in the number of red and white blood cells and platelets (may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections)
- Muscle pain and weakness
- Impaired sense of smell
- Loss of taste

Not known (frequency cannot be estimated from the available data):

- Decreased fertility in females, which is usually reversible on discontinuation of the medicine

In clinical studies not associated with arthritis (inflammation of the joints) or other arthritic conditions, where celecoxib was taken at doses of 400 mg per day for up to 3 years, the following additional side effects have been observed:

Common (may affect up to 1 in 10 people):

- heart problems: angina pectoris (chest pain);

- stomach problems: irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion and wind)
- kidney stones (which may lead to stomach or back pain, blood in urine), difficulty passing urine
- weight gain.

Uncommon (may affect up to 1 in 100 people):

- Deep vein thrombosis (blood clot usually in the leg, which may cause pain, swelling or redness of the calf or breathing problems)
- Stomach problems: stomach infection (which can cause irritation and ulcers of the stomach and intestines)
- Lower limb fracture
- Shingles, skin infection, eczema (dry itchy rash), pneumonia (chest infection (possible cough, fever, difficulty breathing))
- Floaters in the eye causing blurred or impaired vision, vertigo due to inner ear troubles, sore, inflamed or bleeding gums, mouth sores
- Excessive urination at night, bleeding from piles/haemorrhoids, frequent bowel movements
- Fatty lumps in skin or elsewhere, ganglion cyst (harmless swellings on or around joints and tendons in the hand or foot), difficulty speaking, abnormal or very heavy bleeding from the vagina, breast pain
- High levels of sodium in blood test results

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Celecoxib

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label, the blister and the outer carton after "EXP". The expiry date refers to the last day of that month.

ALU/ALU-blister

This medicinal product does not require any special storage conditions.

PVC/PVDC/ALU-blister

Do not store above 30 °C.

Tablet container

This medicinal product does not require any special storage conditions.

Shelf life after first opening: 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Celecoxib 100 mg Capsules, Hard contain

- The active substance is celecoxib. Each capsule contains 100 mg celecoxib.
- The other ingredients are: calcium hydrogen phosphate dihydrate, sodium laurilsulfate, crospovidone (type B), povidone (K30), povidone (K90), magnesium stearate, gelatine, shellac, propylene glycol, purified water, titanium dioxide (E171), indigo carmine aluminium lake (E132).

What Celecoxib 200 mg Capsules, Hard contain

- The active substance is celecoxib. Each capsule contains 200 mg celecoxib.
- The other ingredients are: calcium hydrogen phosphate dihydrate, sodium laurilsulfate, crospovidone (type B), povidone (K30), povidone (K90), magnesium stearate, gelatine, shellac, propylene glycol, purified water, titanium dioxide (E171), yellow iron oxide (E172).

What Celecoxib Capsules look like and contents of the pack

Celecoxib 100 mg Capsules, Hard are white, opaque hard gelatine capsules with a blue imprint "100".

Celecoxib 200 mg Capsules, Hard are white, opaque hard gelatine capsules with a yellow imprint "200".

Celecoxib 100 mg Capsules are available in packs of 5, 10, 20, 30, 50, 60, 90 and 100 capsules, hard in blisters, 50 x 1 and 60 x 1 capsules, hard in perforated unit dose blisters and 100 capsules, hard in tablet container.

Celecoxib 200 mg Capsules are available in packs of 5, 10, 20, 30, 50, 60, 90 and 100 capsules, hard in blisters, 30 x 1 and 50 x 1 capsules, hard in perforated unit dose blisters and 100 capsules, hard in tablet container.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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