

Package leaflet: Information for the user

Celecoxib 100 mg capsules, hard
Celecoxib 200 mg capsules, hard
Celecoxib

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 is used for the relief of signs and symptoms of **rheumatoid arthritis, osteoarthritis and ankylosing spondylitis** (long-term disease arthritis that affects spine).

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 produces a substance 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 prostaglandins, 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 "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 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 **problems with your heart**, such as 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.

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).
- 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 may want to keep a regular check on you.

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.

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 (see section on Pregnancy and breast-feeding).

Other medicines and Celecoxib

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

In particular tell your doctor or pharmacist if you are taking:

- Dextromethorphan (used to treat coughs)
- ACE inhibitors or angiotensin II antagonists (used for high blood pressure and heart failure)
- Diuretics (used to treat excess fluid in the body)
- Fluconazole 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)
- 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 doses** of acetylsalicylic acid (75 mg or less daily). Ask your doctor for advice before taking both medicines together.

Pregnancy and breast-feeding

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.

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.

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

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.

Celecoxib contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Only for Celecoxib 100 mg:
Celecoxib contains Azorubine (E 122)
May cause allergic reactions.

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.

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.

Celecoxib 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 Celecoxib at the same time each day.

If you do not experience any benefits, contact your doctor **within two weeks** of starting treatment.

The recommended dose for osteoarthritis

- The usual dose is **200 mg each day**.
- The usual dose can be taken as one 200 mg capsule once a day, or one 100 mg capsule, twice a day.

Your doctor may increase the dose to a **maximum of 400 mg**, if needed.

The recommended dose for rheumatoid arthritis

- The usual dose is **200 mg each day**.
- The usual dose can be taken as one 100 mg capsule, twice a day

Your doctor may increase the dose to a **maximum of 400 mg**, if needed.

The recommended dose for ankylosing spondylitis

- The usual dose is **200 mg each day**.
- The usual dose can be taken as one 200 mg capsule once a day, or one 100 mg capsule, twice a day.

Your doctor may increase the dose to a **maximum of 400 mg**, if needed.

Patients with liver or kidney problems

Make sure 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 especially if you weigh **less than 50 kg**, your doctor may want to monitor you more closely.

Use in Children and adolescents

Celecoxib is for adults only, it is not for use in children

If you take more Celecoxib than you should

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

If you forget to take Celecoxib

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

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 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.

If any of the following happens, stop taking Celecoxib and tell your doctor immediately:

- 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 (may affect more than 1 in 10 people):

- 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*
- Worsening of existing allergies

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

- Stroke*
- Heart failure, palpitations (irregular heart beat), fast heart rate
- Worsening of existing high blood pressure
- 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)

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 gullet (can cause difficulty in swallowing), inflammation of the pancreas (can lead to stomach pain)
- Reduced number of white blood cells (which help protect the body from infection) and 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

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

- Bleeding within the brain, causing death
- Serious allergic reactions (including potentially fatal anaphylactic shock) which can cause skin rash, swelling of the face, lips, mouth, tongue or throat, wheezing or difficulty breathing; difficulty swallowing
- Bleeding of the stomach or intestines (can lead to bloody stools or vomiting), inflammation of the intestine or colon, nausea (feeling sick)
- 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 (red swollen area with numerous small pustules)
- Liver failure, liver damage and severe liver inflammation (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
- Kidney problems (possible kidney failure, inflammation of the kidneys)
- Blood clot in the blood vessels in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse
- Irregular heartbeat
- Meningitis (inflammation of the membrane around the brain and spinal cord)
- Hallucinations
- Worsening of epilepsy (possible more frequent and/or severe seizures)
- Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
- Blockage of an artery or vein in the eye leading to partial or complete loss of vision, inflammation of the conjunctiva, bleeding in the eye
- 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)
- Chest pain
- Impaired sense of smell
- Skin discolouration (bruising), muscle pain and weakness, painful joints
- Menstrual disturbances
- Headache, flushing
- Low levels of sodium in blood test results (can cause loss of appetite, headache, nausea (feeling sick), muscle cramps and weakness)

In clinical studies not associated with arthritis 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 (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

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 with coughing, 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 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 sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/blister/bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

HDPE bottle:

The shelf life after first opening the bottle is 90 days.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Celecoxib contains

- The active substance is: celecoxib.
Celecoxib 100 mg capsules, hard
Each capsule, hard contains 100 mg celecoxib.
Celecoxib 200 mg capsules, hard
Each capsule, hard contains 200 mg celecoxib.
- The other ingredients are:
Capsule content
Lactose monohydrate, povidone K 30, croscarmellose sodium, sodium lauryl sulphate, magnesium stearate
Capsule shell
Gelatin, sodium lauryl sulphate, titanium dioxide (E 171)
Additional colorants in Celecoxib 100 mg:
Azorubine (E 122)
Patent Blue V (E 131)
Additional colorant in Celecoxib 200 mg:
Iron oxide yellow (E 172)
Imprinting
Shellac, iron oxide black (E 172), potassium hydroxide.

What Celecoxib looks like and contents of the pack

Celecoxib 100 mg
Celecoxib 100 mg are opaque blue coloured, size "3" hard gelatine capsules, imprinted with black ink with "1308" on the cap and "100" on the body, containing white to off white granular powder.

Celecoxib 200 mg
Celecoxib 200 mg are opaque yellow coloured, size "1" hard gelatine capsules, imprinted with black ink with "1309" on the cap and "200" on the body, containing white to off white granular powder.

Celecoxib comes in blister packs containing 10, 20, 30, 40, 50, 60, 100 and 200 capsules and in HDPE containers with 10, 30, 50, 90 and 500 (hospital pack, for use on more than one patient) capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names

Germany	Celecoxib Heumann 100 mg / 200 mg Hartkapseln
Lithuania	Celecoxib Torrent 100 mg / 200 mg kietosios kapsules
Romania	Celeto 100 mg / 200 mg capsula
United Kingdom	Celecoxib 100 mg / 200 mg capsules, hard

This leaflet was last revised in 12/2013.

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:
SIZE : 160 x 700 mm_ Front/Back Side	CODE : 8038830-7803	DATE : 17-12-2013
REMARK : Folding Length 35 mm		
SUBSTRATE :		
Activities	Department	Name
Prepared By	Pkg.Dev	Signature
Reviewed By	Pkg.Dev	Date
Reviewed By	RA	
Approved By	COA	

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

Colour Black



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