

- Liver problems (such as cholelithiasis and cholestatic hepatitis, which may be accompanied by symptoms such as diarrhoea, stools, nausea and yellowing of the skin or eyes)
- Inflammation of kidneys and other kidney problems (such as nephritic syndrome and minimal change disease, which may be accompanied by symptoms such as water retention (oedema), heavy urine, fatigue and loss of appetite)
- Worsening of kidney disease (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. Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
- An infection in the mouth (dried and white blood cells and plaques) may cause tooth, early brushing, frequent nose bleeds and increased risk of infections)
- Muscle pain and weakness
- Impaired sense of smell
- Loss of hair

Decreased fertility: frequency cannot be estimated from the available data

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

- Heart problems: angina (chest pain)
- Stomach problem: irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind)
- Kidney stone (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))
- Flares 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
- Fungy lumps in skin or elsewhere, scaly/itchy (thames) swelling 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 tests/urine

Reporting of side effects

If you get any side effects that you think your doctor or pharmacist, this includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

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 blister and carton after EXP. The expiry date relates to the last day of that month.

This medicine does not require any special storage conditions.

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.

What Celecoxib Capsules contain

The active substance in Celecoxib.

Each capsule contains either 100 mg or 200 mg Celecoxib.

The other ingredients are:

Capsule 100 mg contains: Lactose Monohydrate, Croscarmellose sodium, Povidone K-30, Sodium lauryl sulfate, Magnesium Stearate.

Capsule 200 mg contains: Titanium Dioxide E171 and Gelatin.

Printing ink contains: Shellac, Polyethylene glycol, Black iron oxide E 172 and Potassium hydroxide.

What Celecoxib Capsules look like and contents of the pack

Celecoxib 100 mg capsule: hard.

White opaque / White capsules, size 1" hard gelatin capsule printed with "M" on cap and "12" on the body filled with white or off-white granular powder.

Celecoxib 200 mg capsule: hard.

White opaque / White capsules, size 1" hard gelatin capsule printed with "M" on cap and "13" on the body filled with white or off-white granular powder.

Celecoxib Capsules are packaged in Clear PVC/PVC/Aluminium foil blister pack containing 10, 20, 30, 40, 50, 100, 120, 150, 180, 240, 300, 360, 450, 540, 630, 720, 810, 900, 1080, 1260, 1440, 1620, 1800 capsules.

Marketing Authorisation Holder and Manufacturer:

Brown & Burck UK Ltd
5, Maryon Close
Hemel Hempstead
Herts
TK9 2DQ
United Kingdom

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

PT: Celecoxib Brown, 100mg & 200mg Capsula
UK: Celecoxib 100 mg & 200 mg capsules, hard
DE: Celecoxib-Micro-Las 100 mg & 200 mg Hartkapseln
FR: Celecoxib Brown & Burck 100mg & 200 mg, gélule

This leaflet was last revised in October 2016

Package leaflet: information for the user

Celecoxib 100 mg capsule, hard

Celecoxib 200 mg capsule, 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.

These capsules are available in multiple strengths will be referred to as Celecoxib throughout this leaflet.

What is 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 100 mg and 200 mg capsules belongs to a group of medicinal products called non-steroidal anti-inflammatory drugs (NSAIDs), and specifically is a subgroup 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.

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

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.

2. What you need to know before you take Celecoxib

You have been prescribed Celecoxib by your doctor. The following information will help you get the best results with Celecoxib. If you have any further questions, ask your doctor or pharmacist.

Do not take Celecoxib

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 (hypersensitive) to celecoxib or any of the other ingredients of Celecoxib capsules (See section 4).
- If you have had an allergic reaction to a group of medicines called "sulphonamides" (e.g. some antibiotics used for infections).
- If you currently have ulcers 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 Crohn's disease or Colitis ulcerosa.
- 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 in 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 using 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 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, heparin, like anti-thrombotic or novel oral anti-clotting medicines, e.g. apixaban).
- If you use medicines to reduce inflammation (e.g. prednisone).
- If you are using Celecoxib at the same time as other non-steroidal anti-inflammatory drugs such as ibuprofen or diclofenac. The effect of these medicines together should be avoided.
- If you smoke, have diabetes, raised blood pressure or raised cholesterol.
- If you have heart failure, you are taking any diuretic or you may wish to keep a regular check on you.
- If you have fluid retention (such as swollen ankles and feet).
- If you are dehydrated, for example 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 medication.
- If you feel ill due to an infection or think you have an infection, 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 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 using, have recently used or might use any other medicines:

- Diuretics (water pills) (used to treat cough)
- ACE inhibitors, angiotensin II antagonists, beta blockers and diuretics (used for high blood pressure and heart failure)
- Fluorazole and rifampin (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)
- Clozapine and thioridazine (used for various types of schizophrenia, e.g. after transplant).

Celecoxib can be taken with low dose acetylsalicylic acid (75mg or less daily). Ask your doctor for advice 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.

Contraception

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.

Celecoxib Capsules contains lactose

Celecoxib Capsules contains lactose monohydrate (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Celecoxib

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.

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.

Method of administration

Celecoxib is for oral use. The capsules can be taken at any time of the day, with or without food. However, to take each dose of Celecoxib at the same time each day.

If you have difficulty swallowing capsules. The entire capsule contents can be sprinkled onto a level teaspoon of same-solid food (such as cool or room temperature apple sauce, rice gruel, yogurt or mashed banana) and swallowed immediately with drink approximately 30 ml of water.

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 with any weakness or starting treatment if you do not experience any benefit.

The recommended doses:

For osteoarthritis: the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

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

For rheumatoid arthritis: the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

- one 100 mg capsule twice a day.

For ankylosing spondylitis: the recommended dose is 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.

The dose is usually:

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

Kidney or liver problems: make sure your doctor knows if you have liver or kidney problems as you may need a lower dose.

The elderly especially those with a weight less than 60 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.

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 your doctor, pharmacist or hospital and/or your medicine with you.

If you forget to take Celecoxib

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

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 to stop taking 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 crown polyps. Patients in these studies took Celecoxib at high doses and for a long duration.

Many 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
- low urine (symptoms may include nausea (feeling sick), diarrhoea, jaundice (yellow skin or the whites of your eyes too yellow))

Other side effects:

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

- Heartburn
- 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, cough, cold, flu-like symptoms
- Dizziness, difficulty seeing
- 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

- Stomach pain
- Heart failure, palpitations (awareness of heartbeat), 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 "muscle feeling sick", fatigue, muscle weakness or palpitations)
- Impaired or blurred vision, ringing in the ears, mouth pain and some difficulty hearing
- Constipation, burning, stomach inflammation (indigestion, stomach ache or vomiting), worsening of inflammation of the stomach/intestine
- Leg cramps
- Reduced body pain relief
- Eye inflammation
- Difficulty breathing
- Skin discoloration (bruising)
- Chest pain (generalized pain not related to the heart)
- Pain in mouth

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

- Ulcers (bleeding) in the stomach, gut or intestine; or rupture of the intestine (can cause stomach ache, fever, nausea, vomiting, indigestion, bloating, dark or black stools, inflammation of the gut)
- Meningitis (inflammation of the meninges (can lead to stomach pain))
- Low levels of sodium in the blood (a condition known as hyponatraemia)
- Reduced number of white blood cells (which help protect the body from infection) and blood platelets (increased chance of bleeding or bruising)
- Difficulty coordinating muscle movements
- Frequent confusion, changes in how things may taste
- Increased sensitivity to light
- Loss of hair
- Hallucinations
- Swelling of face
- Acute reaction that may lead to lung inflammation
- Irritable heart beat
- Flushing
- Blood test of the breath or collapse in the lungs. Symptoms may include sudden breathlessness, sharp pains when you breathe or wheeze
- Swelling of the stomach/intestines (can lead to bloody stools and vomiting), inflammation of intestine or colon
- Severe liver inflammation (hepatitis). Symptoms may include nausea (feeling sick), diarrhea, jaundice, (yellow discoloration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills
- Acute kidney failure
- Mental 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 generalized exanthematous pustular eruption (includes 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 leucopenia, a type of severe 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 discoloration of the skin or eyes), dark urine, pale stools, bleeding easily, itching or chills