Celecoxib
100 mg / 200 mg
capsules, hard
ARTWORK CODE 08

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

1. What Celecoxib capsules is and what it is used for

Celecoxib capsules belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAID), and specifically a sub-group known as cyclooxygenase-2 (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 capsules acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

Celecoxib capsules is used in adults for the relief of signs and symptoms of **rheumatoid arthritis, osteoarthritis 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 capsules

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

Do not take Celecoxib capsules

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

- 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 (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 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 capsules:

- if you have **previously** had an ulcer or bleeding in your stomach or intestines.
  (Do not take Celecoxib capsules 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 are taking antiplatelet therapies
- 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 capsules 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 capsules 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.

Serious skin reactions have been reported in association with celecoxib treatment. Stop using celecoxib and seek medical attention immediately if you notice any of the symptoms of serious skin reactions described in section 4, Possible side effects.

Celecoxib capsules 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 capsules

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 or 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 capsules can be taken with low dose acetylsalicylic acid (75 mg 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.

Pregnancy

Celecoxib capsules 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 capsules you should discontinue the treatment and contact your doctor for alternative treatment.

Breast-feeding

Celecoxib capsules must not be used during breast-feeding.

Fertility

NSAIDs, including Celecoxib capsules, 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 capsules before you drive or operate machinery. If you feel dizzy or drowsy after taking Celecoxib capsules, do not drive or operate machinery until these effects wear off.

Celecoxib capsules contains lactose

Celecoxib capsules contains **lactose** (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.

Celecoxib capsules contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Celecoxib capsules

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 capsules 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 capsules for longer than necessary to control symptoms.

Method of administration

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

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 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 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 capsules is for adults only, it is not for use in children.

If you take more Celecoxib capsules 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 take your medicine with you.

If you forget to take Celecoxib capsules

If you forget to take a capsule, 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 capsules

Suddenly stopping your treatment with Celecoxib capsules may lead to your symptoms getting worse. Do not stop taking Celecoxib capsules 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 capsules. Side effects marked with an asterisk (*) are listed below at the higher frequencies that occurred in patients who took Celecoxib capsules to prevent colon polyps. Patients in these studies took Celecoxib capsules at high doses and for a long duration.

If any of the following happen, stop taking Celecoxib capsules 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: 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 Other serious skin conditions such as fixed drug eruption (a distinctive cutaneous allergic reaction that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching) and generalised bullous fixed drug eruption (can involve widespread skin reactions)

In clinical studies not associated with arthritis or other arthritic conditions, where Celecoxib capsules 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 (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 Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Celecoxib capsules

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. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 capsules contain

The active substance is celecoxib.
Each capsule contains 100 mg or 200 mg celecoxib.

The other ingredients are:
Lactose anhydrous, Hydroxypropyl cellulose, Crospovidone, Povidone, Sodium lauril sulfate, Magnesium stearate. Capsule shells contain: Titanium dioxide E171, Gelatin, Sodium lauril sulfate. Printing ink contains Shellac, Propylene glycol, Strong ammonia solution, FD & C blue 2 Aluminum lake E132 (100mg capsules) and Yellow iron oxide E172 (200mg capsules).

What Celecoxib capsules looks like and contents of the pack

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

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

"The capsules are packaged in clear PVC/PVdC/ aluminium blisters and are presented in packs of 20, 30, 40, 50, 60, 100 capsules (100mg dosage strength) and 10, 20, 30, 50, 100 capsules (200mg dosage strength)".

Not all pack sizes may be marketed.

MACLEODS

Marketing Authorisation Holder and Manufacturer
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Wynyard Park House,
Wynyard Avenue,
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PL 34771/0166-0167

This leaflet was last revised in {06/2026}

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Celecoxib 100 mg capsules, hard
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- 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.
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What is in this leaflet:

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1. What Celecoxib capsules is and what it is used for

Celecoxib capsules belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAID), and specifically a sub-group known as cyclooxygenase-2 (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 capsules acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

Celecoxib capsules is used in adults for the relief of signs and symptoms of **rheumatoid arthritis, osteoarthritis 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 capsules

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

Do not take Celecoxib capsules
Tell your doctor if any of the following are true for you as patients with these conditions should not take Celecoxib capsules:

- 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 (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 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 capsules:

- if you have **previously** had an ulcer or bleeding in your stomach or intestines.
  (Do not take Celecoxib capsules 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 are taking antiplatelet therapies
- 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 capsules 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 capsules 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.

Serious skin reactions have been reported in association with celecoxib treatment. Stop using celecoxib and seek medical attention immediately if you notice any of the symptoms of serious skin reactions described in section 4, Possible side effects.

Celecoxib capsules 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).

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

- Dextromethorphan (used to treat coughs)
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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 capsules 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 capsules you should discontinue the treatment and contact your doctor for alternative treatment.

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Celecoxib capsules must not be used during breast-feeding.

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Celecoxib capsules contains **lactose** (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.

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This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

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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 capsules for longer than necessary to control symptoms.

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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 200 mg each day, increased by your doctor to a maximum of 400 mg, if needed.
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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 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 capsules is for adults only, it is not for use in children.

If you take more Celecoxib capsules 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 take your medicine with you.

If you forget to take Celecoxib capsules
If you forget to take a capsule, 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 capsules
Suddenly stopping your treatment with Celecoxib capsules may lead to your symptoms getting worse. Do not stop taking Celecoxib capsules 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 capsules. Side effects marked with an asterisk (*) are listed below at the higher frequencies that occurred in patients who took Celecoxib capsules to prevent colon polyps. Patients in these studies took Celecoxib capsules at high doses and for a long duration.

If any of the following happen, stop taking Celecoxib capsules 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: 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 Other serious skin conditions such as fixed drug eruption (a distinctive cutaneous allergic reaction that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching) and generalised bullous fixed drug eruption (can involve widespread skin reactions)

In clinical studies not associated with arthritis or other arthritic conditions, where Celecoxib capsules 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 (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 Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Celecoxib capsules

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. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 capsules contain

The active substance is celecoxib.
Each capsule contains 100 mg or 200 mg celecoxib.

The other ingredients are:
Lactose anhydrous, Hydroxypropyl cellulose, Crospovidone, Povidone, Sodium lauril sulfate, Magnesium stearate. Capsule shells contain: Titanium dioxide E171, Gelatin, Sodium lauril sulfate. Printing ink contains Shellac, Propylene glycol, Strong ammonia solution, FD & C blue 2 Aluminum lake E132 (100mg capsules) and Yellow iron oxide E172 (200mg capsules).

What Celecoxib capsules looks like and contents of the pack

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

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

"The capsules are packaged in clear PVC/PVdC/ aluminium blisters and are presented in packs of 20, 30, 40, 50, 60, 100 capsules (100mg dosage strength) and 10, 20, 30, 50, 100 capsules (200mg dosage strength)".

Not all pack sizes may be marketed.

MACLEODS

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