Celecoxib 100 mg capsules

Celecoxib 200 mg capsules

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, talk to 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.

1. WHAT CELECOXIB CAPSULES ARE AND WHAT IS IT USED FOR

The name of your medicine is Celecoxib 100 mg and 200 mg Capsules (called celecoxib capsules throughout this leaflet). Celecoxib capsules are used for the relief of signs and symptoms of osteoarthritis and ankylosing spondylitis in adults.

Celecoxib belongs to a group of medicinal products called nonsteroidal anti-inflammatory drugs (NSAIDs).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CELECOXIB CAPSULES

You have been prescribed celecoxib capsules by your doctor. The following sections 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

- if you are allergic to celecoxib or any of the other ingredients of this medicine (listed in section 6.1 Ingredients).
- if you have had an allergic reaction to a group of medicines called "salicylates" (e.g. some antibiotics used to treat infections).
- if you have allergy to any component of celecoxib capsules, or 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 constipation or symptoms of itchy skin rash, swollen of the face, lips, tongue or throat, breathing difficulty or anaphylactic shock.
- if you are pregnant. If you can become pregnant, use an effective method of contraception before starting celecoxib capsules (see section 4). However, if you have been prescribed celecoxib capsules you should discontinue the treatment and consult your doctor.
- if you have severe kidney disease.
- if you have an inflammatory disease of the intestine such as Crohn’s disease or ulcerative colitis.
- if you have had heart failure, established serious heart disease, or have symptoms of heart failure.
- if you have been diagnosed with a heart attack, stroke, or transient ischaemic attack (TIA).
- if you are receiving treatment with blood thinner such as warfarin to reduce blood flow to the brain; also known as “metal stents”, angioplasty, or blockage of your heart.
- if you have or had problems with blood circulation (peripheral arterial disease) or if you have had surgery or leg procedures.

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 intestines.)

- if you are taking acetylsalicylic acid (at least low dose for heart protective purposes).

- if you use medicines to reduce blood clotting (e.g. warfarin).

- if you are taking celecoxib capsules at the same time as other non-steroidal anti-inflammatory drugs such as diclofenac or ibuprofen. These medicines should not be taken together.

- if you smoke, hyper tension, raised blood pressure or raised cholesterol.

- if your heart, liver or kidney is not working well, your doctor may want to keep a regular check on you.

- if you have had a severe 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 during treatment.

- if you are over 65 years of age your doctor may want to keep a regular check on you.

- if you have had an intolerance to some sugars, contact your doctor (see section 6.4 Special precautions for use).

- Celecoxib 100mg and 200mg Capsules contain 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 for alternative treatment.

- if you have an allergy to milk, milk derivatives, soya, soya derivatives, or egg protein, ask your doctor or pharmacist for advice before taking this medicinal product.

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 that you feel the effect of celecoxib capsules is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you what dose to take. As the risk of side effects associated with heart problems may increase with dose and duration of use it is important that you use the lowest dose that controls your pain and you should not increase the dose for longer than necessary to control symptoms.

Celecoxib capsules 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 celecoxib capsule at the same time each day.

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

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

Dosage may need to be reduced in the elderly especially those with a weight less than 50 kg (e.g. over 65 years of age) or if you weigh less than 50 kg, by your doctor.

3.3 The usual dose

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

4. POSSIBLE SIDE EFFECTS

4.1 How should you deal with side effects

- 2. 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.

4.2 Possible side effects

- 1. How to take celecoxib capsules

- 6. Contents of the pack and other information

Some cases of severe liver reactions, including serious liver disease (e.g. liver failure, liver liver, liver failure with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that have reported to time onset, most severe liver reactions occurred within one month of start of treatment with celecoxib.

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 becoming pregnant. You should inform your doctor on Pregnancy, breast-feeding and fertility.

Other medicines and celecoxib capsules

Tell your doctor or pharmacist if you are taking, have recently taken or think you may take any medicines that interact with celecoxib capsules.

- ACE inhibitors or angiotensin II antagonists (used for blood pressure or heart failure).

- Diuretics (used to treat excess fluid in the body).

- Some antibiotics (e.g. macrolides that reduce blood clotting).

- Warfarin (used to prevent blood clots in the body).

- Some of the things you should think about include:

- You have been prescribed celecoxib capsules by a doctor or pharmacist.

- If you have any further questions please ask your doctor or pharmacist.

- This includes any possible side effects not listed in this leaflet. See section 4.

- Talk to your doctor or pharmacist before taking celecoxib capsules

- If you are taking, have problems becoming pregnant.

- Ask your doctor or pharmacist for alternative treatment.

- If you have any further questions, ask your doctor or pharmacist.

- The following information will help you understand your pain and you should not take celecoxib capsules

- You have been prescribed celecoxib capsules by a doctor or pharmacist.

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Celecoxib 100 mg capsules are opaque hard gelatin size contents of the pack. What Celecoxib 100mg and 200mg Capsules looks like and contains. Polyols (sorbitol, mannitol, glycerol), maize starch, hypromellose, yellow iron oxide (E172). Imprinting ink contains shellac, shellac, propylene glycol, strong ammonia solution (E527), 100 mg or 200 mg of celecoxib.

Do not use this medicine after the expiry date which is stated on the pack. Keep this medicine out of the sight and reach of children. Protect from moisture. Store below 30 °C. Store in the original package in order to protect the environment. Do not throw away any medicines via wastewater or solids of that month.

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

• Severe liver inflammation (hepatitis). Symptoms may include sudden breathlessness, sharp pains when you may cause pain, swelling or redness of the calf or breathing problems. Fatigue, weakness, muscle weakness or pain, difficulty hearing*

• High levels of potassium in blood test results (can cause muscle weakness, tingling, numbness, weakness, changes in blood tests (e.g. liver, blood cell (eosinophilia, a increased discharge of blood from the nose)

• Increase sensitivity to light

• Feeling confused, changes in the way things taste

• Low levels of sodium in the blood (a condition known as hyponatraemia)

• Rash, itching

• Dizziness, difficulty sleeping

• Hair loss

• Blocked or runny nose

• Headache

• Muscle stiffness

• Rash, itching

• Dizziness, difficulty sleeping

• Heart attack*

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

• Swollen areas covered in numerous small pustules)

• Exfoliative dermatitis, toxic epidermal necrolysis, erythema

• Breast pain

• Bleeding within the brain causing death

• Meningitis (inflammation of the membrane around the brain and spinal cord)

• Immune-mediated haemolytic anaemia

• Inflammatory bowel disease (sometimes fatal or requiring long-term treatment).

• Significant increases in liver enzymes (may be accompanied by symptoms such as symptoms (pins and needles)

• Angina, depression, tiredness, drowsiness, tingling

• Skin infections, abscesses, boils

• Worsening of epilepsy more frequent and/or severe

• Blockage of an artery or vein in the eye leading to partial or complete loss of vision

• Fatty lumps in skin or elsewhere, ganglion cyst (harmless swelling of the face, lips, mouth or throat, or difficulty swallowing)

• Swelling of the face, lips, mouth or throat

• Menstrual disturbances

• Fluid retention

• Thickening of the lining of blood vessels

• Anemia (changes in red blood cells that can cause fatigue and weakness)

• Anaemia, shortness of breath, fatigue, dizziness, pale skin, feeling cold, heart rate

• Low blood pressure*

• Serious allergic reactions (including potentially fatal anaphylaxis)

• Skin conditions such as Stevens-Johnson syndrome, with blisters, sloughing of the skin, and severe skin rashes

• Malignancy

• Mucosal bleeding

• Worsening of epilepsy

• High levels of sodium in blood test results

• Nausea (feeling sick), diarrhoea, jaundice (yellow discolouration of the skin or eyes), dark urine, pale stools, blooding easily, itching or chills.

• Acute kidney injury

• Worsening of existing of high blood pressure or stroke

• Diabetes, glucose intolerance, impaired glucose tolerance

• Fever, aches, purple blotches

• A reduction in the number of red and white blood cells and platelets, bleeding, easy bruising, frequent nose bleeds and increased risk of infections

• Migraine headaches

• Impaired sense of taste

• Impaired sense of taste

• Unusual bleeding

• Changes in how you feel, such as feeling unusually tired or cold

• Progression of Raynaud’s disease

• Benign prostatic hyperplasia (enlargement of the prostate

• Swollen lymph glands

• Excessive haemorrhoids

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