

PATIENT PACKAGE INSERT IN
ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986
This medicine is dispensed with a doctor's
prescription only

Celcox 100 mg Celcox 200 mg Capsules

Composition:
Celcox 100 mg: each capsule contains:

Celecoxib 100 mg

Celcox 200 mg: each capsule contains:

Celecoxib 200 mg

Inactive ingredients in the preparation - see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for adults above the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?
Treatment of the symptoms of inflammation and pain caused by osteoarthritis and rheumatoid arthritis.

Therapeutic group: A subgroup of nonsteroidal anti-inflammatory drugs (NSAIDs): COX-2 inhibitors (cyclooxygenase 2 inhibitors).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are pregnant or breastfeeding.
- You are sensitive (allergic) to the active ingredient Celecoxib, or to any of the other ingredients contained in the medicine (see section 6: "Further information") or to sulfonamides (an antibiotic to treat infections).
- You developed asthma, a rash or other sensitivity after taking aspirin or other nonsteroidal anti-inflammatory preparation, including other specific inhibitors of the COX-2 enzyme.
- You are suffering from a severe problem with liver or kidney function.
- You are suffering from active gastrointestinal bleeding (e.g., ulcer).
- You are suffering, or have suffered in the past, from ischemic heart disease or from any other heart disease, from stroke of any kind in the heart or brain (including mini-stroke in the brain).
- You are due to undergo or underwent coronary bypass surgery.

- You are suffering, or have suffered in the past, from blood circulation problems – peripheral artery disease.
- You are suffering from inflammatory bowel disease (e.g., Crohn's or colitis).

Do not use this medicine without consulting a doctor before starting treatment if:

- you are planning to become pregnant, or you do not use contraceptives.
- you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the liver, the kidneys/urinary system, blood vessels or the blood system (e.g., anemia, coagulation, etc.).
- you have suffered in the past from gastrointestinal impairment (e.g., ulcer or gastrointestinal bleeding).
- you have risk factors for heart disease, such as: hypertension, hyperlipidemia (high level of cholesterol and/or lipids in the blood), diabetes, smoking.
- you are suffering from edema (e.g., swelling of the legs and ankles).
- you are taking blood thinners or aspirin.
- you are dehydrated (due to illness, diarrhea or use of diuretics).
- you are sick or think you are suffering from an infection, since Celcox may mask the effects of fever or effects that indicate an infection and inflammation.

Special warnings regarding use of the medicine

- Your doctor will want to discuss the treatment periodically.
- It is important that you use the lowest dose that controls your pain and not take Celcox for longer than needed, because the risk of heart attack and stroke may increase after prolonged treatment, especially with high dosages.
- Celcox may raise blood pressure in some people. Your doctor will want to check your blood pressure periodically in order to ascertain that continuation of treatment is safe for you.
- Celcox may increase the risk of developing ulcers in the digestive system, especially in elderly patients. In long-term treatment, periodic blood tests should be performed.
- Celcox is not a substitute for aspirin (acetylsalicylic acid), it does not thin the blood and does not prevent platelet aggregation (formation of small blood clots); therefore, do not stop taking low-dosage aspirin without consulting a doctor.
- However, you should be aware that the risk of developing stomach ulcers is greater if you take aspirin in combination with Celcox and that you should not take additional anti-inflammatory medicines or higher dosages of aspirin while you are taking Celcox.
- Do not stop taking steroids or antibiotics without consulting a doctor, even if signs of infection or inflammation may improve.
- In order to reduce the risk of cardiovascular side effects (related to the heart and/or blood vessels), the doctor will determine for you the lowest effective dosage for the shortest period of time.

Patients above 65 years old who weigh less than 50 kg will be treated with the lowest recommended starting dosage.

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Cases of severe hepatic side effects have been reported, most of which occurred within one month of initiation of treatment with Celecoxib, including: hepatitis, liver damage and liver failure that sometimes required liver transplantation or caused death.

If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking the following medicines:

- Warfarin or other blood thinners – monitoring of anticoagulant activity should be performed.
- Aspirin and salicylates – see "Special warnings regarding use of the medicine".
- Medicines for reducing blood pressure, ACE inhibitors or angiotensin II antagonists, diuretics (thiazides and furosemide) – since the combination impairs the effectiveness of these medicines.
- Lithium, other antidepressants, medicines to treat sleep disturbances, medicines to treat irregular heart rate, dextromethorphan (for cough), neuroleptic medicines (to treat mental disorders) – since the combination increases their concentration in the blood.
- Fluconazole (to treat fungi) – since the combination increases the concentration of Celcox in the blood.
- Rifampicin (antibiotics), carbamazepine, barbiturates (to treat epilepsy) – since the combination lowers the concentration of Celcox in the blood.

Celcox may raise blood pressure in some people. Your doctor will want to check your blood pressure periodically in order to ascertain that continuation of treatment is safe for you.

- Other anti-inflammatories from the NSAID group – greater risk of side effects, especially in the digestive system.
- Methotrexate (to treat rheumatoid arthritis, psoriasis and leukemia), cyclosporine and tacrolimus (to depress the immune system, for example, after transplants), monitoring of the patient for possible toxicity of these medicines should be performed.

Use of the medicine and food

Can be taken with or without a meal.

Pregnancy and breastfeeding

Do not use if you are pregnant or if there is a chance you will become pregnant (e.g., if you are not using contraceptives).

If you become pregnant during the course of treatment with the medicine, stop treatment and refer to a doctor for alternative treatment.

Do not use the preparation when breastfeeding.

Fertility

Medicines of the NSAID group, including Celcox, may make it difficult to become pregnant (reversible). Consult the doctor if you are trying to become pregnant.

Driving and operating machinery after taking Celcox

If you feel dizzy or tired after taking the medicine, avoid driving and operating dangerous machinery until these effects pass.

Important information regarding some of the ingredients of the medicine

The medicine contains lactose.
If you have been told by a doctor that you are suffering from sensitivity to certain sugars, consult a doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

This medicine is intended for adults above the age of 18.

The doctor should determine for you the lowest effective dose for the shortest period of time, to reduce the risk of cardiac side effects.

Usual dosage unless otherwise instructed by a doctor:

Osteoarthritis: 200 mg, once daily, or 100 mg twice daily (100 mg in the morning and 100 mg in the evening), and in any case, no more than 400 mg per day.

Rheumatoid arthritis: 100-200 mg twice daily, and in any case, no more than 400 mg per day.

Do not exceed the recommended dose.

Swallow the medicine with a glass of water. There is no information regarding opening and dispersing the contents of the capsule.

Refer to a doctor two weeks after starting treatment if you do not feel any improvement in your health.

Tests and Follow-up

During the course of treatment, blood pressure and periodic blood tests (including kidney and liver function) should be performed.

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the dose, take it as soon as you remember, but never take a double dose. Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor, as abrupt discontinuation of treatment may cause exacerbation of the symptoms from which you are suffering. The doctor may instruct you to lower the dosage before stopping treatment.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Celcox may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop treatment and refer to a doctor immediately in the event of:

- Severe allergic symptoms: shortness of breath or difficulty breathing, swelling or edemas of the face, lips, throat, legs and/or hands, rash or blisters or skin irritation, eosinophilia.
- Symptoms that can indicate heart problems, such as pains/angina, arrhythmias, palpitations, rapid heart rate, hypertension, heart failure, myocardial infarction.

- Severe abdominal pains, gastrointestinal discomfort (e.g., dyspepsia, heartburn), gastrointestinal bleeding, black or bloody stool, vomiting blood.
- Symptoms that may indicate liver damage (e.g., nausea, fatigue, vomiting, itching, yellowing of the skin or eyes, increase in liver enzymes, right upper abdominal sensitivity), jaundice, liver necrosis, fatty tumor, liver failure, liver damage or severe hepatitis.

- Weakness on one part or side of the body.
- Abnormal weight gain.
- Cerebral hemorrhage (that can be lethal), speech difficulty, meningitis.
- Hallucinations.

Side effects that occur rarely:

Confusion, ulcers in the esophagus/stomach/duodenum/intestine, intestinal perforation, esophagitis, pancreatitis, sensitivity to light.

Additional side effects of unknown frequency:

Conjunctivitis, subcutaneous hemorrhages, severe skin conditions such as: Stevens-Johnson syndrome, toxic epidermal necrolysis, a red and swollen area with numerous pustules, severe kidney failure, kidney inflammation.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine like any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package/blister. The expiry date refers to the last day of that month.
- Store in a cool and dry place, below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, povidone, carmellose sodium LS, sodium lauryl sulphate, magnesium stearate, hard gelatin capsule: white body, white cap (100 mg), white body, orange cap (200 mg). Celcox 100 mg capsule contains 40 mg lactose monohydrate and approximately 0.3 mg sodium.

Celcox 200 mg capsule contains 80 mg lactose monohydrate and approximately 0.5 mg sodium.

What does the medicine look like and what are the contents of the package?

Celcox 100 mg: A capsule made of two white parts. Each package contains 20 capsules.

Celcox 200 mg: A capsule that is half white and half orange. Each package contains 10 capsules.

Manufacturer: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

This leaflet was checked and approved by the Ministry of Health in: January 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Celcox 100 mg: 134.40.30074.00

Celcox 200 mg: 120.44.30096.00



Maabarot 4023000
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