

Drugs & Supplements

Celecoxib (oral route)

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Brand Name

US Brand Name

CeleBREX

Elyxyb

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Description

Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID) used to treat mild to moderate pain and help relieve symptoms of arthritis (eg, osteoarthritis, rheumatoid arthritis, or juvenile rheumatoid arthritis), such as inflammation, swelling, stiffness, and joint pain. However, this medicine does not cure arthritis and will help you only as long as you continue to take it.

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Celecoxib is also used to treat ankylosing spondylitis, which is a type of arthritis that affects the joints in the spine. This medicine may also be used to treat acute pain and menstrual cramps.

Celecoxib is also used to treat acute migraine headaches with or without aura. However, this medicine is not used to prevent migraines.

This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

- Capsule
- Solution

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Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of celecoxib capsules in children 2 years of age and older. However, safety and efficacy have not been established in children younger than 2 years of age.

Appropriate studies have not been performed on the relationship of age to the effects of celecoxib oral liquid in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of celecoxib in the elderly. However, elderly patients are more likely to have age-related heart, kidney, or stomach problems, which may require caution.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to

change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Ketorolac

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Abciximab
- Aceclofenac
- Acemetacin
- Acenocoumarol
- Acoramidis
- Amiloride
- Amineptine
- Amiodarone
- Amitriptyline
- Amitriptylinoxide
- Amoxapine
- Amtolmetin Guacil
- Anagrelide
- Apixaban

- Aprepitant
- Ardeparin
- Argatroban
- Aripiprazole
- Asciminib
- Aspirin
- Atomoxetine
- Balsalazide
- Balsalazide Disodium
- Bemetizide
- Bemiparin
- Bendroflumethiazide
- Benzthiazide
- Betrixaban
- Bismuth Subsalicylate
- Bivalirudin
- Bromfenac
- Budesonide
- Bufexamac
- Bumetanide
- Cangrelor
- Cannabidiol
- Capecitabine
- Carbamazepine
- Ceritinib
- Certoparin

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Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may h

Feedback

the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Acebutolol
- Apalutamide
- Atenolol
- Azilsartan
- Azilsartan Medoxomil
- Benazepril
- Betaxolol
- Bisoprolol
- Candesartan
- Captopril
- Carteolol
- Carvedilol
- Celiprolol
- Enalapril
- Enalaprilat
- Eprosartan
- Esmolol
- Fosinopril
- Irbesartan
- Labetalol
- Levobunolol
- Lisinopril
- Losartan
- Mavacamten
- Metipranolol
- Metoprolol
- Moexipril

- Nadolol
- Nebivolol
- Olmesartan
- Oxprenolol
- Penbutolol
- Perindopril
- Pindolol
- Propranolol
- Quinapril
- Ramipril
- Sotalol
- Spirapril
- Telmisartan

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Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Anemia or
- Bleeding problems or



- Congestive heart failure or
 - Edema (fluid retention or body swelling) or
 - Heart attack, history of or
 - Heart disease or
 - Hypertension (high blood pressure) or
 - Kidney disease, mild to moderate or
 - Stomach ulcers or bleeding, history of or
 - Stroke, history of—Use with caution. May make these conditions worse.
-
- Aspirin-sensitive asthma, history of or
 - Aspirin sensitivity, history of or
 - Kidney disease, severe or
 - Liver disease, severe or
 - Sulfa or sulfonamide allergy (eg, sulfamethoxazole, Bactrim®, or Septra®)—Should not be used in patients with these conditions.
-
- Certain genetic conditions (poor CYP2C9 (a liver enzyme) metabolizers) or
 - Liver disease, mild or moderate—Use with caution. You may need a reduced dose of this medicine.
-
- Dehydration or
 - Hypovolemia—Must be corrected first before using this medicine.
-
- Heart surgery (eg, coronary artery bypass graft [CABG] surgery)
—This medicine should not be used to relieve pain right before or after the surgery.

Proper Use

For safe and effective use of this medicine, do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. Taking too much of this medicine may increase the chance of unwanted effects.

This medicine should come with a Medication Guide. It is very important that you read and understand this information. Be sure to ask your doctor about anything you do not understand.

You may take this medicine with or without food.

If you cannot swallow the capsule, you may open it and pour the medicine to a teaspoon of cool or room temperature applesauce. This mixture must be swallowed right away without chewing and followed with a glass of water to make sure all of the mixture is swallowed.

To use the oral liquid:

- If you are taking 120 milligrams (mg), take the medicine directly from the bottle. Hold the bottle upside down for 10 seconds to make sure the full amount of medicine is taken.
- If you are taking 60 mg, use an oral dosing syringe to withdraw and measure 2.4 milliliters (mL) of the medicine from the bottle and take it directly from the syringe. Do not use a household teaspoon to measure the medicine.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (capsules):
 - For acute pain or pain during menstruation:
 - Adults—At first, 400 milligrams (mg). A second dose of 200 mg can be taken if needed on the first day. Then, 200 mg 2 times a day as needed.
 - Children—Use and dose must be determined by your doctor.
 - For ankylosing spondylitis or osteoarthritis:
 - Adults—200 milligrams (mg) once a day or 100 mg 2 times a day. Your doctor may increase your dose if needed.
 - Children—Use and dose must be determined by your doctor.
 - For rheumatoid arthritis or juvenile rheumatoid arthritis:
 - Adults—100 to 200 milligrams (mg) 2 times a day.
 - Children 2 years of age and older and weighing more than 25 kilograms (kg)—Dose is based on body weight and must be determined by your doctor. The dose is usually 100 milligrams (mg) 2 times a day.

- Children 2 years of age and older and weighing less than 25 kilograms (kg)—Dose is based on body weight and must be determined by your doctor. The dose is usually 50 milligrams (mg) 2 times a day.
- Children younger than 2 years of age—Use and dose must be determined by your doctor.
- For oral dosage form (solution):
 - For acute migraine with or without aura:
 - Adults—120 milligrams (mg) once a day. Your doctor may adjust your dose as needed and tolerated.
 - Children—Use and dose must be determined by your doctor.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Celecoxib capsule that has been mixed with applesauce may be stored in a refrigerator and used within 6 hours.

Do not store the oral liquid bottle and reuse the remaining medicine. Throw away the bottle with the unused medicine.

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Precautions

It is very important that your doctor check the progress of you or your child at regular visits. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it. Blood and urine tests may be needed to check for unwanted effects.

Using this medicine during the later part of pregnancy can harm your unborn baby. If you think you have become pregnant while using the medicine, tell your doctor right away.

This medicine may cause a delay in ovulation for women and may affect their ability to have children. If you plan to have children, talk with your doctor before using this medicine.

This medicine may raise your risk of having a heart attack or stroke. This is more likely in people who already have heart disease. People who use this medicine for a long time might also have a higher risk.

This medicine may cause bleeding in your stomach or bowels. These problems can happen without warning signs. This is more likely if you or your child have had a stomach ulcer in the past, if you smoke or drink alcohol regularly, are over 60 years of age, are in poor health, or using certain other medicines (eg, steroids or a blood thinner).

Liver problems may occur while you are using this medicine. Check with your doctor right away if you have stomach pain or tenderness, clay-colored stools, dark urine, decreased appetite, fever, headache, itching, loss of appetite, nausea and vomiting, skin rash, swelling of the feet or lower legs, unusual tiredness or weakness, or yellow eyes or skin.

Check with your doctor right away if you have bloody urine, a decrease in frequency or amount of urine, an increase in blood pressure, increased thirst, loss of appetite, lower back or side pain, nausea, swelling of the face, fingers, or lower legs, trouble breathing, unusual tiredness or weakness, vomiting, or weight gain. These could be symptoms of a serious kidney problem.

Hyperkalemia (high potassium in the blood) may occur while you are using this medicine. Check with your doctor right away if you have stomach pain, confusion, difficulty with breathing, irregular heartbeat, nausea or vomiting, nervousness, numbness or tingling in the hands, feet, or lips, or weakness or heaviness of the legs.

Using this medication in certain patients under the age of 18 for the treatment of juvenile rheumatoid arthritis may increase the risk of disseminated intravascular coagulation (bleeding problem). Talk with your doctor if you have concerns about this.

Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis (AGEP), fixed drug eruption (FDE), and generalized bullous fixed drug eruption (GBFDE) can occur with this medicine. Check with your doctor right away if you have blistering, peeling, or loosening of the skin, chills, cough, diarrhea, itching, joint or muscle pain, red irritated eyes, red skin lesions, sore throat, sore

ulcers, or white spots in the mouth or on the lips, or unusual tiredness or weakness.

Check with your doctor right away if you have black, tarry stools, chest pain, chills, cough, fever, painful or difficult urination, sore throat, sores, ulcers, or white spots in the mouth or on the lips, swollen glands, unusual bleeding or bruising, or unusual tiredness or weakness. These may be symptoms of serious skin reaction called drug reaction with eosinophilia and systemic symptoms (DRESS).

Serious side effects can occur during treatment with this medicine and can occur without warning. However, possible warning signs often occur, including black, tarry stools, decreased urination, severe stomach pain, skin rash, swelling of the face, fingers, feet, or lower legs, unusual bleeding or bruising, unusual weight gain, vomiting of blood or material that looks like coffee grounds, or yellow eyes and skin. Also, signs of serious heart problems could occur such as chest pain, tightness in the chest, fast or irregular heartbeat, or unusual flushing or warmth of the skin. **Check with your doctor right away if you notice any of these warning signs.**

This medicine may cause a serious allergic reaction called anaphylaxis, which can be life-threatening and requires immediate medical attention. Call your doctor right away if you have a rash, itching, trouble breathing or swallowing, or any swelling of your hands, face, or mouth while you are using this medicine.

Tell your doctor if you or your child have unexplained weight gain or edema (fluid retention or body swelling) with this medicine.

Before having any kind of surgery or medical tests, tell your doctor that you are taking this medicine. It may be necessary for you to stop

treatment for a while, or to change to a different NSAID before your procedure.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

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Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- Cough
- Fever
- Skin rash
- Sneezing
- Sore throat
- Swelling of the face, fingers, feet, or lower legs

Less common or rare

- Abnormal growth in the breast
- Arm, back, or jaw pain
- Bloody or black, tarry stools
- Blurred vision

- Burning feeling in the chest or stomach
- Burning or stinging of the skin
- Burning, tingling, numbness, or pain in the hands, arms, feet, or legs
- Chest pain, discomfort, tightness, or heaviness
- Chills
- Confusion
- Cramps
- Diarrhea
- Dry mouth
- Earache
- Fast or irregular heartbeat
- Heartburn
- Heavy bleeding
- Heavy non-menstrual vaginal bleeding
- High blood pressure
- Increased hunger
- Increased thirst
- Increased urination
- Loss of appetite
- Loss of consciousness
- Muscle aches and pains
- Nausea
- Nerve pain
- Painful blisters on the trunk of body
- Painful cold sores or blisters on the lips, nose, eyes, or genitals
- Pale skin
- Redness or swelling in the ear
- Sensation of pins and needles
- Soreness or redness around the fingernails and toenails

- Stabbing pain
- Stiff neck
- Stomachache
- Stomach pain (severe)
- Sweating
- Tenderness in the stomach area
- Trouble breathing
- Unexplained weight loss
- Unusual bleeding or bruising
- Unusual tiredness or weakness
- Unusual weight gain
- Vomiting
- Vomiting of blood or material that looks like coffee grounds
- Weakness

Incidence not known

- Area rash
- Blistering, peeling, or loosening of the skin
- Changes in skin color
- Clay-colored stools
- Dilated neck veins
- Itching
- Joint or muscle pain
- Light-colored stools
- Pale or a bluish color skin of the fingers or toes
- Red irritated eyes
- Red skin lesions, often with a purple center
- Seizures
- Slurred speech
- Sores, welting, or blisters
- Sudden and severe inability to speak

- Ulcers or white spots in the mouth or on the lips
- Unpleasant breath odor
- Weakness in the arm or leg on one side of the body
- Yellow eyes and skin

Get emergency help immediately if any of the following symptoms of overdose occur:

Symptoms of overdose

- Continuing thirst
- Dizziness
- Drowsiness
- Headache, severe or continuing
- Sudden decrease in the amount of urine
- Trouble breathing
- Weight gain

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Back pain
- Change in sense of taste
- Gas
- Headache
- Heartburn



- Inability to sleep
- Loss of taste
- Pain or burning in the throat
- Stuffy or runny nose

Less common

- Anxiety
- Bleeding after defecation
- Bloody or cloudy urine
- Breast pain
- Bone deformity
- Buzzing or ringing noise in the ears
- Constipation
- Decrease in height
- Decreased appetite
- Depression
- Difficult, burning, or painful urination
- Difficulty with moving or walking
- Difficulty with swallowing
- Excessive muscle tone, muscle tension, or tightness
- Excessive tearing
- Feeling of pressure
- Hair loss
- Hives
- Hoarseness
- Increased sweating
- Infection
- Inflammation
- Itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at site

- Itching of the vagina or genital area
- Joint or muscle pain or stiffness
- Large, flat, blue, or purplish patches in the skin
- Loss of energy or weakness
- Loss of hearing
- Muscle pain increased
- Muscle stiffness
- Nervousness
- Numbness or tingling in the fingers or toes
- Pain during sexual intercourse
- Pain in the back, ribs, arms, or legs
- Pounding heartbeat
- Puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- Redness or swelling in the arms or legs
- Sensitivity of the skin to sunlight
- Severe sunburn
- Sleepiness
- Straining while passing stool
- Sudden sweating and feelings of warmth
- Swelling
- Swelling or inflammation of the mouth
- Tenderness
- Thick, white vaginal discharge with no odor or with a mild odor
- Thinning of the hair
- Trouble with swallowing
- Uncomfortable swelling around anus
- Unexplained weight loss
- Voice changes
- Warmth on the skin

- Weakness or heaviness of the legs

Incidence not known

- Bleeding gums
- Bloating
- Large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- Loss of sense of smell
- Pain
- Pinpoint red spots on the skin
- Shakiness and unsteady walk
- Stomach cramps
- Swelling of the neck
- Tenderness
- Trembling, or other problems with muscle control or coordination
- Unsteadiness
- Watery or bloody diarrhea


Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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