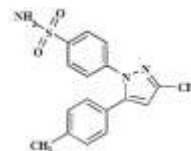
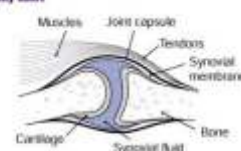


Rx
CELECOXIB
 (Celecoxib is a nonsteroidal antiinflammatory drug (NSAID))



A Healthy Joint



GENERIC NAME: celecoxib

DRUG CLASS AND MECHANISM

Celecoxib is a nonsteroidal antiinflammatory drug (NSAID) that is used to treat arthritis, pain, menstrual cramps, and colonic polyps. Prostaglandins are chemicals that are important contributors to the inflammation of arthritis that causes pain, fever, swelling and tenderness. Celecoxib blocks the enzyme that makes prostaglandins (cyclooxygenase 2), resulting in lower concentrations of prostaglandins. As a consequence, inflammation and its accompanying pain, fever, swelling and tenderness are reduced. Celecoxib differs from other NSAIDs in that it causes less inflammation and ulceration of the stomach and intestine (at least with short-term use) and does not interfere with the clotting of blood.

NSAIDs have been found to prevent the formation and reduce the size of polyps in patients with the genetic disease, familial adenomatous polyposis (FAP). In FAP, patients develop large numbers of polyps in their colons, and the polyps invariably become malignant. The only cure of FAP is removal of the entire colon. Celecoxib is approved as an adjunctive (secondary) treatment among patients with FAP. The cramping and pain during menstrual periods is due to prostaglandins, and blocking the production of prostaglandins with celecoxib reduces the cramps and pain.

PRESCRIPTION: Yes

PREPARATIONS: Capsules: 50, 100, 200, and 400 mg

PRESCRIBED FOR

Celecoxib is used for the relief of pain, fever, swelling, and tenderness caused by osteoarthritis, juvenile arthritis, rheumatoid arthritis, and ankylosing spondylitis. Celecoxib does not prevent the progression of either type of arthritis. It reduces only the symptoms and signs of arthritis. Celecoxib is approved for patients with familial FAP who have not had their colons removed. Celebrex also is also used for the relief of acute pain and the pain of menstrual cramps (primary dysmenorrhea).

DOSING

The lowest effective dose should be used for each patient.

* For the management of osteoarthritis, the dose usually is 100 mg twice daily or 200 mg as a single dose.

* For rheumatoid arthritis, the dose usually is 100 or 200 mg twice daily.

* For acute pain or menstrual cramps, the dose is 400 mg as a single dose on the first day followed by an additional 200 mg if needed, then 200 mg twice daily as needed.

* For FAP, the recommended dose is 400 mg twice daily.

DRUG INTERACTIONS

Concomitant use of celecoxib with aspirin or other NSAIDs (for example, ibuprofen, naproxen, etc.) may increase the occurrence of stomach and intestinal ulcers. It may be used with low dose aspirin.

Fluconazole (Diflucan) increases the concentration of celecoxib in the body by preventing the elimination of celecoxib in the liver. Therefore, treatment with celecoxib should be initiated at the lowest recommended doses in patients who are taking fluconazole.

USES

This medication is a nonsteroidal anti-inflammatory drug (NSAID), specifically a COX-2 inhibitor, which relieves pain and swelling (inflammation). It is used to treat arthritis, acute pain, and menstrual pain and discomfort. The pain and swelling relief provided by this medication helps you perform more of your normal daily activities. Celecoxib is also used to decrease growths found in the intestines (colon polyps) of persons with a family history of this condition. This drug works by blocking the enzyme in your body that makes prostaglandins. Decreasing prostaglandins helps to reduce pain and swelling.

HOW TO USE

Read the Medication Guide provided by your pharmacist before you start using celecoxib and each time you get a refill. If you have any questions regarding the information, consult your doctor or pharmacist. Take by mouth, usually once or twice daily, or as directed by your doctor. To decrease the chance of stomach upset, this drug is best taken with food. Dosage is based on your medical condition and response to therapy. The lowest effective dosage should always be used, and only for the prescribed length of time (see also Warning section). Take this medication with a full glass of water (8

ounces or 240 milliliters) unless your doctor directs you otherwise. Do not lie down for 30 minutes after taking this medication. In certain conditions (e.g., arthritis), it may take up to two weeks, taken regularly, before significant benefits of this drug take effect. If you are taking this drug on an "as needed" basis (not on a regular schedule), remember that pain medications work best if they are used as the first signs of pain occur. If you wait until the pain has significantly worsened, the medicine may not work as well.

SIDE EFFECTS

See also Warning section. Stomach upset or gas may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: severe headache, unexplained weight gain, swelling of the hands or feet, pain/swelling/warmth in the groin/calf, change in amount of urine, difficult/painful swallowing. This drug may rarely cause serious liver disease. If you notice any of the following highly unlikely but very serious side effects, stop taking celecoxib and consult your doctor or pharmacist immediately: yellowing eyes or skin, dark urine, persistent stomach/abdominal pain, unusual fatigue. In the unlikely event you have a serious allergic reaction to this drug, seek immediate medical attention. Symptoms of a serious allergic reaction include: rash, itching/swelling (especially of the face/tongue/throat), dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking celecoxib, tell your doctor or pharmacist if you are allergic to it; or to aspirin, other NSAIDs (e.g., ibuprofen), other COX-2 inhibitors; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: aspirin-sensitive asthma (a history of worsening breathing with runny/stuffy nose after taking aspirin or other NSAIDs), recent heart bypass surgery (CABG). Before using this medication, tell your doctor or pharmacist your medical history, especially of: blood flow problem in the brain (e.g., stroke, cerebrovascular disease), kidney problems, liver problems, heart disease (e.g., angina, heart attack, high blood pressure, congestive heart failure), alcohol use, swelling (e.g., edema), blood disorders (e.g., anemia), serious infections, stomach/intestine/esophagus problems (e.g., bleeding, ulcers, recurring heartburn), bleeding/clotting problems, asthma, growths in the nose (nasal polyps), dehydration, poorly controlled diabetes. This medicine may cause stomach bleeding. Daily use of alcohol and tobacco, especially when combined with this medicine, may increase your risk for stomach bleeding. Limit alcohol and smoking. Consult your doctor or pharmacist for more information. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of this medication, especially stomach bleeding and kidney effects. Caution is advised when using this drug in children with a certain type of arthritis (systemic onset juvenile rheumatoid arthritis) because they may be at increased risk for a very serious bleeding/clotting problem (disseminated intravascular coagulation). Seek immediate medical attention if your child develops sudden bleeding/bruising or bluish skin in the fingers/toes. This medication should be used only when clearly needed during the first 6 months of pregnancy. It should not be used during the last 3 months of pregnancy. Discuss the risks and benefits with your doctor. This medication passes into breast milk. While there have been no reports of harm to nursing infants, consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include severe stomach pain, coffee ground-like vomit, change in amount of urine, slow or shallow breathing, severe headache or loss of consciousness.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is

permitted. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

WARNING: Rarely, this medication can cause serious (very rarely fatal) stomach/intestinal bleeding. Also, this medication and related drugs have rarely caused blood clots to form, resulting in possibly fatal heart attacks and strokes. Talk to your doctor or pharmacist about the benefits and risks of treatment, as well as other medication choices.

If you notice any of these rare but very serious side effects, stop taking celecoxib and seek immediate medical attention: coffee-ground vomit, black stools, persistent stomach/abdominal pain, chest pain, weakness on one side of the body, slurred speech, sudden vision changes.

This medication should not be used right before or after heart bypass surgery.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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