



## Patient Information Sheet

### Celecoxib (marketed as Celebrex)

This is a summary of the most important information about Celebrex. For details, talk to your healthcare professional.

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**FDA ALERT-[04/07/2005]: Celebrex has been linked to an increased risk of serious cardiovascular (CV) events (such as heart attack or stroke) which appears to be a risk shared by all medicines called non-steroidal anti-inflammatory drugs (NSAIDs) (excluding aspirin). FDA has requested that the package insert (labeling) for all NSAIDs, including Celebrex, be revised to include a “boxed” or serious warning to highlight the potential increased risk of CV events, and the well known risk of serious, and potentially life-threatening, stomach bleeding. FDA has also requested that the package insert for all NSAIDs be revised to state that patients who have just had heart surgery should not take these medicines.**

*This information reflects FDA’s current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.*

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#### What is Celebrex?

Celebrex is used to:

- relieve symptoms of osteoarthritis (the arthritis caused by age-related “wear and tear” on bones and joints)
- relieve symptoms of rheumatoid arthritis in adults
- manage acute pain in adults (like the short term pain you can get after a dental or surgical operation)
- treat painful menstrual cycles
- reduce the number of colon and rectum growths (colorectal polyps) in patients with a disease called Familial Adenomatous Polyposis (FAP). FAP is an inherited disease in which the rectum and colon are covered with many polyps. Celebrex is used along with the usual care for FAP patients such as surgery and exams of the rectum and colon.

#### Who Should Not Take Celebrex?

Do not take Celebrex if you:

- have had an allergic-type reaction to sulfa medicines.
- have had asthma, hives or allergic-type reactions after taking aspirin or other NSAID (nonsteroidal anti-inflammatory drugs) medicines. If you have asthma, you may have aspirin-sensitive asthma. If an aspirin-sensitive asthmatic takes aspirin it can cause severe narrowing of

the airway (bronchospasm), and even death. Since this type of reaction also has occurred after taking NSAIDs Celebrex should not be given to aspirin-sensitive patients.

Some examples of NSAIDs are ibuprofen (Motrin, Advil), naproxen (Naprosyn, Aleve), diclofenac (Voltaren, Cataflam), and ketoprofen (Orudis). You can ask your doctor or pharmacist for a complete list of these medications.

- are pregnant, especially during your last 3 months

#### What are The Risks?

Celebrex and other NSAID medicines can cause serious problems such as:

- ***Stomach ulcers that bleed.*** The chance of this serious problem increases the longer you take Celebrex, but it can also happen suddenly. Stop taking Celebrex and call your healthcare professional right away if you get a burning stomach pain, black bowel movements that look like tar, or vomit that looks like blood or coffee grounds.
- ***Liver damage.*** Some of the warning signs of liver damage are nausea, vomiting, tiredness, loss of appetite, itching, yellow coloring of skin or eyes, “flu-like” symptoms and dark urine. If this happens, stop taking Celebrex and call your healthcare professional right away.
- ***Kidney problems*** that include sudden kidney failure or worsening of kidney problems that you already have.
- ***Fluid retention*** (holding of water in your body) and swelling. Fluid retention can be a serious problem if you have high blood pressure or heart failure.

In addition to the serious side effects listed above, some common, but less serious side effects with Celebrex may include:

- headache
- indigestion
- upper respiratory tract infection (a "cold")
- diarrhea
- sinus inflammation
- stomach pain
- nausea

#### What Should I Tell My Healthcare Professional?



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
Druginfo@cder.fda.gov



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Tell your healthcare professional if you:

- have heart problems or high blood pressure
- have liver or kidney problems
- have or had stomach ulcers or stomach bleeding
- have asthma
- are allergic to aspirin or other NSAID medicines
- are trying to become pregnant, are already pregnant, or are breast-feeding

medicines work. Your healthcare professional may have to adjust your dose or watch you closely if you take any of the following medications:

- certain blood pressure medicines called ACE inhibitors
- furosemide
- fluconazole or ketoconazole
- lithium
- phenytoin
- warfarin
- aspirin

#### Are There Any Interactions With Drugs or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Celebrex works or Celebrex may affect how your other

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