

Drug Information Sheet("Kusuri-no-Shiori")

Internal
Revised: 02/2015

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Celecox Tablets 200mg

Active ingredient: Celecoxib

Dosage form: white tablet with split line (major axis: 13.0mm, minor axis: 6.5mm, thickness: 5.1mm)

Print on wrapping: (Face) セレコックス, 200mg, house-mark+215, (Back) セレコックス, 200mg, 消炎鎮痛剤, house-mark



Effects of this medicine

This medicine selectively blocks cyclooxygenase-2 in an inflammatory site and inhibits production of prostaglandin, thus relieves inflammation or pain by exhibiting anti-inflammatory or anti-analgesic activities.

It is usually used for the treatment of rheumatoid arthritis, osteoarthritis, low back pain, periarthritis scapulohumeralis, neck, shoulder and arm syndrome or tendonitis/tenosynovitis with anti-inflammatory/analgesic effects. It is also used to reduce inflammation and pain after operation, traumatic injuries or tooth removal.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you have a current or past history of aspirin asthma.
If you have peptic ulcer, hepatic disorder, renal disorder or cardiac function failure.
If you are in the perioperative period of coronary-bypass surgery.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is << to be written by a healthcare professional >>
- For rheumatoid arthritis: In general, for adults, take 0.5 to 1 tablet/s (100 to 200 mg of the active ingredient) at a time, twice daily after meal in the morning/evening.
For osteoarthritis, low back pain, periarthritis scapulohumeralis, neck, shoulder and arm syndrome or tendonitis/tenosynovitis: In general, for adults, take 0.5 tablet (100 mg of the active ingredient) at a time, twice daily after meal in the morning/evening.
In either case, strictly follow the instructions of your doctor/pharmacist.
For after operation, traumatic injuries or tooth removal: In general, for adults, take the initial dose of 2 tablets (400 mg of the active ingredient), and subsequently take 1 tablet (200 mg) at a time, twice daily. Take the medicine at least 6 hours apart.
If the medicine is taken as needed, take the initial dose of 2 tablets (400 mg), and subsequently take 1 tablet (200 mg) at a time as needed 6 hours apart. The daily maximum dosing should be 2 times.
In either case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause dizziness and somnolence (getting sleepy). Pay close attention when performing dangerous operation such as driving a car, etc.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include abdominal pain, stomatitis, diarrhea, nausea and rash. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor

immediately.

- facial pallor, cold sweat, dizziness on standing up [shock, anaphylaxis]
- abdominal pain, vomiting of blood, melena [peptic ulcer, bleeding of digestive tract, gastrointestinal perforation]
- feeling of anterior chest pressure, chest constriction, cold sweat [cardiac infarction, stroke]
- shortness of breath, general edema, coughing [cardiac failure, congestive cardiac failure]
- fever, erythema, water blister/pustule/erosion [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme, acute generalized exanthematous pustulosis, dermatitis exfoliative]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of infants and children. Store away from direct sunlight, heat and humidity.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.