

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

Internal

Published: 06/2020

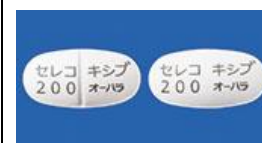
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name: CELECOXIB TABLETS 200mg 「OHARA」

Active ingredient: Celecoxib

Dosage form: white oval tablet, major axis: 13.0 mm, minor axis: 6.5 mm, thickness: 5.2 mm

Print on wrapping: セレコキシブ錠 200mg「オーハラ」、セレコキシブ、200mg、消炎鎮痛薬、Celecoxib 200mg「OHARA」



Effects of this medicine

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

It is usually used to treat rheumatoid arthritis, osteoarthritis, low back pain, shoulder peri-arthritis, neck-shoulder-arm syndrome or tendonitis/tenosynovitis with anti-inflammatory/analgesic effects. It is also used to reduce inflammation and pain after surgery, traumatic injury 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 or have a history of aspirin asthma.
If you have peptic ulcer, liver 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 (100 to 200 mg of the active ingredient) at a time, twice a day after breakfast and dinner.
For osteoarthritis, low back pain, shoulder peri-arthritis, neck-shoulder-arm syndrome or tendonitis/tenosynovitis : In general, for adults, take 0.5 tablet (100 mg of the active ingredient) at a time, twice a day after breakfast and dinner.
For after surgery, traumatic injury 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 a day. Take the next dose at least 6 hours apart.
If this 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 at least 6 hours apart. However, the maximum daily dose should be 2 times.
In any 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 follow 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 operations such as driving a car.

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, gastrointestinal bleeding, gastrointestinal perforation]
- pressure in front chest, chest tightness with pain, cold sweat [myocardial infarction, stroke]
- shortness of breath, general edema, cough [cardiac failure, congestive cardiac failure]

- fever, erythema, blister/pustule/erosion [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythema multiforme, acute generalized exanthematous pustulosis, exfoliative dermatitis]

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 children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Consult with your pharmacy or medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

SIE①