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

Internal

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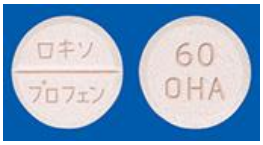
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:LOXOPROFEN Na TABLETS 60mg「OHA」

Active ingredient: Loxoprofen sodium hydrate

Dosage form:slightly rose pink tablet with split line (diameter: 8.0 mm, thickness: 3.1 mm)

Imprint or print on wrapping:ロキソプロフェン Na 60mg「OHA」, 鎮痛・抗炎症・解熱のお薬です, LoxoprofenNa 60mg「OHA」



Effects of this medicine

This medicine shows anti-inflammatory, analgesic and antipyretic action by blocking cyclooxygenase to suppress biosynthesis of prostaglandin involving in inflammation.

It is usually used for analgesia and anti-inflammation in rheumatoid arthritis, osteoarthritis, low back pain, shoulder periarthritis, cervico-omo-brachial syndrome, toothache, after a surgery, an injury and a tooth removal, and pyretolysis and analgesia in acute upper respiratory inflammation.

The following patients may need to be careful when 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 or foods.
If you have: peptic ulcer, blood abnormality, hepatic disorder, renal disorder, heart dysfunction, aspirin-induced asthma, or its history.

・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))

・To reduce inflammation or pain induced by rheumatoid arthritis, osteoarthritis, low back pain, shoulder periarthritis, cervico-omo-brachial syndrome, toothache, after a surgery, an injury, and a tooth removal : In general, for adults, take 1 tablet (60 mg of the active ingredient anhydride) at a time, 3 times a day. If you take the medicine as needed, take 1 to 2 tablets (60 to 120 mg) at a time. The dosage may be adjusted according to the age or symptoms.

To reduce fever or pain induced by acute upper respiratory inflammation : In general, for adults, take 1 tablet (60 mg of the active ingredient anhydride) at a time, as needed. The dosage may be adjusted according to the age or symptoms, however, it is limited to 2 times a day, maximum 3 tablets (180 mg) a day.

Avoid taking the medicine on an empty stomach in any case. Strictly follow the instructions.

・If you miss a dose, take a dose as soon as possible when you remember that you missed a dose. 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include gastric discomfort, abdominal pain, nausea, vomiting, loss of appetite, peptic ulcer, ulcer of the small and large intestine, edema, rash, hives, drowsiness, fever and itch. 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.

・hives, edema of larynx, respiratory distress [shock, anaphylactoid symptoms]

・general malaise, fever, subcutaneous hemorrhage, submucosal hemorrhage [agranulocytosis, hemolytic anemia, leukocytopenia, thrombocytopenia]

・redness/swelling/rash/blister of skin/mucous membrane, fever, general malaise [toxic epidermal necrosis, Stevens-Johnson syndrome, erythema multiforme, acute generalized exanthematous pustulosis]

・decreased urine output, edema, fever [acute renal failure, nephrotic syndrome, interstitial nephritis]

・respiratory distress, systemic edema [congestive heart failure]
・vomiting of blood, bloody stool [haemorrhages of digestive tract]
・nausea/vomiting, abdominal pain, abdominal bloating [stenosis/obstruction of small/large intestine]

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. If you do not know how to discard the remainder, ask your pharmacist or medical institution. Do not give the medicine to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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