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

Internal

Revised: 07/2018

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:LOXONIN TABLETS 60mg

Active ingredient:Loxoprofen sodium hydrate

Dosage form: faintly reddish tablet, diameter: 9.1mm, thickness: 3.3mm

Print on wrapping:ロキソニン 60mg, 157, Loxonin 60mg, 鎮痛・抗炎症・解熱剤

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Effects of this medicine

This medicine suppresses prostaglandin synthesis that causes inflammation, and acts to ease swelling/pain induced by inflammation as well as to bring down fever.

It is usually used to treat rheumatoid arthritis and osteoarthritis. It is also used to reduce pain and inflammation after surgery, wounds and tooth removal, as well as to bring down fever or ease pain induced by acute inflammation of upper respiratory tract.

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: peptic ulcer, blood disease, liver/kidney/heart disorders, aspirin 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))
- For the use in reducing inflammation and pain induced by rheumatoid arthritis, osteoarthritis, lumbar pain, frozen shoulder, neck-shoulder-arm syndrome, tooth pain, as well as after surgery/wounds/tooth removal: In general, for adults, take 1 tablet (60 mg of loxoprofen sodium) at a time, 3 times a day. If taken as on-demand use, take 1 to 2 tablets (60 to 120 mg) at a time.

For the use in reducing fever or pain induced by acute inflammation of upper respiratory tract: In general, for adults, take 1 tablet (60 mg of loxoprofen sodium) at a time, as needed. Usually up to twice a day. Do not exceed 3 tablets (180 mg) a day.

The dose may be adjusted according to your age and symptoms. Avoid taking the medicine on an empty stomach. Strictly follow the instructions.

- If you miss a dose, take the missed dose as soon as possible. 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, pain in the pit of the stomach, stomachache, nausea/vomiting, loss of appetite, edema/swelling, 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.

- •pale face, breathing difficulty, cold sweat [shock, anaphylaxis]
- ·nose/gums bleeding, bruising on the limbs [agranulocytosis, hemolytic anemia, leukopenia, thrombocytopenia]
- •redness/swelling/rash/blister of skin/mucous membrane, fever, general malaise [toxic epidermal necrosis, oculomucocutaneous syndrome]
- ·decreased urine output, swelling, loss of appetite [acute renal disorder, nephrotic syndrome, interstitial nephritis]
- •breathing difficulty, general swelling [congestive heart failure]
- •fever, cough, breathing difficulty [interstitial pneumonia]
- ·blood vomiting, blood in stool [digestive tract bleeding]
- •pain in the pit of the stomach, stomachache [digestive tract perforation]
- · nausea, stomachache, abdominal enlarged feeling [constriction and obstruction of the intestinal tract]
- •general fatigue, nausea, yellowing of the skin/white of eyes [liver dysfunction, jaundice]
- •breathlessness, wheezing [asthma attack]
- ·fever, headache, nausea [aseptic meningitis]



•sore muscle, feeling of weakness [rhabdomyolysis]

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 reach of children. Store away from direct sunlight, heat and moisture.
- •Discard the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.