

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

Internal

Revised: 09/2018

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: NAIXAN Tablets 100mg

Active ingredient: Naproxen

Dosage form: white tablets, diameter: 7.0mm, thickness: 3.5mm

Imprint or print on wrapping: (face) Naixan100mg, ナイキサン 100mg, ナイキサン 100, TA124
(back) ナイキサン 100mg, ナイキサン, 100mg



Effects of this medicine

This medicine relieves pain, inflammation and fever by suppressing the biosynthesis of prostaglandins that cause pain and inflammation, and by inhibiting lysosomal enzymes.

It is usually used to treat rheumatoid arthritis, osteoarthritis, gout attack, ankylosing spondylitis, lower back pain, peri-arthritis scapulothoracalis, neck/shoulder and arm syndrome, tendinitis/tenosynovitis, dysmenorrhoea, anti-inflammation/analgesia/antipyresis for herpes zoster, anti-inflammation/analgesia after trauma or surgery, tooth extraction or oral small surgery.

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, bleeding tendency, liver disorder, renal disorder, cardiac dysfunction, hypertension, aspirin asthma.
- If you have a history of peptic ulcer, blood abnormality, liver disorder, renal disorder or aspirin asthma.
- 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))
- In general, for adults, take 3 to 6 tablets (300 to 600 mg as active ingredient) a day in 2 to 3 divided doses. Avoid taking this medicine on an empty stomach if possible. For gout attack, take the initial dose of 4 to 6 tablets (400 to 600 mg). If the medicine is taken as needed, or after trauma or surgery, take the initial dose of 3 tablets (300 mg). The dosage may be adjusted according to the disease, age, or symptoms. Strictly follow the instructions.
- If you miss a dose, take the dose as soon as possible. If it is a short 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 gastrointestinal disorder, abdominal pain, gastric pain/gastric distress, nausea, vomiting, loss of appetite, diarrhea, constipation, stomatitis, rash, itch, drowsiness and edema. 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.

- respiratory distress, hives, swollen around eyes/mouth [shock]
- fever, cough, phlegm [PIE (pulmonary infiltration with eosinophilia) syndrome]
- fever, turning red of a wide area of skin, conjunctival hyperemia and mucosal erosion in lips [oculomucocutaneous syndrome]
- abdominal pain, haematemesis/melena, black stools [gastrointestinal haemorrhage, ulcer]
- anaemia, sore throat, nose/gum bleeding [aplastic anemia, hemolytic anemia, agranulocytosis, thrombocytopenia]

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 light, heat and moisture.
- Discard the remainder. Consult with your dispensing pharmacy or healthcare provider when you discard the remainder.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.