Category I Medicines

Antipyretic analgesics

NARON Loxy

◆NARON Loxy fast-melting tablets, taken as one tablet per dose, provide prompt pain relief.◆ Loxoprofen sodium hydrate, an antipyretic analgesic component, inhibits the synthesis of prostaglandins, which contribute to pain and fever, providing prompt pain relief.◆ Since loxoprofen sodium hydrate becomes active after being absorbed into the body, it is gentle on the stomach.◆ NARON Loxy contains no components that may induce drowsiness.

Indication

◆Relief of headache, toothache, pain after tooth extraction, sore throat (throat pain), earache, joint pain, neuralgia, lumbago, muscular pain, pain due to stiff shoulders, contusion pain, bone fracture pain, pain associated with sprain (sprain pain), painful menses (menstrual pain), and traumatic pain◆Relief of fever at the time of chills (feeling cold due to fever) and fever

Dosage and administration

When the symptom appears, take the following dose with cold or lukewarm water. Avoid taking the drug on an empty stomach whenever possible.
Adults (15 years or over): 1 tablets per dose, up to twice daily
* However, you may take the third dose when the symptom recurs.
Take at least 4 hours between doses.
Under 15 years: Do not take

[Precaution]

Comply with the prescribed dosage and administration instructions.
How to take out the tablets
・Press the convex part of the PTP sheet containing the tablet firmly with your fingertips, break the aluminum foil on the back side, and take out the tablets.
(If the tablets are inadvertently taken together with the PTP sheet containing them, it will lead to unexpected accidents, such as the sharp edge sticking into the esophageal mucosa.)

ingredient and amount

In 1 tablets
Loxoprofen sodium hydrate 68.1 mg (60 mg as anhydride)

Excipients

anhydrous silicic acid
D-Mannitol
Hydroxypropylcellulose
Crospovidone
Acesulfame K
Sucralose
Lemon oil
Sunset Yellow FCF
Magnesium stearate

Precautions

When not to use the product

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions are more likely to occur.)
●This product should not be used in the following persons:
Patients who have had an allergic symptom to this drug or its ingredients.
Persons who experienced asthma after taking this drug, other antipyretic analgesics, or cold medicine.
Children under 15 years old
Individuals who are being treated at a medical institution for any of the following symptoms:
Gastric/duodenal ulcer,Liver disease,kidney disease,heart disease
Individuals with physician-confirmed hematological (blood) disorder such as decreased red blood cell count (anemia), decreased platelet count (difficulty in blood coagulation, bleeding tendency), and decreased white blood cell count
Pregnant women who are expected to give birth within 12 weeks.
● This medicine should not be taken together with any of the following medicines:
Other antipyretics/analgesics, cold medicine, sedatives
●Do not drink alcohol before and after taking this drug.
● Please be careful not to take the product for a prolonged period of time.
(If symptoms such as pain do not improve after administration of this product for 3 to 5 days, discontinue administration and consult your physician.)

Consultation

●The following persons should contact a physician, dentist, pharmacist, registered salesperson for a consultation before administration.
Patients undergoing medical treatment from a physician or dentist.
Pregnant women or women suspected of being pregnant.
Nursing women.
The elderly
Patients who have experienced allergic symptoms associated with drugs, etc.
Persons diagnosed as having the following
Bronchial asthma
Ulcerative colitis
Crohn's disease
Systemic lupus erythematosus
Mixed connective tissue disease
Patients who experienced any of the following diseases.
Gastric/duodenal ulcer
Liver disease
kidney disease
Blood disease
●If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician or pharmacist for a consultation.
▪ When symptoms such as an excessive decrease in body temperature, loss of vigor, and coldness of limbs occur after administration of antipyretic analgesics such as this product
▪ When peptic ulcer or swelling occurs. The following serious symptoms may occur, though with a low incidence: gastrointestinal bleeding (symptoms include vomiting of blood, nausea/vomiting, abdominal pain, dark tarry stool, and bloody stool), gastrointestinal perforation (a hole in the wall of part of the gastrointestinal tract; symptoms include nausea/vomiting and severe abdominal pain), and small/large bowel stenosis or obstruction (symptoms include nausea/vomiting, abdominal pain, and abdominal distention). If any of these symptoms occur, immediately consult your physician.
If the following symptoms occur after taking this drug
Skin : rash/redness,itching
Gastrointestinal disorders: Abdominal pain, gastric discomfort, decreased appetite, nausea/vomiting, abdominal distention, heartburn, stomatitis, dyspepsia
Neuropsychiatric disorders: Drowsiness, numbness, dizziness, headache
Cardiovascular disorders: Increased blood pressure, palpitation
Other disorders: Chest pain, malaise, facial flushing, fever, anemia, bloody urine
The following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid:
Shock (anaphylaxis): Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after take.
Hematologic disorders: throat pain, fever, general malaise, paleness of the face or inside of the eyelid, bleeding tendency (bleeding from gum or nose, etc.), bruising (does not disappear when pressure is applied to the site)
Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis (persistent or rapidly worsening symptoms such as high fever, redness of the eye, eye mucus, soreness of the lip, throat pain, and extensive rash/redness of the skin)
Kidney disorders: Symptoms, such as fever, rash, reduced urinary volume, general oedema, general malaise, arthralgia (painful joints) and diarrhea, etc. may occur.
Congestive heart failure: Whole body tiredness, palpitations, shortness of breath, chest discomfort, chest pain, dizziness and faint may appear
Interstitial pneumonia: Shortness and/or difficulties of breath when go upstairs or overwork, sudden dry cough and/or fever and its continuance
Hepatic function failure: Symptoms, such as fever, itching, rash, jaundice (yellowing of skin and white of eyes), brown urine, general malaise, loss of appetite, etc. may occur.
Rhabdomyolysis: symptoms may include pain in the muscles of the limbs/shoulders/lower back, numbness, weakness or stiffness in the limbs, general malaise and reddish-brown urine.
Aseptic meningitis: Symptoms, such as severe headache with a tight sensation along the neck, fever and feeling nausea/vomiting, etc. may occur. (these symptoms are frequently reported particularly in patients under treatment for systemic lupus erythematosus or mixed connective tissue disease.)
Asthma: Symptoms, such as wheezing or hissing when breathing, and difficult breathing, etc. may occur.
●The following symptoms may be observed after taking this drug. If these symptoms persist or worsen, discontinue the use of this drug, and show this document to a physician or pharmacist for a consultation.
Diarrhea, constipation, and dry mouth
If symptoms do not improve after administration of one or two doses of this product (may be caused by another disease), discontinue administration and consult your physician, dentist, or pharmacist showing him/her this leaflet.

Precautions for storage and handling

Avoid direct sunlight, and store the product in a cool place with little humidity.
Store the product beyond the reach of children.

Do not transfer the drug to other containers. (It may lead to misuse or quality deterioration)
Do not take the product past the expiration date.
Even before the expiration date, use up to within 6 months after it is opened (to assure quality).

11

【Disclaimer on Multilingual OTC Product Information】
・This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.
・Multilingual product information is a translation of the product labeling written in Japanese and provided for your information only. It does not warrant that its contents and the product itself conforms to laws and regulations in countries other than Japan.
・Multilingual product information is a tentative translation by the provider (or Our Company), and may be modified or altered without notice.
・The provider (or Our Company) assumes no responsibility for any occurred problem attributable to the contents of the multilingual product information.