

# 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 tablet 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

In 1 tablets

Loxoprofen sodium hydrate 68.1mg (60mg as anhydride)

## Excipients

Anhydrous silicic acid, D-mannitol, hydroxypropylcellulose, crospovidone, acesulfame K, sucralose, sunset yellow FCF, magnesium stearate, flavoring, vanillin, ethyl vanillin

## 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 taken in the following persons
  - Patients who have had an allergic symptom to this drug or its ingredients.
  - Patients who have experienced asthma from taking this drug, other antipyretic analgesics, cold remedies.
  - 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 consult a physician, dentist, or pharmacist before taking this drug:
  - 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
  - Persons who have a history 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, dentist, or pharmacist for 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 the 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, erythema multiforme: hyperthermia, ocular hyperaemia, eye discharge, lip erosion, pain throat, widespread skin rash/redness, blisters appearing on the red skin areas, etc. may persist or suddenly worsen.
  - 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 your physician or pharmacist for consultation
  - Dry mouth, constipation and diarrhea

- 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 use the product past the expiration date. Even before the expiration date, use the product within 6 months after it is opened (to assure the quality).

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#### 【Disclaimer on Multilingual 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.
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