

LOXOPROFEN SODIUM HYDRATE

Category I Medicines

Antipyretic analgesics

◆ Each dose of LOXOPROFEN SODIUM HYDRATE oral solution is individually packaged, making it easy to take wherever you are. ◆ 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. ◆ LOXOPROFEN SODIUM HYDRATE 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 . Avoid taking the drug on an empty stomach whenever possible.

Adults (15 years or over): Take 1 bottle (10 mL) 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.

Administration method: Remove one tube from the pack, and open it by turning the cap slowly in the direction of the arrow, keeping the tube upright. (The medicinal fluid could fly out if you open the packet quickly.)

ingredient and amount

In 1 bottle (10 mL)

Loxoprofen sodium hydrate 68.1 mg (60 mg as anhydride)

Excipients

Butyl parahydroxybenzoate

Saccharin sodium

Sodium citrate

Citric acid

Flavoring

Propylene glycol

Anhydrous ethanol

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 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

Store this in a cool place, avoiding direct sunlight.

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.

Do not mistake this for eye drops and use on eyes.

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- 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.
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