

Quick relief from aches and pains
ロキソニンS
 LOXONIN S
 Japanese Pharmacopoeia
 Loxoprofen Sodium Tablets

Quick relief + Ingredients that are easy on your stomach
ロキソニンS プラス
 LOXONIN S plus

Quick relief + Ingredients that protect your stomach
ロキソニンS クイック
 LOXONIN S QUICK

Quick relief from painful aches and pains + Ingredients that protect your stomach
ロキソニンS プレミアム
 LOXONIN S PREMIUM

Quick relief + Focusing on the mechanism of menstrual pain
ロキソニンS プレミアムファイン
 LOXONIN S PREMIUM fine

| Product Name | LOXONIN S | LOXONIN S plus | LOXONIN S QUICK | Product Name | LOXONIN S PREMIUM | LOXONIN S PREMIUM fine |
|---------------------------------------|--|---|--|--|--|--|
| Ingredients and Quantities (1 tablet) | Loxoprofen sodium hydrate (60 mg as anhydrate) 68.1 mg | Loxoprofen sodium hydrate (60 mg as anhydrate) 68.1 mg Magnesium oxide 33.3 mg | Loxoprofen sodium hydrate (60 mg as anhydrate) 68.1 mg Magnesium aluminometasilicate 100 mg | Ingredients and Quantities (2 tablets) | Loxoprofen sodium hydrate (60 mg as anhydrate) 68.1 mg Allylisopropylacetylurea 60 mg Anhydrous caffeine 50 mg Magnesium aluminometasilicate 100 mg | Loxoprofen sodium hydrate (60 mg as anhydrate) 68.1 mg Passion dry extract (252 mg as whole crude drug) 36 mg Hesperidin 30 mg Magnesium aluminometasilicate 100 mg |
| Pharmaceutical Classification | Class 1 OTC medicine | Class 1 OTC medicine | Class 1 OTC medicine | Pharmaceutical Classification | Class 1 OTC medicine | Class 1 OTC medicine |

What effect does this medicine have?

- This medicine is an antipyretic analgesic that belongs to a group called non-steroidal anti-inflammatory and analgesic drugs (NSAIDs).
- This medicine suppresses the production of "prostaglandins", the substances that cause pain, inflammation, and fever, thereby relieving pain and reducing fever.
- This medicine can be taken for the following purposes
 - Analgesic for headache, menstrual pain, toothache, pain after tooth extraction, sore throat, back pain, joint pain, neuralgia, muscle pain, stiff shoulder pain, earache, bruise pain, fracture pain, sprain pain, trauma pain
 - Relief from chills and fever

What should be checked before purchasing this medicine?

Please check the following items to make sure that you can take this product.

It is known that side effects (adverse reactions to medication) may include stomach/duodenal ulcers, induction of severe asthma attacks, rashes, and swelling.

For more information, please see [What caution should be taken when using this medicine?].

The following persons should not take this medicine.

- Persons who have experienced allergic symptoms or other hypersensitive reactions to this product or the ingredients contained in this product in the past.
- Persons who have experienced asthma after taking this medicine or other antipyretic analgesics, or cold medicine.
[Persons who have experienced asthma after taking antipyretic analgesics or cold medicine containing loxoprofen sodium hydrate, aspirin (acetylsalicylic acid), aspirin aluminum, ethenzamide, ibuprofen, acetaminophen, or isopropylantipyrine.]
- Children under the age of 15
- Persons undergoing treatment for the following conditions at medical institutions
 - Stomach / duodenal ulcers ● liver disease ● kidney disease ● heart disease
- Persons who have been diagnosed by a doctor with the following blood abnormalities (blood diseases)
 - Low red blood cell count (anemia)
 - Low platelet count (difficulty in stopping bleeding, bleeds easily)
 - Low white blood cell count
- Pregnant women within 12 weeks of the expected delivery date

The following persons should use caution when taking this medicine. Consult your doctor, dentist, or pharmacist before purchasing.

- Patients undergoing medical treatment from a physician or dentist.
- Women who are pregnant (excluding pregnant women within 12 weeks of the expected delivery date) or considered to be pregnant
- Persons who are breastfeeding
- Elderly people (the age of 65 or over)
- Patients who have experienced allergic symptoms associated with drugs, etc.
- Persons with the following diagnoses:
 - Bronchial asthma ● ulcerative colitis ● Crohn's disease ● systemic lupus erythematosus ● mixed connective tissue disease
- Persons who have ever had the following diseases:
 - Stomach and duodenal ulcer ● liver disease ● kidney disease ● blood disease

What should be confirmed before using this medicine?

- This medicine is not intended to treat the disease that is causing the pain, fever, etc., but to suppress the symptoms that are occurring. Therefore, **it should be taken only when symptoms are present.**
- If symptoms do not improve after 1 or 2 doses, stop taking the medicine and bring these instructions to a consultation with your doctor, dentist, or pharmacist.
- **Do not use this medicine continuously for a long term.** (If pain or other symptoms recur after 3 to 5 days of use, stop taking the medicine and seek medical attention.)
- Do not take any of the following medicines while taking this medicine. Other antipyretic analgesics containing aspirin (acetylsalicylic acid), aspirin aluminum, ethenzamide, ibuprofen, acetaminophen and isopropylantipyrine, cold remedies and sedatives containing Allylisopropylacetylurea and bromovaleril urea, **motion sickness medication [Loxonin S Premium only]**
- **Do not operate vehicles or machinery after taking the medicine.** (Drowsiness and other symptoms may occur.) [Loxonin S Premium only]
- Do not drink alcohol before or after taking the medicine. [Do not take the medicine when consuming alcohol.]

How is this medicine used?

- **Dosage and Administration**
For adults (the age of 15 or over), when symptoms appear, take the following dosage with water or lukewarm water, avoiding an empty stomach if possible. The usual dosage is **2 times a day**.
If pain or other symptoms occur again, a third dose may be taken. The interval between doses should be at least 4 hours.
- | LOXONIN S | LOXONIN S PLUS | LOXONIN S QUICK | LOXONIN S PREMIUM | LOXONIN S PREMIUM fine |
|-------------------|-------------------|-------------------|---------------------------|---------------------------|
| 1 tablet per dose | 1 tablet per dose | 1 tablet per dose | 2 tablets per dose | 2 tablets per dose |
- * **When taking the product, be sure to read the enclosed instructions to follow the dosage and administration strictly.**
 - How is this medicine ingested?
Drink with a cup of water or lukewarm water
 - What to do if you take too much (overdose)
In case of accidental overdose, consult a doctor or pharmacist.

What caution should be taken when using this medicine?

- After taking antipyretic analgesics such as this medication, symptoms such as excessive decrease in body temperature, weakness (lack of strength), and cooling of the extremities (cold hands and feet) may occur. If any of these symptoms occur, stop taking the medicine immediately and bring these instructions to your doctor or pharmacist.
- **If you experience peptic ulcers (upset stomach, heartburn, back pain) or swelling** after taking this medicine, stop taking it immediately and bring these instructions to your doctor or pharmacist. In addition, in rare cases, the following severe symptoms such as gastrointestinal bleeding (vomiting blood, nausea and vomiting, abdominal pain, black tarry stools, bloody stools, etc.), gastrointestinal perforation (perforation of the gastrointestinal tract; nausea, vomiting, severe abdominal pain, etc.), and narrowing or obstruction of the small or large intestine (nausea, vomiting, abdominal pain, abdominal distention, etc.) may occur. In such cases, seek medical attention immediately.

What are the side effects?

- (1) If the following symptoms occurs after using this product, you could be experiencing side effects. In such case, stop taking it immediately and bring these instructions to a consultation with your doctor or pharmacist.

| Related Part | Symptoms |
|-------------------------------|---|
| Skin | Rash, redness, itching |
| Digestive organs | Abdominal pain, gastric discomfort, loss of appetite, nausea and vomiting, abdominal distention, heartburn, mouth ulcers, indigestion |
| Circulatory organs | Increased blood pressure, palpitations |
| Psychoneurotic systems | Drowsiness, numbness, dizziness, headache |
| Other | Chest pain, fatigue, facial hot flashes, fever, anemia, hematuria |

- (2) The following is a list of rare side effects that you should pay special attention to and the main subjective symptoms for each. If you experience a side effect, it is common for several of the main subjective symptoms listed for each to appear at the same time. If this happens, stop taking the medicine immediately and seek medical attention.

| Symptom Names | Symptoms |
|--|---|
| Shock (anaphylaxis) | Immediately after taking the medicine, itchy skin, hives, hoarse voice, sneezing, itchy throat, breathlessness, palpitations, and confusion in consciousness may occur. |
| Blood disorders | Sore throat, fever, general lethargy, pale face and whitish underneath the eyelids, easy bleeding (bleeding gums, nose bleeds, etc.), blue bruises (color does not disappear when pressed), etc. |
| Mucocutaneous ocular syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, erythema multiforme, acute generalized exanthematous pustulosis | High fever, redness of the eyes, eye discharge, sore lips, sore throat, widespread rash/redness, blisters on red areas of the skin, etc. that persist or worsen rapidly. |
| Renal impairment | Fever, rash, decreased in urine volume, general swelling, general lethargy, joint pain (pain in the joints), diarrhea, etc. |
| Congestive heart failure | General lethargy, palpitations, shortness of breath, chest discomfort, chest pain, dizziness, fainting, etc. |
| Myocardial infarction | Clenching chest pain, breathing difficulties, cold sweats. |
| Cerebrovascular Disease | Sudden decrease or loss of consciousness, difficulty moving limbs on one side, headache, vomiting, dizziness, slurred speech, sudden difficulty speaking, etc. |
| Interstitial pneumonia | Shortness of breath or breathlessness when climbing stairs or exerting oneself a little, dry cough, fever, etc. These symptoms may appear suddenly or persist. |
| Impairment of liver function | Fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, general lethargy, and loss of appetite may occur. |
| Rhabdomyolysis | Muscle aches in limbs, shoulders, and hips; numbness, weakness, and stiffness in limbs, general lethargy, and reddish-brown urine. |
| Aseptic meningitis | Severe headache with neck tightness, fever, nausea and vomiting may occur. (These symptoms have been reported in many patients, especially those undergoing treatment for systemic lupus erythematosus or mixed connective tissue disease.) |
| Asthma | When you breathe, you may hear a wheezing sound or have difficulty breathing. |

The subjective symptoms listed above in [What caution should be taken when using this medicine?] are sorted in the following list by the location of the symptoms. If you notice any of these symptoms, please refer to the table in (2) "Side effects to especially watch out for" above.

| Parts | Subjective Symptoms |
|-------------------------|--|
| Whole body | Lower than normal body temperature, lack of strength, general swelling, oedema, fever, general lethargy, high fever, drowsiness, muscle stiffness, cold sweats |
| Head | Dizziness, severe headache with neck tightness, headache, fainting, decreased or total loss of consciousness |
| Face | Face turns pale, nosebleeds, hot flashes |
| Eyes | Whitish underneath the eyelids, yellowing of the whites of the eyes, redness of the eyes, eye discharge |
| Ears | Tinnitus |
| Mouth and throat | Vomiting blood, sore throat, bleeding gums, nausea, vomiting, dry cough (cough without phlegm), mouth ulcers, sores on lips and in mouth, hoarse voice, sneezing, itchy throat, slurred speech, sudden difficulty speaking |
| Chest | Heartburn, breathlessness, palpitations, shortness of breath, chest discomfort, clenching chest pain, chest pain, difficulty breathing, asthma (Symptoms, such as wheezing or hissing when breathing) |

| | |
|-------------------|--|
| Abdomen | Upset stomach, abdominal pain, stomach discomfort, loss of appetite, abdominal distention, indigestion, severe abdominal pain |
| Back | Back pain, muscle pain in shoulders, lower back, etc. |
| Hands/Feet | Cold hands and feet, numbness, joint pain (pain in the joints), muscle pain, difficulty moving limbs on one side |
| Skin | Hives, blue bruises, rash, redness, widespread rash/redness, blisters on red areas of the skin, yellowing of the skin, itching |
| Feces | Black tarry stools, bloody stools, diarrhea |
| Urine | Decrease in urine volume, hematuria, brown urine, reddish brown urine |
| Other | Increased blood pressure, bleeding easily |

- (3) The following symptoms may appear, but if any of those symptoms persist or increase, discontinue taking the medicine and bring these instructions to a doctor or pharmacist.

Dry mouth, constipation, diarrhea

What is included in this medicine?

LOXONIN S Red spots due to additives may appear on some tablets.

| | | |
|---------------------------|---|---------|
| Active Ingredients | 1 tablet Loxoprofen sodium hydrate (60 mg as anhydrate) | 68.1 mg |
| Additives | hydroxypropylcellulose, magnesium stearate, lactose monohydrate, red ferric oxide | |

LOXONIN S PLUS

| | | |
|---------------------------|---|---------|
| Active Ingredients | 1 tablet Loxoprofen sodium hydrate (60 mg as anhydrate) | 68.1 mg |
| | Magnesium oxide | 33.3 mg |
| Additives | lactose, cellulose, hydroxypropylcellulose, croscarmellose sodium, calcium stearate, hypromellose, titanium oxide, red ferric oxide, carnauba wax | |

LOXONIN S QUICK

| | | |
|---------------------------|---|---------|
| Active Ingredients | 1 tablet Loxoprofen sodium hydrate (60 mg as anhydrate) | 68.1 mg |
| | Magnesium aluminometasilicate | 100 mg |
| Additives | anhydrous dibasic calcium phosphate, lactose, croscarmellose sodium, hydroxypropylcellulose, magnesium stearate | |

LOXONIN S PREMIUM

| | | |
|---------------------------|---|---------|
| Active Ingredients | 2 tablets Loxoprofen sodium hydrate (60 mg as anhydrate) | 68.1 mg |
| | Allylisopropylacetylurea | 60 mg |
| | Anhydrous caffeine | 50 mg |
| | Magnesium aluminometasilicate | 100 mg |
| Additives | lactose, cellulose, hydroxypropylcellulose, croscarmellose sodium, magnesium stearate, hypromellose, titanium oxide, talc, red ferric oxide, carnauba wax | |

LOXONIN S PREMIUM fine

| | | |
|---------------------------|--|---------|
| Active Ingredients | 2 tablets Loxoprofen sodium hydrate (60 mg as anhydrate) | 68.1 mg |
| | Paeonia dry extract (252 mg as whole crude drug) | 36 mg |
| | Hesperidin | 30 mg |
| | Magnesium aluminometasilicate | 100 mg |
| Additives | D-Mannitol, cellulose, croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, hypromellose, magnesium stearate, titanium oxide, macrogol, red ferric oxide, carnauba wax | |

Other

- How is this medicine stored?
 - Store in a cool place with little humidity and out of direct sunlight.
 - Store out of reach of children.
 - Don't put in a different container. (It can lead to misuse or lowering of quality.)

[LOXONIN S]

- Do not use the product after the expiration date indicated on the outer packaging.

[LOXONIN S QUICK]

- Please do not take medicine after the expiration date.

[Loxonin S PLUS, Loxonin S PREMIUM, Loxonin S PREMIUM fine]

- Do not use the product after the expiration date indicated on the outer packaging. Also, once the aluminum bag is opened, use within 6 months.
- Write the date you opened the aluminum bag in the "Date Opened" field on the box.

Who should be contacted about this medicine?

- If you have any questions about general matters, please contact us at the address below.

Daichi Sankyo Healthcare Co., Ltd.

(<https://www.daiichisankyo-hc.co.jp/>)

Customer Relations Office

3-14-10, Nihonbashi, Chuo-ku, Tokyo, Japan zip/postal code 103-8234

TEL: 0120-337-336

Reception Hours: 9:00 am -5:00 pm (Closed on Saturdays, Sundays, national holidays, and other days the company is closed)

- If you have more questions about symptoms, side effects, etc., please contact your doctor, dentist, or pharmacist. LOX241001