

Information material for users

Please read before using.

ロキソニン 総合かぜ薬
LOXONIN® Common cold medicine

Pharmaceuticals requiring guidance

Medicine Guide for Users

Comprehensive cold medicine that contains loxoprofen sodium hydrate.

- Pregnant women within 12 weeks of the expected delivery date should not take this medicine.
- If you have taken the medicine for 5 days with no sign of symptoms abating, stop taking the medicine and seek medical attention.

Be sure to read the following instructions to follow the dosage and administration strictly.

What is this medicine?

Product Name	LOXONIN Common cold medicine
Ingredients and Quantities (Daily dosage, per 6 tablets)	Loxoprofen sodium hydrate 204.3 mg (180 mg as anhydrate) Dihydrocodeine phosphate..... 24 mg dl -methylephedrine hydrochloride..... 60 mg Bromhexine hydrochloride..... 12 mg Clemastine fumarate..... 1.34mg

What effect does this medicine have?

- This Comprehensive cold medicine that exhibits an effect on cold symptoms that contains following active ingredients including loxoprofen sodium hydrate, an antipyretic analgesic that belongs to a group called non-steroidal anti-inflammatory and analgesic drugs (NSAIDs), dihydrocodeine phosphate and dl-methylephedrine hydrochloride to relieve coughing, bromhexine hydrochloride makes it easier to transform of phlegm, and clemastine fumarate suppresses runny nose and nasal congestion.
- This medicine can be taken for the following purposes.
Relief of various symptoms of a cold (runny nose, nasal congestion, sneezing, sore throat, cough, phlegm, chills, fever, headache, joint pain, muscle pain)



What should be checked before taking this medicine? ①

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 etc. 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 to this product or the ingredients contained in this product in the past.
 - Persons who have experienced asthma after taking this medicine or other cold medicine, or antipyretic analgesics.
[Persons who have experienced asthma after taking cold medicine or antipyretic analgesics 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

What should be checked before taking this medicine? ②

The following persons should use caution when taking this medicine. Please consult your doctor or pharmacist before taking this medicine.

- 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
- Elderly people (the age of 65 or over)
- Patients who have experienced allergic symptoms associated with drugs, etc.
- Persons who have the following symptoms:
High fever, dysuria
- Persons with the following diagnoses:
 - Thyroidal functional disorder ●Diabetes ●Heart disease
 - Hypertension ●Glaucoma ●Bronchial asthma ●Ulcerative colitis
 - Crohn's disease ●Systemic lupus erythematosus
 - Mixed connective tissue disease ●Respiratory dysfunction,
 - Obstructive sleep apnea, ●Obesity
- Persons who have ever had the following diseases:
 - Stomach and duodenal ulcer ●Liver disease ●Kidney disease
 - Blood disease

What should be checked before purchasing this medicine?

- Do not take this medicine more than 5 days. Cautionary points
If you have taken the medicine for 5 days with no sign of symptoms abating, stop taking the medicine and seek medical attention.
- Do not take Other cold medicines, antipyretics, analgesics, sedatives, antitussives, expectorants, oral medicines containing antihistamine (oral medicines for rhinitis, motion sickness medicines, anti-allergic medicines, or such), while taking this medicine.
【 Other medicine that contains Anti-inflammatory ingredients [Aspirin (Acetylsalicylic Acid), Aspirin Aluminum, Ethenzamide, Ibuprofen, Acetaminophen and Isopropylantipyrine], Sedative ingredients [Allylisopropylacetylurea, Bromovalerylurea], Antitussive ingredients [Tipepidine Citrate, Cloperastine Hydrochloride, Cloperastine Fendizoate, Codeine Phosphate Hydrate, Tipepidine Hibenzone, Dextromethorphan Hydrobromide Hydrate, Dextromethorphan Phenolphthalinate, Pentoxyverine Citrate, Noscapine, Noscapine Hydrochloride Hydrate], Expectorant ingredients [Guaifenesin, Potassium Guaiacolsulfonate, Potassium Cresolsulphonate], Antihistamine Components [Chlorpheniramine Maleate, d-Chlorpheniramine Maleate, Diphenylpyraline Hydrochloride, Diphenhydramine Hydrochloride, Diphenhydramine Salicylate, Triprolidine Hydrochloride Hydrate, Promethazine Methylene disalicylate, Carbinoxamine Maleate, Mequitazine] etc.】
- Do not operate vehicles or machinery after taking this medicine.
(Drowsiness and other symptoms may occur.)
- Persons who are breastfeeding should not take this medicine or stop breastfeeding while take this medicine.
- Do not drink alcohol before or after taking this medicine.

How is this medicine used?

○Dosage and Administration


When taking this medicine, be sure to read the enclosed instructions to follow the dosage and administration strictly.

Take the following amount with cold or lukewarm water.

Age	Amount per dose	Daily dose
Adult (age of 15 and above)	2 tablets	3 times Take within 30 minutes after a meal if possible.
Under 15 years	Do not use.	

- If symptoms do not improve after 5 to 6 doses, it is possible that other diseases or complications may occur, stop taking the medicine and bring these instructions to a consultation with your doctor or pharmacist.
(Especially if a fever lasts more than 3 days or recurring)
- 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?

- Symptoms such as excessive decrease in body temperature, weakness (lack of strength), and cooling of the extremities (cold hands and feet) may occur after taking this medicine. If any of these symptoms occur, stop taking the medicine immediately and bring these instructions to your doctor or pharmacist.
-  **Cautionary points**
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 caution should be taken when using this medicine?

- (1) If the following symptoms occurs after taking this medicine, 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 system	Abdominal pain, gastric discomfort, loss of appetite, nausea and vomiting, abdominal distention, heartburn, mouth ulcers, indigestion
Cardiovascular system	Increased blood pressure, palpitations
Neuropsychiatric system	Numbness, dizziness, headache, excitement, convulsions
Urinary system	Urination difficulty, hematuria
Other	Chest pain, fatigue, facial hot flashes, fever, anemia

- (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, small pimples (small pustules) on reddened skin, general malaise, anorexia, etc. may persist or suddenly worsen.
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.
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.

Symptom Names	Symptoms
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.
Hypoventilation	Symptoms, such as shortness of breath and breathing difficulties, etc. may occur.

- (3) If any of the following symptoms appear, and persist or increase after taking this medicine, discontinue taking this medicine and consult a doctor, or pharmacist with this instruction.

Dry mouth, constipation, diarrhea, drowsiness

What is included in this medicine?

Product Name	LOXONIN Common cold medicine
Ingredients and Quantities (Daily dosage, per 6 tablets)	Loxoprofen sodium hydrate 204.3 mg (180 mg as anhydrate)
	Dihydrocodeine phosphate 24 mg
	dl -methylephedrine hydrochloride 60 mg
	Bromhexine hydrochloride 12 mg
	Clemastine fumarate 1.34 mg
Additives:	D-Mannitol, Cellulose, Hydroxypropylcellulose, Croscarmellose Sodium, Magnesium Stearate, Hypromellose, Titanium oxide, Talc, 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.)
- Do not use this medicine after their expiration dates written.

Who should be contacted about this medicine?

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

Daiichi 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 Saturday, Sunday, and holidays)

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



Manufacturer and seller

Daiichi Sankyo Healthcare Co., Ltd.

Daiichi-Sankyo 3-14-10, Nihonbashi, Chuo-ku, Tokyo, Japan