

Loxonin S Tape/Tape L, Loxonin S Poultice, Loxonin S Gel

Check sheet

Before use, please check that this product can be used according to this flowchart.

Please answer **Yes** or **No**. (Tick appropriate checkboxes.)

Do you correspond to any of the following?

- Having had an allergic symptoms with this medicine or its ingredients.
- Having had an asthma by taking this medicine, or other antipyretic analgesics, cough/cold remedies, topical anti-inflammatory analgesics.
- Aged under 15 years old

Yes

Do not use.

Allergic symptoms or asthma attack may recurrent if you have experienced such symptoms in the past

No

Do you correspond to any of the following?

- Being treated by a physician
- Women who is pregnant or supposed to be pregnant
- Having diagnosed as having the following disease : bronchial asthma
- Having experienced allergic symptoms with medicines, etc.
- The elderly

Yes

Consult a physician or pharmacist before using these medicines, as it may not suitable for you

No

You can use Loxonin S Tape/Tape L, Loxonin S Poultice, and Loxonin S Gel.
Please be informed by pharmacist, and read the information carefully on the outer box (or the package insert for Gel) before use.

Please keep the following instructions in using these medicines

- These medicines should not be applied on the following body parts:
 - ① Surrounding area of the eyes, mucosal membrane, etc.
 - ② [For Gel only] Sensitive areas of the skin (face, arm pit, etc.)
 - ③ Eczematous skin, irritated skin, wounded site
 - ④ Athlete' s foot/tinea or purulent lesions
- Do not use other topical anti-inflammatory medicine while using these medicines
- Do not use these medicines continuously for more than 2 weeks.

These medicines does not cure the disease which is causing pain or inflammation, but temporarily relieve the symptoms. Consult a physician if the symptom continues. If you have any questions about the use of these medicines, please consult a pharmacist.

Please read this instruction before use

Start date of use

Loxonin S Tape/Tape L, Loxonin S Poultice, Loxonin S Gel

Year, Month, Day

What are these medicines?

| Brand name | Loxonin S Tape/Tape L | Loxonin S Poultice | Loxonin S Gel |
|-------------------|---|--|------------------------------------|
| Active ingredient | Loxoprofen sodium hydrate | | |
| Content | 5.67 g in 100 g of plaster (5 g as anhydride) | 1.134 g in 100 g of plaster (1 g as anhydride) | 1.13 g in 100 g (1 g as anhydride) |

These medicines are topical preparations containing loxoprofen sodium hydrate, classified in the group called non-steroidal anti-inflammatory drugs (NSAIDs), as an active ingredient. Loxoprofen sodium hydrate alleviates pain and swelling by blocking the production of "prostaglandin," a substance that causes pain/inflammation.

What are these medicines used for?

These medicines are effective in the treatment of low back pain, shoulder pain associated with stiff shoulder, joint pain, muscle pain, peritendinitis (pain in the hand/wrist), elbow pain (e.g., tennis elbow), bruise, and sprain.

What should be confirmed before using these medicines?

Following persons should not use these medicines:

- Persons who have experienced allergic reaction (such as rash/redness, itching, etc.) in association with these medicines or their ingredients. (Allergic symptoms may recurrent.)
- Persons who have experienced asthma after using these medicines, other antipyretic analgesics, cough/cold medicines, or topical anti-inflammatory drug.* (Asthma attack may recurrent by non-steroidal anti-inflammatory ingredients)
[* Typical ingredients: aspirin (acetylsalicylic acid), aspirin aluminum, acetaminophen, isopropylantipyrine, ibuprofen, indomethacin, ethenzamide, diclofenac sodium, felbinac, and loxoprofen sodium hydrate]
- Children under 15 years old.

These medicines should not be applied on the following body parts:

- Surrounding area of the eyes, mucosal membrane, etc. (Severe irritation or pain may occur)
- Sensitive areas of the skin (face, arm pit, etc.)
*For Gel only (severe irritation or pain may occur)
- Eczematous skin, irritated skin, wounded site (Damaged skin tends to be irritated, and eczematous skin may be worsened)
- Athlete's foot/tinea or purulent lesions (Symptoms may be worsened)

Following persons should pay attention in using these medicines. Consult a physician or pharmacist before use them.

- Persons who are currently seeing a physician (for treatment or administrating medicines for following diseases: treatment may be affected by concomitant use of drugs prescribed by the physician)
- Persons who have experienced allergic symptoms (rash/redness, itchiness, irritation) associated with medicines, etc. (Use of similar medicines should be avoided.)
- Women who is pregnant or supposed to be pregnant. (Since the medicines may adversely affect the fetus, due caution must be exercised when using medicines)
- The elderly (In general, skin of the elderly are relatively sensitive, and it is reported that the incidence of skin disorder is high in the elderly. Attention must be paid to the skin condition at the site of application)
- Persons diagnosed as having the following disease;
Bronchial asthma (Clinical condition may be worsened)

These medicines do not cure the disease which is causing pain or swelling, but are exclusively designed to treat symptoms such as pain and swelling. For this reason, only use these drugs when you have a relevant symptom.

How should these medicines be used?

[Loxonin S Tape/Tape L]

(Dosage and administration)

Peel off the liner (film) on the surface of Tape, and apply it to the affected area, **once daily**.

(Directions for Use)

- Do not use more than four pieces of Tape, or two pieces of Tape L, on the whole body per day.
- When the affected area is sweaty or wet, wipe it off well before use.
- Before using Tape/Tape L, persons who have sensitive skin are advised to confirm the availability of these medicines. Apply the small piece of Tape/Tape L, 1cm×1cm to 2cm×2cm square, on the inside of the arm for more than a half day, and check whether any symptoms such as rash/redness, itchiness, or irritation appears or not.

① Peel off the center part of film by slightly bending the Tape.

② Apply the center part of the adhesive side of Tape, where film was removed area, on the affected area to fix position.

③ Pinch the edge of left film, and slowly remove the film one by one. Whichever side of film can be removed earlier.



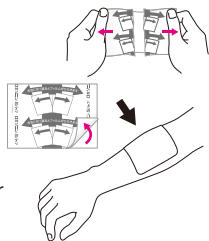
[Loxonin S Poultice]

(Dosage and administration)

Peel the liner (film) on the surface of Poultice, and apply it to the affected area, **once daily**.

(Directions for Use)

- Do not use more than two pieces of Poultice on the whole body per day.
- When the affected area is sweaty or wet, wipe it off well before use.
- Before using Poultice, persons who have sensitive skin are advised to confirm the availability of these medicines. Apply the small piece of Poultice, 1cm×1cm to 2cm×2cm square, on the inside of the arm for more than a half day, and check whether any symptoms such as rash/redness, itchiness, or irritation appears or not.



[Loxonin S Gel]

(Dosage and administration)

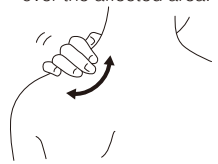
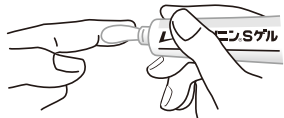
Apply an appropriate amount of Gel to the affected area, **three to four times per day**.

(Directions for Use)

- Do not cover the applied site with a plastic film or other non-breathing materials. (May cause irritation, or increase the permeability of the drug to increase stimulation.)
- Do not use more than 8 cm (approx. 2 g) on the whole body per application, or more than a total of 50 g per week.
- Be careful not to apply to the eyes. If the drug reaches the eyes, immediately wash it off with water or lukewarm water. When a severe symptom appears, please consult an ophthalmologist.
- Persons who are hypersensitive to alcohol should not use Gel, as it contains ethanol.
- This medicine is only for external use.
- Wash your hands after use.

① Squeeze one dose of Gel from tube.

② Spread Gel in a thin layer over the affected area.



※Recommended dose per application

Shoulder, elbow, knee : Approx. 2-3 cm (approx. 3 g in total with 4 doses)

Low back : Approx. 3-5 cm (approx. 6 g in total with 4 doses)

What attention should be payed while using these medicines?

- Following symptoms may appear while using these medicines. As such symptoms may be side effects, stop using these medicines immediately. Then consult a physician or pharmacist, bringing the box of the product (or the package insert for Gel) .

| Affected site | Symptoms |
|------------------------|---|
| Skin | Rash/redness, itching, swelling, burning sensation, rash, blisters, bruise*, and pigmentation |
| Gastrointestinal tract | Stomach discomfort, pain in pit of stomach |
| Other | edema |

※Only for Tape, Tape L, and Poultice

- Following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid.

| Type of symptoms | Symptoms |
|---------------------|--|
| Shock (anaphylaxis) | Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness, those occurred immediately after use. |

- Following symptoms may appear while using these medicines. If such symptoms continue or get worsen, stop using these medicines. Then consult a physician or pharmacist, bringing the box of the product (or the package insert for Gel) .
Diarrhea, Soft stool
- Do not use thee medicines continuously for more than 2 weeks. These medicines are designed to control pain temporarily. If the pain or other symptoms* continue, stop using these medicines. Then ask a physician for medical treatment, bringing the box of the product (or the package insert for Gel) .
*In the elderly, there are many cases with fracture by low external force (fragility fracture) owing to decreased bone strength. If the pain or other symptoms continue, consult with an orthopedist.
- If the symptoms were not improved after using the medicines for five to six days, stop use and consult a physician or pharmacist taking the outer box of the medicine (or the package insert for Gel) as you may have some other problem*.
*Consult a dermatologist when a new skin rash (e.g., herpes zoster) appears.
- Do not use other topical anti-inflammatory medicines having similar effects while using these medicines. (Concomitant use may intensify side effects.)

What are the dosage forms of these medicines?

| Brand name | Loxonin S Tape | Loxonin S Tape L | Loxonin S Poultice | Loxonin S Gel |
|-------------|----------------|------------------|--------------------|----------------|
| Dosage form | Tape | Tape | Poultice | Gelatinous gel |
| Size | 7cm×10cm | 10cm×14cm | 10cm×14cm | — |

What are the ingredients of these medicines?

| | |
|-------------|--|
| Brand name | Loxonin S Tape/Tape L |
| Dosage form | 5.67 g of loxoprofen sodium hydrate in 100 g of plaster (5 g as anhydride) |
| Size | Styrene-isoprene-styrene block copolymer, polyisobutylene, hydrogenated rosin glycerol ester, BHT, l-menthol, liquid paraffin, and other 2 ingredients |

| | |
|-------------|---|
| Brand name | Loxonin S Poultice |
| Dosage form | 1.134 g of loxoprofen sodium hydrate in 100 g of plaster (1 g as anhydride) |
| Size | Peppermint oil, polysorbate 80, titanium oxide, tartaric acid, disodium edetate, glycerol, carmellose sodium, talc, dried aluminum hydroxide, crotamiton, partially neutralized polyacrylic acid, and other 2 ingredients |

| | |
|-------------|---|
| Brand name | Loxonin S Gel |
| Dosage form | 1.13 g of loxoprofen sodium hydrate in 100 g of gel (1 g as anhydride) |
| Size | Ethanol, 1,3-butylene glycol, hypromellose, carboxyvinyl polymer, and triethanolamine |

Other information

- How should these medicines be stored?
[Loxonin S Tape/Tape L, Loxonin S Poultice]
 - Store in a cool, dry, low humidity area away from direct sunlight.
 - Keep out of reach of children.
 - Do not transfer to other containers. (May lead to misuse or change in quality)
 - To maintain the quality, keep unused tapes/poultices in the bag sealed tightly.

[Loxonin S Gel]

- Seal tightly and store in a cool area away from direct sunlight.
 - Keep out of reach of children.
 - Do not transfer to other containers. (May lead to misuse or change in quality)
 - Do not place the medicine close to fire. (This medicine contains ethanol)
 - Be careful not to allow gel past to contact floor, furniture, eyeglasses as these medicine may melt chemical fibers, plastics, and paints.
- Do not use these medicines after their expiration dates.

Contact Information for Inquiries

- For more specific questions (symptoms, usage, side effects, etc.), please contact a physician or pharmacist.
- For general questions, please contact the Customer center.

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<http://www.daiichisankyo-hc.co.jp/>

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(except Sat., Sun., public holiday and company holiday)