

Product information

【Drug Facts】



＜Kyowa-Gifu-Japan＞

Please be sure to read this product information carefully before use. Keep this product information in a safe place so that you can read again, when you need it.

Class 3 drugs

Mouth Ulcer

(TABLETS)

OLOFANIC TX JYOU

It contains tranexamic acid about an anti-inflammatory component, and effects under inflammation to reduce sore throat and swelling, and to suppress painful sores. It also contains vitamin B2, vitamin B6 and vitamin C, which function normally on the skin and mucous membranes.

Active ingredients (in 6 tablets/daily dose)

Purpose

Tranexamic acid	750mg	Antiplasmin ingredient
Dried licorice extract	198mg	Suppress the sore throat
Pyridoxine hydrochloride	50mg	Vitamin B6 supplementation
Riboflavin	12mg	Vitamin B2 supplementation
L-Ascorbic acid sodium	500mg	Vitamin C supplementation

[PRECAUTIONS CONCERNING INGREDIENTS]

- (1) Urine may become yellow due to riboflavin (vitamin B2) contained in this medicine.
- (2) By taking this medicine, medical test values may be affected about urine and stool. In this case, please notify the doctor that you are taking the medicine containing vitamin C.

Uses

Stomatitis, Pharyngitis, Tonsillitis (a swelling throat, sore throat).

Warnings

Do not use for children under 7 years old.

[To be avoided]

(Failure to observe the following may result in the current symptoms worsening or adverse reactions/ accidents occurring.)

1. Do not take this medicine for the next person.

A person who is receiving dialysis. (Convulsions may appear.)

2. Please do not take any of the following medical components while taking this medicine.

- (1) Internal medicine containing Glycyrrizhae radix (licorice) or its main component glycyrrhizin. (Swelling, elevated blood pressure and muscle disease (myopathy) etc. may occur.)
- (2) Another medication for allergy, and oral medication containing tranexamic acid. (Rhinitis medicine, cold medicine, antipyretic analgesic medicine, antitussive expectorant, etc.)

3. Please do not take long-term continuously.

[Consultation]

1. The following persons should consult a doctor, pharmacist, or registered distributor before taking this medicine.

- (1) A person undergoing medical treatment from a doctor or dentist.
- (2) A pregnant woman or a woman suspected of being pregnant.
- (3) Senior persons.
- (4) A person who have ever had allergic symptoms due to any medication.
- (5) A person with the following symptoms: Swelling.
- (6) A person diagnosed as having the following:

High blood pressure, Heart disease, Kidney disease, Thrombus (Brain thrombosis, Myocardial infarction, Thrombophlebitis, etc.), and a person who may develop Thrombosis.

2. The following symptoms may be adverse reactions to this medicine. If any of these symptoms occur, discontinue use immediately and consult a doctor, pharmacist, or registered distributor with the Japanese package insert.

Related area	Symptoms
Skin	Rash · Redness, Itching.
Digestive organ	Nausea / vomiting, heartburn, loss of appetite or increased appetite, stomach discomfort.
Cental nervous system	Dizzy.
Others	Frequent urination.

In rare cases, the following serious symptoms may occur. In that case, please get medical attention immediately.

Symptom name	Symptom
Pseudoaldosteronism, Myopathy	In addition to the languor, numbness, firmness and stiffness of the hands and feet, weakness and muscle pain appear, gradually becoming stronger.

3. The following symptoms may appear after taking it, so if such symptoms persist or increase. Please stop taking it and consult a doctor, pharmacist or registered distributor with the Japanese package insert.

Diarrhea

4. If symptoms do not improve after using between 5 and 6 days, stop taking the medicine, bring the Japanese package insert, and consult a doctor, pharmacist or registered distributor.

Directions

The following daily dose on three times a day after meals.

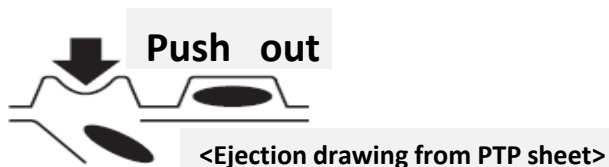
Age	One dose	Number of doses per day
adult and children 15 years old and over	2 tablets	3 times
children 7 years old to under 15 years old	1 tablet	
children under 7 years old	Do not use	

[When using this product]

- (1) Please follow the recommended dosage and directions.
- (2) Can be took any before or after meals.
- (3) This medicine should be given to children only under adult supervision.
- (4) When using this medicine for the first time,

Please push the projection of the PTP sheet containing tablets strongly with your fingertips as shown below, break the aluminum sheet on the back side, push out and take it.

(If you mistakenly swallow the PTP sheet as it is, it leads to an unexpected accident such as stabbing into the esophagus mucosa.)



Other information

- (1) Store in a cool and dry with less humidity place free from direct sunlight by a seal tightly.
- (2) Keep all medicine out of the reach of children.
- (3) Do not transfer this medicine to a different container. (In this case, cause misuse or change quality.)
- (4) Do not handle this medicine with wet hands. (If water gets on the tablet, the surface may be partially melted to cause discoloration or uneven color.)
- (5) Please do not take the medicine that have passed the expiration date.

Inactive ingredients:

Cellulose, Hydroxypropyl cellulose, Silicon dioxide, Cross CMC-N, Sucrose fatty acid ester, Hypromellose, Macrogol, Titanium oxide, Talc and Ferric oxide.

Questions or comments

If you have any suggestions about this product, please contact the shop you purchased or the following address.

Consumer consultation window: Kyowa Pharmaceutical Industry Co., Ltd.
Customer consultation room ☎ 058-246-8771

Reception time 9:00~12:00・13:00~17:00 (Excluding weekends and holidays)

[Request of limited correspondence] **<Kyowa-Gifu-Japan>**

- (1) In case of telephone consultation, please only in Japanese for a while.
- (2) The latest Japanese package insert is available on the website of Kyowa Pharmaceutical Co., Ltd. (www.kyowa-ci.co.jp).

Disclaimer statement

- (1) We use a format similar to the FDA OTC Drug Regulations, but this is not an OTC Drug approved under the FDA. Please note that it is licensed for domestic use in accordance with the Pharmaceutical Affairs Law of Japan.

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