Revision January 2024

Product information

[Drug Facts]

Ҟ <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

Medicine for the oral cavity and throat

(TABLETS)

PALWIN 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)] Effects

Tranexamic acid 750mgAntiplasmin ingredientDried licorice extract198mgSuppress the sore throat(equivalent to 990mg of the herbal medicine Glycyrrhiza Radix)Pyridoxine hydrochloride50mgVitamin B6 supplementationRiboflavin12mgVitamin B2 supplementationL-Ascorbic acid sodium500mgVitamin C supplementation

〈PRECAUTIONS CONCERNING INGREDIENTS〉

- (1) Urine may become yellow due to riboflavin (vitamin B2) contained in this medicine.
- (2) Taking this drug may affect urine and stool test values. If you are being tested by your doctor, let him or her know that you are taking any preparations containing vitamin C.

[Indication]

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

\land [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.)

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

Patients undergoing dialysis. (Convulsions may appear.)

- 2. Please do not take any of the following medical components while taking this medicine.
- (1) Internal medicine containing Grycyrrizhae 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 contact a physician, pharmacist, or registered salesperson for a consultation before administration.
- (1) Patients undergoing medical treatment from a physician or dentist.
- (2) Pregnant women or women suspected of being pregnant.
- (3) The elderly
- (4) Patients who have had an allergic symptom to this drug or its ingredients.
- (5) Persons with the following symptoms:

Oedema

(6) Persons diagnosed as having the following

Thyroid dysfunction, diabetes, heart disease, hypertension, liver disease, Stomach and duodenal ulcer, glaucoma, systemic lupus erythematosus, mixed connective tissue disease, respiratory dysfunction, obstructive sleep apnea syndrome, obesity.

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 salesperson 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 salesperson with the Japanese package insert.

Diarrhea

4. If these symptoms are not good even after taking between 5 and 6 times, please stop taking the medicine and consult a doctor, pharmacist or registered salesperson with the Japanese package insert.

【Dosage and administration】

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	2 tablets 3 times 1 tablet	
children 7 years old to under 15 years old	1 tablet		
children under 7 years old	Do not use		

<Precautions regarding usage and dosage>

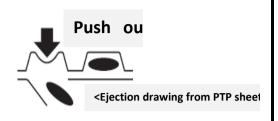
- (1) Please follow the recommended dosage and directions.
- (2) Can be took any before or after meals.

(3) This medicine should be given to children only under adult supervision.

(4) How to take out the tablet.

As shown in the image on the right, firmly press the convex part of the PTP sheet containing the tablet with your fingertips, break the aluminum foil on the back, take it out, and take it.

(If you accidentally swallow it whole, it may lead to unexpected accidents such as sticking to the esophageal mucosa.)



[Precautions for storage and handling]

(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 drug with wet hands. (If water gets on the tablet, part of the surface may melt, causing discoloration or uneven color.)
- (5) Please do not take the medicine that have passed the expiration date.
- (6) Once you open the inner bag (made of aluminum), please use it within 6 months after opening to maintain quality.

[Inactive ingredients]

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

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.



Reception time $9:00 \sim 12:00 \cdot 13:00 \sim 17:00$ (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.
- (2) This English translation was created by a manufacturer and distributor, but Japanese is a correct sentence and it should be as a reference material. In the case of any discrepancy between the two versions, the original Japanese version prevails.
- (3) The provider of this translation shall not be responsible for any damage that may be attributed to the use of the translation.
- (4) Do not use for commercial purpose reproduction, publication etc. of this English translation.
- (5) This English translation has been created based on the Japanese attached document, but since the attached document is revised from time to time, it may not be the latest translation.