

Revised: June 2017 (8th version, change of trade name)
 Revised: June 2009 (7th version)

Vitamin E Preparation
TOCOPHEROL ACETATE TABLETS 50mg "TOWA"

Storage:




Store at room temperature. (avoiding moisture after opening the package)

Expiration date:

Indicated on the package and label

Standard Commodity Classification No. of Japan 87315	
Approval No.	22900AMX00120
Date of listing in the NHI reimbursement price	June 2017
Date of initial marketing in Japan	January 1969
Date of result of reevaluation	September 1995

DESCRIPTION

Active ingredient per tablet	Tocopherol Acetate (JP)..... 50 mg		
Inactive ingredient	Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Magnesium Aluminometasilicate, Carmellose Sodium, Carmellose Calcium, Magnesium Stearate, White Soft Sugar, Precipitated Calcium Carbonate, Talc, Powdered Acacia, Titanium Oxide, Gelatin, Potato Starch, Polyoxyethylene (105) Polyoxypropylene (5) Glycol, Yellow No.5		
Product description	Orange sugar-coated tablets		
Identification code	Tablet	Tw303	
	Package		
Appearance	Top surface	Bottom surface	Side surface
			
Diameter (mm)	10.5		
Thickness (mm)	6.0		
Weight (mg)	500		

INDICATIONS

- 1) Prevention and treatment of vitamin E deficiency
- 2) Peripheral circulatory disorders (intermittent claudication, arteriosclerosis, venous thrombosis, thrombophlebitis, diabetic retinopathy, chilblain, feeling of coldness in the extremities)
- 3) Prevention of increase of lipid peroxides
 For the indications other than the above 1), Tocopherol Acetate Tablets should not be administered unthoughtfully for a number of months if no response to treatment is observed.

DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 50-100mg of tocopherol acetate at a time, twice or 3 times daily. The dosage may be adjusted according to the patient's age and symptoms.

PRECAUTIONS**1. Adverse Reactions**

No investigation such as a drug use investigation clearly showing the incidence of adverse reactions has been conducted.

	Incidence unknown
Gastrointestinal	Constipation, stomach discomfort, diarrhea
Hypersensitivity	Rash

2. Precautions Concerning Use

Precautions regarding dispensing:

For drugs that are dispensed in a PTP (press-through package) sheet, instruct the patient to remove the drug from the package prior to use [It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, causing perforation and resulting in severe complications such as mediastinitis.]

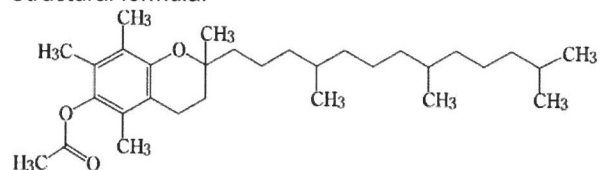
PHARMACOKINETICS**1. Bioequivalence test**

<Reference data>

In a cross-over study, single doses of 6 tablets of Tocopherol Acetate Tablets 50mg "TOWA" and 6 tablets of a reference drug (equivalent to 300 mg of tocopherol acetate) were orally administered to male beagles (n = 10) under fasted conditions; serum free tocopherol concentrations were measured, and stochastic analysis was performed to compare the measurement results. According to the analysis results, it has been estimated that there is no significant difference in the bioavailability of these drugs.¹⁾

PHYSICOCHEMISTRY

Structural formula:



Nonproprietary name:

Tocopherol Acetate

Commonly used name:

Tocopherol acetate

Chemical name:

2,5,7,8-Tetramethyl-2-(4,8,12-trimethyltridecyl) chroman-6-yl acetate

Molecular formula:

C₃₁H₅₂O₃

Molecular weight:

472.74

Description:

Tocopherol Acetate is a clear, colorless or yellow, viscous and odorless liquid.

It is miscible with ethanol (99.5), with acetone, with chloroform, with diethyl ether, with hexane and with vegetable oils.

It is freely soluble in ethanol (95), and practically insoluble in water. It is optically inactive. It is affected by air and light.

PRECAUTIONS FOR HANDLING

Stability test

In a long term stability test using final packaged products (at room temperature for 3 years), Tocopherol Acetate Tablets 50mg "TOWA" was confirmed to be stable for 3 years under normal distribution conditions²⁾

PACKAGING

TOCOPHEROL ACETATE TABLETS 50mg "TOWA":
Boxes of 100 tablets, 1,000 tablets (PTP)
Polyethylene containers of 1,000 tablets

REFERENCES

- 1) Internal data of Towa Pharmaceutical Co., Ltd.:
Bioequivalence test
- 2) Internal data of Towa Pharmaceutical Co., Ltd.:
Stability test

Manufacturer and Distributor
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