※※Revised: June 2017（6th version）
※ Revised: December 2016

Standard Commodity Classification No. of Japan:
873172

Storage : Store at a cold light-proof place
Expiration date : Do not use after the expiration date indicated on the outer package

Prescription drug
(Caution – Use only pursuant to the prescription issued of physician, etc.)

Multi Vitamin Preparation

Plevita S Injection "FUSO"

Approval No.	(60AM) 4105
Date of listing in the NHI reimbursement price	August 1985
Date of initial marketing in Japan	August 1985
Date of latest reexamination	July 1985

CONTRAINDICATIONS (Plevita S Injection is contraindicated in the following patients.)

Patients with a history of hypersensitivity to this product and thiamine chloride hydrochloride.

**DESCRIPTION

In a 5 mL ampoule

Brand name	Plevita S Injection	
Ingredient/content	JP thiamine chloride hydrochloride	10 mg
	JP riboflavin phosphate ester sodium (5 mg as riboflavin)	6.355 mg
	JP ascorbic acid	200 mg
Excipient	Propylene glycol 50 mg, taurine 20 mg, citric acid monohydrate, pH adjuster	
Dosage form	Aqueous injection	
Description	Yellow to orange yellow clear solution	
pH	4.5 - 5.5	
Osmotic pressure	Ca. 2 (ratio to physiological saline)	

INDICATIONS

Supplementation of the vitamins in Plevita S Injection when their demand increases and intake from meals is insufficient (wasting disease, during pregnancy and delivery, nursing women, etc.)
Plevita S Injection should not be aimlessly administered when an effect is not achieved.

DOSAGE AND ADMINISTRATION

Usually, for adults, administer 5 to 10 mL of Plevita S Injection per day by intravenous injection or intravenous infusion after mixing with a glucose solution, electrolyte, physiological saline or total amino acid injection solution, etc.
The dose may be increased or decreased according to age and symptom.

PRECAUTIONS

1. Adverse Reactions
No such investigations have been performed that can definitely determine the incidence of adverse drug reactions (e.g., Drug Use Results Surveys) in patients treated with this product.

(1) **Clinically significant adverse reactions** (incidence unknown)
Shock: Since shock may develop, administration should be immediately discontinued and appropriate measures taken when symptoms such as decreased blood pressure, precordial oppression, or dyspnea, etc. develop.

(2) **Other adverse reactions**

	Incidence unknown
Hypersensitivity Note)	Rash, pruritus, etc.
Gastrointestinal	Nausea/vomiting, etc.

Note) Administration should be discontinued when hypersensitivity develops.

2. Effects on Laboratory Tests
(1) Plevita S Injection may interfere with the detection of urinary glucose in various urinary glucose tests (due to ascorbic acid).
(2) Results of various urinalyses (occult blood, bilirubin, nitrite) and fecal occult blood tests may become pseudo-negative (due to ascorbic acid).
(3) Urine may turn yellow and affect laboratory tests (due to riboflavin phosphate ester sodium).

****3. Precautions for Use**
(1) **When cutting an ampoule:** Plevita S Injection uses a clean-cut ampoule (CC ampoule) that aims to prevent the solution from being contaminated with microparticle glass when cutting the ampoule. As with conventional products, it is desirable to clean the ampoule with ethanol before use to ensure further safety.
(2) **Precaution before preparation:** When this product is mixed with an amino acid preparation, decomposition of vitamins may be accelerated.
(3) **Injection rate:** Since angialgia may develop by intravenous administration, this product should be administered as slowly as possible.
(4) **Precaution before administration:** Place a light-proof cover (orange, yellow, or brown polyethylene cover, etc.) on the infusion bottle or infusion bag to prevent photolysis of vitamins.

**PHARMACOLOGY

◇ **Thiamine**
Thiamine (vitamin B_1) is converted into thiamine diphosphate in the presence of ATP and manifests its physiological action. It is involved in the metabolism of glucose, protein, and lipid; decarboxylation of pyruvate which holds an important position as a barrier in the TCA cycle; and decarboxylation of α-ketoglutaric acid in the TCA cycle. It is also involved in glycometabolism and nucleic acid metabolism in the pentose phosphate pathway as a coenzyme of transketolase.[1)]

◇ **Riboflavin**
After absorption, riboflavin (vitamin B_2) goes through phosphorylation in the small intestine and liver and becomes flavin mononucleotide (FMN). Most of it is converted into flavin adenine dinucleotide (FAD) by the action of ATP. FAD and FMN act on the cellular oxidation-reduction system and mitochondrial electron transmission system as coenzymes of flavin enzyme, and are widely involved in the biological metabolism of glucose, lipid, and protein.[2)]

◇ **Ascorbic acid**
A typical deficiency of ascorbic acid (vitamin C) is scurvy, which increases bleeding tendency, delays development of the bone/tooth, and lowers antibody production and wound healing ability. Administration of vitamin C is effective for these diseases and symptoms, but its physiological significance and action have not been fully elucidated. It was reported that vitamin C is involved in collagen production, in the improvement of bleeding tendency by enhancement of capillary vascular resistance and shortening of blood coagulation time, in adrenocortical function (suppression of stress reaction), and in suppressed formation of melanin pigment.[3)]

PRECAUTIONS FOR HANDLING

◇ **Stability study
In a long-term storage study (15ºC for 2 years) of the final package product, all test parameters were within the specification range, and the product was confirmed to be stable for 2 years under ordinary marketing distribution.[4)]

PACKAGING

Plevita S Injection 5 mL 50 ampoules brown glass ampoule

REFRENCES

**1) 17th Japanese Pharmacopoeia Manual, C-3053（2016）

**2) 17th Japanese Pharmacopoeia Manual, C-5819（2016）

**3) 17th Japanese Pharmacopoeia Manual, C-69（2016）

**4) Stability study : On file at Fuso Pharmaceutical Industries, Ltd.

Manufactured and Marketed by:

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