Revised: April 2023 (1st version)

Standard Commodity Classification No. of Japan:
87319

Storage : Store at room temperature.
Expiration date : 3 years

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

Vitamin H preparation

Biotin Injection 1mg "FUSO"

Approval No.	21800AMX10535
Date of initial marketing in Japan	October 1959

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product name	Biotin Injection 1mg "FUSO"
Volume	2 mL
Active Ingradients	In one ampoule, Japanese Pharmacopoeia Biotin 1mg
Inactive Ingredients	In one ampoule, Sodium acetate anhydrous Sodium chloride Sodium hydroxide pH adjuster

3.2 Product Description

Product name	Biotin Injection 1mg "FUSO"
Dosage form	Aqueous injection
Appearance	Clear and colorless liquid
pH	6.0 – 7.0
Osmotic pressure ratio (ratio to saline)	1.0 – 1.1

4. INDICATIONS

Acute/chronic eczema, pediatric eczema, contact dermatitis, seborrheic eczema, acne vulgaris

6. DOSAGE AND ADMINISTRATION

The usual adult dosage of biotin is 0.5 to 2 mg per day for subcutaneous, intramuscular, or intravenous injection.
The dosage may be adjusted according to age and symptoms.

7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION

7.1 Daily dosage

	1 day pitch and volume
Injection 1 mg	1～4mL

14. PRECAUTIONS CONCERNING USE

14.1 Precautions Concerning Administration of the Drug

14.1.1 Intramuscular injection

To avoid affecting the tissues and nerves, please note the following points.

・ Intramuscular injections should only be given when absolutely necessary, and should be kept to a minimum.

In addition, repeated injections in the same area should be avoided. Also, special care should be taken with low birth weight babies, newborns, infants, young children and children.

・ Care should be taken to avoid areas where nerves run.

・ If the patient complains of severe pain or if blood flows back when the needle is inserted,immediately remove the needle and inject at a different site.

16. PHARMACOKINETICS

16.1 Blood Concentration

16.1.1 Single dose

Twenty healthy adults were given a single intramuscular (10 cases) or subcutaneous (10 cases) dose of 0.03 mL/kg (0.015 mg/kg as biotin) of 1 mg of biotin injection "Fuso". When administered intramuscularly, the concentration of free biotin in the whole blood reached its highest level (3.7 ng/mL) after 40 minutes, and then gradually decreased to 0.9 ng/mL after 6 hours. The half-life in the blood was about 3 hours. When administered subcutaneously, the concentration of free biotin in the whole blood reached its maximum (3.8 ng/mL) after 20 minutes, and then gradually decreased to 0.9 ng/mL after 6 hours. The half-life in the blood was about 3 hours 1).

18. PHARMACOLOGY

18.1 Mechanism of Ation

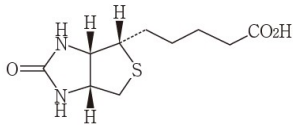
Biotin is biosynthesized mainly by intestinal bacteria and is an essential coenzyme for fatty acid synthesis and carboxylation reactions. In addition, although the details are unknown, it has also been reported to have indirect biochemical effects, such as purine synthesis, protein synthesis, sugar metabolism, deamination enzyme action, and dehydration enzyme action.

18.2 Effects on Biotin Deficiency

It is said that biotin deficiency in humans can be caused by a large intake of egg white or by a disruption in the balance of intestinal flora due to the oral administration of antibiotics with a wide antibacterial spectrum or sulfonamides.
The symptoms of deficiency include scaly or patchy dermatitis, atrophy of the papillae of the tongue, muscle pain, and fatigue 2).
In addition, it has been reported that the degeneration of sebum, increased secretion, and fat degeneration of the stratum corneum of the skin occur, and that infants are more susceptible to eczema when biotin is lacking in their milk 3).
These symptoms have been shown to improve with the administration of biotin.

19.PHYSICOCHEMICAL FINDINGS ON THE ACTIVE INGREDIENT

Nonproprietary name: Biotin
Structural formula:



Molecular formula: C10H16N2O3S
Molecular weight: 244.31
Chemical name: 5-[(3aS, 4S, 6aR)-2-oxohexahydro-1H-thieno [3,4-d] imidazol-4-yl] pentanoic acid
Description: Biotin occurs as white crystal or crystalline powder. It is very slightly soluble in water or ethanol (99.5) and soluble in dilute sodium hydroxide reagent.
Melting point: ca. 231°C (decomposition)

22. PACKAGING

2 mL, 50Ampules, Glass Ampoule

23. REFERENCES

1) In-house data: blood concentration
2) Sydenstricker, V. P., et al.: J. Am. Med. Assoc. 1942; 118: 1199-1120
3) Nisenson, N.: Pediatrics. 1969; 44: 1014-1016

26. MARKETING AUTHORIZATION HOLDER, ETC

26.1 Manufactured and Marketed by

FUSO PHARMACEUTICAL INDUSTRIES, LTD.
2-3-11, Morinomiya, Joto-ku, Osaka 536-8523, Japan