

108 San'oshashinto

	Date of Making or Revision of Package Insert	Product Name Manufacturer Distributor	Approval No. Date of Initial Marketing in Japan	Dose for One Day (g)	Extract Content in One Day Dose (g)	Inactive Ingredients	Dosage Form	ID Code (Item Number, etc.)	Indications	Daily Dosage and Administration (Adult)	Packaging	Component Ratio		
												Rhubarb	Scutellaria Root	Coptis Rhizome
1	Revised: Sep 2023 (1st version)	<b>Honzo San'oshashinto Extract Granules-M</b> Honzo Pharmaceutical Co., Ltd.	16100AMZ04148000 Oct 1986	7.5	0.7	Lactose Hydrate, Magnesium Aluminometasilicate, Magnesium Stearate	Granules	H13	A	before or between meals, 3 times	500g (loose) [bottle] 2.5g x 294 packets [sachets] 2.5g x 42 packets [sachets]	2.0	1.0	1.0
2	Revised: Dec 2023 (1st version)	<b>JPS San'oshashinto Extract Granules for Ethical Use</b> JPS Pharmaceutical Co., Ltd.	16100AMZ04659000 Oct 1987	2.5	0.7	Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate	Granules	J-113	A	before or between meals, once	750g (2.5g x 300 packets) 105g (2.5g x 42 packets)	1.0	1.0	1.0
3	Revised: Jan 2023 (1st version)	<b>Kotaro San'oshashinto Extract Capsules</b> Kotaro Pharmaceutical Co., Ltd.	16100AMZ04028000 Oct 1986	0.84 (3 capsules)	0.6	Carmellose Calcium, Light Anhydrous Silicic Acid, Microcrystalline Cellulose, Synthetic Aluminum Silicate, Magnesium Stearate, Corn Starch, Hydroxypropyl Starch, Magnesium Aluminometasilicate Capsule Materials: Food Blue No.1, Food Yellow No.5, Food Red No.3, Titanium Oxide, Gelatin, Sodium Lauryl Sulfate	Capsules	NC113	B	before or between meals, 2 or 3 times	600 capsules [bottle, loose] 300 capsules (10 capsules x 30) [PTP] 600 capsules (10capsules x 60) [PTP]	1.0	1.0	1.0
4	Revised: Jan 2023 (1st version)	<b>Kotaro San'oshashinto Extract Capsules</b> Kotaro Pharmaceutical Co., Ltd. Fuso Pharmaceutical Industries Ltd.	16100AMZ04028000 Dec 1992	0.84 (3 capsules)	0.6	Carmellose Calcium, Light Anhydrous Silicic Acid, Microcrystalline Cellulose, Synthetic Aluminum Silicate, Magnesium Stearate, Corn Starch, Hydroxypropyl Starch, Magnesium Aluminometasilicate Capsule Materials: Food Blue No.1, Food Yellow No.5, Food Red No.3, Titanium Oxide, Gelatin, Sodium Lauryl Sulfate	Capsules	FS113	B	before or between meals, 2 or 3 times	500 capsules (10 capsules x 50) [PTP]	1.0	1.0	1.0
5	Revised: Jan 2023 (1st version)	<b>Kotaro San'oshashinto Extract Fine Granules</b> Kotaro Pharmaceutical Co., Ltd.	16100AMZ03953000 Oct 1986	6.0	0.6	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate	Fine granules	N113	C	before or between meals, 2 or 3 times	500g [bottle, loose] 2.0g x 231 packets [sachets] 2.0g x 42 packets [sachets]	1.0	1.0	1.0
6	Revised: Oct 2023 (1st version)	<b>Kracie San'oshashinto Extract Fine Granules</b> Kracie, Ltd. Kracie Pharmaceutical, Ltd.	16100AMZ03849000 Oct 1986	6.0	0.7	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide	Fine granules	KB-13 (3.0g per sachet) EK-13 (2.0g per sachet)	A	before or between meals, 2 or 3 times	(KB-13) 3.0g x 28 packets [sachets] 3.0g x 168 packets [sachets] (EK-13) 2.0g x 42 packets [sachets] 2.0g x 294 packets [sachets] 500g [bottle]	2.0	1.0	1.0
7	Revised: Mar 2022 (1st version)	<b>OHSUGI San'oshashinto Extract Granules G</b> Ohsugi Pharmaceutical Co., Ltd.	16100AMZ04807000 Oct 1987	3.0	1.4	Lactose Hydrate, Corn Starch, Magnesium Stearate	Granules	SG-113	A	before or between meals, 2 or 3 times	500g [bottle] 294g (1.0g x 294 packets) [sachets] 84g (1.0g x 84 packets) [sachets]	3.0	3.0	3.0
8	Revised: Feb 2024 (1st version)	<b>Taikodo San'oshashinto Extract Granules</b> Taikoseido Pharmaceutical Co., Ltd.	16100AMZ03853000 Nov 1986	4.5	0.6	Lactose Hydrate, JP Magnesium Stearate	Granules	Tai TM-113	A	before or between meals, 3 times	500g [bottle] 1.5g x 84 packets [sachets] 1.5g x 336 packets [sachets]	2.0	1.0	1.0
9	Revised: Dec 2023 (1st version)	<b>TSUMURA San'oshashinto Extract Granules for Ethical Use</b> Tsumura & Co.	16100AMZ03283000 Oct 1986	7.5	1.75	JP Carboxymethylcellulose Calcium, JP Magnesium Stearate, JP Lactose Hydrate	Granules	TSUMURA/113	A	before or between meals, 2 or 3 times	500g [bottle] 5kg (500g x 10) [pouch] 2.5g x 42 packets [sachets] 2.5g x 189 packets [sachets]	3.0	3.0	3.0

Table of Indications

A	The following symptoms of those patients with a comparatively strong constitution who have a slight feeling of hot flush and have facial hot flushes, mental instability, and are likely to have constipation: Symptoms associated with hypertension (flushing, shoulder stiffness, tinnitus, dull headache, insomnia, and anxiety), nose bleeding, hemorrhoidal bleeding, constipation, climacteric disturbance, and automatic imbalance syndrome peculiar to women resembling climacteric disturbance
B	The following symptoms of those patients with hot flush, anxious feeling, blocked feeling in the stomach, severe constipation, hyperemia or tendency to bleeding: Hypertension, arteriosclerosis, cerebral hemorrhage, melena, nasal bleeding, and chronic constipation
C	The following symptoms of those patients with hot flush, mental dysequilibrium, blocked feeling in the stomach, severe constipation, bright red hyperemia, and tendency to bleeding: Hypertension, arteriosclerosis, insomnia due to hypertension, cerebral hemorrhage, hematemesis, melena, nasal bleeding, and chronic constipation