

108 San'oshashinto

	Date of Making or Revision of Package Insert	Product Name Manufacturer Distributor	Approval No. Date of Listing in the NHI Reimbursement Price 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		
												Roshub	Sanjūriku Root	Cornis Rhizome
1	Revised: Feb 2011 (5th version)	Honzo San'oshashinto Extract Granules-M Honzo Pharmaceutical Co., Ltd.	(61AM)4148 Oct 1986 Oct 1986	7.5	0.7	Lactose Hydrate, Magnesium Aluminometasilicate, Magnesium Stearate	Granules	H13	A	before or between meals, 3 times	500g 2.5g x 294 packets 2.5g x 42 packets	2.0	1.0	1.0
2	Revised: Feb 2011 (4th version)	JPS San'oshashinto Extract Granules for Ethical Use JPS Pharmaceutical Co., Ltd.	61AM-4659 Oct 1987 Oct 1987	2.5	0.7	Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate	Granules	(J-113)	A	before or between meals, once	500g 750g (2.5g x 300 packets) 105g (2.5g x 42 packets)	1.0	1.0	1.0
3	Revised: Feb 2011 (5th version)	Kotaro San'oshashinto Extract Capsules Kotaro Pharmaceutical Co., Ltd.	(61AM)4028 Oct 1986 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	300 capsules (PTP) 600 capsules (PTP) 600 capsules	1.0	1.0	1.0
4	Revised: Feb 2011 (5th version)	Kotaro San'oshashinto Extract Capsules Kotaro Pharmaceutical Co., Ltd. Fuso Pharmaceutical Industries Ltd.	(61AM)4028 Oct 1986 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)	1.0	1.0	1.0
5	Revised: Feb 2011 (6th version)	Kotaro San'oshashinto Extract Fine Granules Kotaro Pharmaceutical Co., Ltd.	(61AM)3953 Oct 1986 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 2.0g x 231 packets (462g) 2.0g x 42 packets (84g)	1.0	1.0	1.0
6	Revised: Feb 2011 (3rd version)	Kracie San'oshashinto Extract Fine Granules Kracie Pharma, Ltd. Kracie Pharmaceutical, Ltd.	(61AM)3849 Jul 2007 Jul 2007	6.0	0.7	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide	Fine granules	KB-13 3.0g EK-13 2.0g	A	before or between meals, 2 or 3 times	3.0g x 28 packets 3.0g x 168 packets 2.0g x 42 packets 2.0g x 294 packets 500g	2.0	1.0	1.0
7	Revised: Apr 2016 (5th version)	Matsuura San'oshashinto Extract Granules Matsuura Yakugyo Co., Ltd.	(61AM)4220 Oct 1987 Oct 1987	3.0	1.0	Hypromellose, Macrogol 6000, Lactose Hydrate, Dextrin, Corn Starch	Granules	113, Matsuura	A	before or between meals, 2 or 3 times	500g 1g x 84 packets 1g x 300 packets	2.0	1.0	1.0
8	Revised: Feb 2011 (2nd version)	OHSUGI San'oshashinto Extract Granules G Ohsugi Pharmaceutical Co., Ltd.	(61AM)4807 Oct 1987 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 294g (1.0g x 294 packets) 84g (1.0g x 84 packets)	3.0	3.0	3.0
9	Revised: Feb 2011 (4th version)	Taikodo San'oshashinto Extract Granules Taikoseido Pharmaceutical Co., Ltd.	(61AM)3853 Oct 1986 Nov 1986	4.5	0.6	Lactose Hydrate, JP Magnesium Stearate	Granules	TM-113	A	before or between meals, 3 times	500g 1.5g x 84 packets 1.5g x 336 packets	2.0	1.0	1.0
10	Revised: Aug 2017 (7th version)	TEIKOKU San'oshashinto Extract Granules Teikoku Kampo Seiyaku Co., Ltd. Teikoku Seiyaku Co., Ltd.	(61AM)3676 Oct 1987 Oct 1987	7.5	1.21	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate	Granules	TEIKOKU 113	A	before meals, 3 times	500g 2.5g x 42 packets 2.5g x 252 packets	3.0	3.0	3.0
11	Revised: Feb 2011 (6th version)	TSUMURA San'oshashinto Extract Granules for Ethical Use Tsumura & Co.	(61AM)3283 Oct 1986 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 500g (500g x 10) 2.5g x 42 packets 2.5g x 189 packets	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