

058 Keishibukuryogan

	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					
												Cinnamon Bark	Cinnamon Twig	Poria Sclerotium	Moutan Bark	Peach Kernel	Pony Root
1	Revised: May 2007 (4th version)	Honzo Keishibukuryoganryo Extract Granules-M Honzo Pharmaceutical Co., Ltd.	(61AM)4152 Oct 1986 Oct 1986	7.5	2.5	Lactose Hydrate, Magnesium Aluminummetasilicate, Magnesium Stearate	Granules	H25	A	before or between meals, 3 times	500g 2.5g x 294 packets 2.5g x 42 packets	4.0		4.0	4.0	4.0	4.0
2	Revised: Dec 2008 (5th version)	JPS Keishibukuryoganryo Extract Granules for Ethical Use JPS Pharmaceutical Co., Ltd.	61AM-4197 Oct 1986 Nov 1986	7.5	2.6	Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate	Granules	(J-25)	A	before or between meals, 2 or 3 times	500g 750g (2.5g x 300 packets) 105g (2.5g x 42 packets)	4.0		4.0	4.0	4.0	4.0
3	Revised: Dec 2016 (3rd version)	JUNKOU Keishibukuryoganryo FC Extract Fine Granules for Ethical Use Kohwayakutuu Inc. Ohsugi Pharmaceutical Co., Ltd.	16100AMY00366000 Oct 1986 Oct 1986	4.5	2.25	Corn Starch, Lactose Hydrate	Fine granules	FC 25	A	before or between meals, 2 or 3 times	126g (1.5g x 84 packets)	4.0		4.0	4.0	4.0	4.0
4	Revised: Mar 2008 (7th version)	Kotaro Keishibukuryoganryo Extract Fine Granules Kotaro Pharmaceutical Co., Ltd.	(61AM)3803 Oct 1986 Oct 1986	6.0	2.8	Magnesium Stearate, Corn Starch, Lactose, Pullulan, Magnesium Aluminummetasilicate	Fine granules	N25	A	before or between meals, 2 or 3 times	500g 2.0g x 231 packets (462g) 2.0g x 42 packets (84g)	4.0		4.0	4.0	4.0	4.0
5	Revised: Jul 2010 (2nd version)	Kracie Keishibukuryoganryo Extract Fine Granules Kracie Pharma, Ltd. Kracie Pharmaceutical, Ltd.	(61AM)3503 Jul 2007 Jul 2007	6.0	2.3	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide	Fine granules	KB-25 3.0g EK-25 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	4.0		4.0	4.0	4.0	4.0
6	Revised: Jul 2010 (2nd version)	Kracie Keishibukuryoganryo Extract Tablets Ominedo Pharmaceutical Industry Co.,Ltd. Kracie Pharmaceutical, Ltd.	21900AMX00615000 Jul 2007 Jul 2007	5.94 (18 tablets)	2.2	JP Magnesium Stearate, JP Talc, JP Carmellose Calcium, JP Light Anhydrous Silicic Acid, JP Lactose Hydrate, JP Microcrystalline Cellulose, Magnesium Hydroxide-Aluminium Hydroxide Co-Precipitate	Tablets	(EKT-25)	A	before or between meals, 2 or 3 times	252 tablets (3 tablets x 6 packets x 14 sheets) 1,764 tablets (3 tablets x 6 packets x 98 sheets)	4.0		4.0	4.0	4.0	4.0
7	Revised: Jul 2005 (4th version)	Matsuura Keishibukuryoganryo Extract Granules Matsuura Yakugyo Co., Ltd.	(61AM)4046 Oct 1986 Oct 1986	4.5	Viscous extract 5.1*	Hypromellose, Magnesium Stearate, Lactose Hydrate, Dextrin, Corn Starch	Granules	25, Matsuura	A	before or between meals, 2 or 3 times	500g 1.5g x 84 packets 1.5g x 300 packets	4.0		4.0	4.0	4.0	4.0
8	Oct 2005 (1st version)	OHSUGI Keishibukuryoganryo Extract Granules G Ohsugi Pharmaceutical Co., Ltd.	(61AM)3869 Oct 1986 Oct 1986	4.5	2.0	Lactose Hydrate, Corn Starch, Magnesium Stearate	Granules	SG-25	A	before or between meals, 2 or 3 times	500g 441g (1.5g x 294 packets) 126g (1.5g x 84 packets)	4.0		4.0	4.0	4.0	4.0
9	Revised: Dec 2015 (4th version)	SANWA Keishibukuryoganryo Extract Fine Granules Sanwa Shoyaku Co., Ltd.	(61AM)3601 Oct 1987 Oct 1987	4.5	2.6	Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregelatinized Starch, Light Anhydrous Silicic Acid	Fine granules	S-27	B	before or between meals, 3 times	500g 1.5g x 300 packets	4.0		4.0	4.0	4.0	4.0
10	Revised: Dec 2010 (6th version)	Taikodo Keishibukuryoganryo Extract Granules Taikoseido Pharmaceutical Co., Ltd.	(61AM)3852 Oct 1986 Nov 1986	7.5	4.15	JP Lactose Hydrate, JP Magnesium Stearate	Granules	TM-25	A	before or between meals, 3 times	500g 2.5g x 84 packets 2.5g x 252 packets	4.0		4.0	4.0	4.0	4.0
11	Revised: Aug 2017 (7th version)	TEIKOKU Keishibukuryoganryo Extract Granules Teikoku Kampo Seiyaku Co., Ltd. Teikoku Seiyaku Co.,Ltd.	(61AM)3700 Oct 1987 Oct 1987	7.5	2.03	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate	Granules	TEIKOKU 25	A	before meals, 3 times	500g 2.5g x 42 packets 2.5g x 252 packets	4.0		4.0	4.0	4.0	4.0
12	Revised: Jan 2014 (7th version)	Toyo Keishibukuryoganryo Extract Fine Granules Toyo Yakuko Co., Ltd.	(61AMY)0408 Oct 1986 Dec 1986	6.0	3.6	Corn Starch	Fine granules	TY-034	A	on empty stomach, 3 times	500g 2.0g x 252 packets		4.0	4.0	4.0	4.0	4.0
13	Revised: May 2007 (6th version)	TSUMURA Keishibukuryogan Extract Granules for Ethical Use Tsumura & Co.	(61AM)3288 Oct 1986 Oct 1986	7.5	1.75	JP Light Anhydrous Silicic Acid, JP Magnesium Stearate, JP Lactose Hydrate	Granules	TSUMURA/25	C	before or between meals, 2 or 3 times	500g 5kg (500g x 10) 2.5g x 42 packets 2.5g x 189 packets	3.0		3.0	3.0	3.0	3.0

*: correspond to 2.3g of dry extract

Table of Indications

A	The following symptoms of those patients with comparatively strong constitution who sometimes have lower abdominal pain, shoulder stiffness, dull headache, dizziness, feeling of hot flushes with lower limbs being susceptible to cold, etc.: Menstrual irregularity, abnormal menstruation, menses painful, climacteric disturbance, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, shoulder stiffness, dizziness, dull headache, contusion, chilblain, and spots
B	The following symptoms of those patients with feeling of hot flushes and being congested easily who have headache, shoulder stiffness, dizziness, palpitation, oversensitivity to cold, tenderness in the lower abdomen: Dysmenorrhea, endometritis, myometritis, ovaritis, perimetritis, menorrhagia, hemorrhoidal bleeding, eczema, urticaria, acne, spots, dermatitis, chilblain, contusion, and subcutaneous bleeding
C	The following symptoms of those patients with solid constitution who have ruddy face and generally solid abdomen with resistance in the lower abdomen: Inflammation in the uterus and its adnexa, endometritis, menstrual irregularity, dysmenorrhea, leukorrhea, climacteric disturbance (headache, dizziness, feeling of hot flushes, shoulder stiffness, etc.), oversensitivity to cold, peritonitis, contusion, hemorrhoid and orchitis