

102 Saikokaryukotsuboreito

	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										
												Bupleurum Root	Pinellia Tuber	Portia Sclerotium	Cinnamon Bark	Junbe	Ginseng	Longgan	Oyster Shell	Ginger	Rhubarb	Saccharina Root
1	Revised: May 2007 (5th version)	Honzo Saikokaryukotsuboreito Extract Granules-M Honzo Pharmaceutical Co., Ltd.	(61AM)4150 Oct 1986 Oct 1986	7.5	4.0	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Aluminometasilicate, Magnesium Stearate	Granules	H12	A-1	before or between meals, 3 times	500g 2.5g x 294 packets 2.5g x 42 packets	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	1.0	1.0	2.5
2	Revised: Mar 2006 (5th version)	JPS Saikokaryukotsuboreito Extract Granules for Ethical Use JPS Pharmaceutical Co., Ltd.	61AM-4196 Oct 1986 Nov 1986	7.5	4.1	Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose	Granules	(J-12)	A-1	before or between meals, 2 or 3 times	500g 750g (2.5g x 300 packets) 105g (2.5g x 42 packets)	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	0.8	1.0	2.5
3	Revised: Jan 2022 (1st version of new form)	JUNKOU Saikokaryukotsuboreito FC Extract Fine Granules for Ethical Use Kohwayakutuu Inc. Ohsugi Pharmaceutical Co., Ltd.	16100AMY00369000 - Oct 1986	6.0	4.0	Corn Starch, Lactose Hydrate	Fine granules	FC 12	A-1	before or between meals, 2 or 3 times	168g (2.0g x 84 packets)	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	1.0	1.0	2.5
4	Revised: Jul 2009 (8th version)	Kotaro Saikokaryukotsuboreito Extract Fine Granules Kotaro Pharmaceutical Co., Ltd.	(61AM)4038 Oct 1986 Oct 1986	7.5	5.0	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate	Fine granules	N12	B	before or between meals, 2 or 3 times	500g 2.5g x 189 packets (472.5g) 2.5g x 42 packets (105g)	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	0.7	1.0	2.5
5	Revised: Jul 2010 (2nd version)	Kracie Saikokaryukotsuboreito Extract Fine Granules Kracie Pharma, Ltd. Kracie Pharmaceutical, Ltd.	(61AM)3520 Jul 2007 Jul 2007	6.0	3.9	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide	Fine granules	KB-12 3.0g EK-12 2.0g	A-1	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	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	0.8	1.0	2.5
6	Revised: Jul 2010 (2nd version)	Kracie Saikokaryukotsuboreito Extract Tablets Ominedo Pharmaceutical Industry Co., Ltd. Kracie Pharmaceutical, Ltd.	21900AMX00627000 Jul 2007 Jul 2007	5.94 (18 tablets)	4.2	JP Sodium Lauryl Sulfate, JP Magnesium Stearate, JP Light Anhydrous Silicic Acid, JP Lactose Hydrate, JP Microcrystalline Cellulose, JP Croscarmellose Sodium	Tablets	(EKT-12)	A-1	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)	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	0.8	1.0	2.5
7	Revised: Apr 2016 (6th version)	Matsuura Saikokaryukotsuboreito Extract Granules Matsuura Yakugyo Co., Ltd.	(61AM)4174 Oct 1986 Oct 1986	6.0	2.9	Hypromellose, Macrogol 6000, Lactose Hydrate, Dextrin, Corn Starch	Granules	12, Matsuura	A-1	before or between meals, 2 or 3 times	500g 2g x 84 packets 2g x 300 packets	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	0.8	1.0	2.5
8	Revised: Jan 2022 (1st version of new form)	OHSUGI Saikokaryukotsuboreito Extract Granules G Ohsugi Pharmaceutical Co., Ltd.	16100AMZ04820000 - Oct 1987	7.5	3.4	Lactose Hydrate, Corn Starch, Magnesium Stearate	Granules	SG-12	A-2	before or between meals, 2 or 3 times	500g [bottle] 735g (2.5g x 294packets) 210g (2.5g x 84packets)	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	1.0	1.0	2.5
9	Revised: Jan 2012 (6th version)	Taikodo Saikokaryukotsuboreito Extract Granules Taikoseido Pharmaceutical Co., Ltd.	(61AM)3855 Oct 1986 Nov 1986	6.0	4.47	JP Lactose Hydrate, JP Magnesium Stearate	Granules	TM-12	A-1	before or between meals, 3 times	500g 2.0g x 84 packets 2.0g x 315 packets	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	0.8	1.0	2.5
10	Revised: Aug 2017 (8th version)	TEIKOKU Saikokaryukotsuboreito Extract Granules Teikoku Kampo Seiyaku Co., Ltd. Teikoku Seiyaku Co., Ltd.	(61AM)3675 Oct 1987 Oct 1987	9.0	4.33	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate	Granules	TEIKOKU 12	A-1	before meals, 3 times	500g 3.0g x 42 packets 3.0g x 252 packets	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	1.0	1.0	2.5
11	Revised: Jul 2009 (7th version)	TSUMURA Saikokaryukotsuboreito Extract Granules for Ethical Use Tsumura & Co.	(61AM)3265 Oct 1986 Oct 1986	7.5	4.5	JP Magnesium Stearate, JP Lactose Hydrate, Sucrose Esters of Fatty Acids	Granules	TSUMURA/12	C	before or between meals, 2 or 3 times	500g 5kg (500g x 10) 2.5g x 42 packets 2.5g x 189 packets	5.0	4.0	3.0	3.0	2.5	2.5	2.5	2.5	1.0	/	2.5

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A-1	The following symptoms of those patients with palpitation and insomnia who have mental instability: Symptoms associated with hypertension (palpitation, anxiety, and insomnia), neurosis, climacteric neurosis, and night cry in children
A-2	The following symptoms of those patients with palpitation and insomnia who have mental instability: Symptoms associated with hypertension (palpitation, anxiety, and insomnia), neurosis, climacteric disturbance, and night cry in children
B	The following symptoms of those patients with mental dysequilibrium and irritability accompanied by increase in heart beat, chest discomfort, dizziness, hot flush, insomnia or awareness of palpitation around the umbilicus, and blocked feeling in the epigastric region with constipation and decreased urinary output: Arteriosclerosis, hypertension, kidney disease, insomnia, neurological increase in heart beat, cardiac debility, epilepsy, pediatric night terrors, climacteric neurosis, impotence, neurosis
C	The following symptoms of those patients with comparatively strong constitution, palpitation, insomnia, and neurological symptoms such as irritability: Hypertension, arteriosclerosis, chronic renal disease, neurasthenia, neurotic palpitation, epilepsy, hysteria, night cry in childhood, and impotence