

020 Daisaikoto

	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	Pineal Tubers	Ginger	Fresh Ginger	Scutellaria Root	Peony Root	Jujube	Immature Orange	Rhubarb
1	Revised: May 2007 (5th version)	Honzo Daisaikoto Extract Granules-M Honzo Pharmaceutical Co., Ltd.	(61AM)4154 Oct 1986 Oct 1986	7.5	3.4	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Aluminometasilicate, Magnesium Stearate	Granules	H08	A	before or between meals, 3 times	500g 2.5g x 294 packets 2.5g x 42 packets	6.0	4.0	1.5	/	3.0	3.0	3.0	2.0	2.0
2	Revised: Feb 2015 (5th version)	JPS Daisaikoto Extract Granules for Ethical Use JPS Pharmaceutical Co., Ltd.	61AM-4127 Oct 1986 Nov 1986	7.5	4.5	Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate	Granules	(J-08)	A	before or between meals, 2 or 3 times	500g 750g (2.5g x 300 packets) 105g (2.5g x 42 packets)	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
3	Revised: Feb 2022 (1st version of new form)	JUNKOU Daisaikoto FC Extract Fine Granules for Ethical Use Kohwayakutai Inc. Ohsugi Pharmaceutical Co., Ltd.	16100AMY00363000 - Oct 1986	6.0	3.85	Corn Starch, Lactose Hydrate	Fine granules	FC 08	A	before or between meals, 2 or 3 times	168g (2.0g x 84 packets)	6.0	3.0	1.0	/	3.0	3.0	3.0	2.0	1.0
4	Revised: Feb 2008 (7th version)	Kotaro Daisaikoto Extract Fine Granules Kotaro Pharmaceutical Co., Ltd.	(61AM)3827 Oct 1986 Oct 1986	9.0	6.0	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate	Fine granules	N8	B	before or between meals, 2 or 3 times	500g 3.0g x 168 packets (504g) 3.0g x 42 packets (126g)	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	2.0
5	Revised: Mar 2015 (3rd version)	Kracie Daisaikoto Extract Fine Granules Kracie Pharma, Ltd. Kracie Pharmaceutical, Ltd.	(61AM)3517 Jul 2007 Jul 2007	6.0	5.4	JP Magnesium Stearate, JP Light Anhydrous Silicic Acid, JP Microcrystalline Cellulose, Hydrated Silicon Dioxide	Fine granules	KB-8 3.0g EK-8 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	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
6	Revised: Mar 2015 (3rd version)	Kracie Daisaikoto Extract Tablets Ominedo Pharmaceutical Industry Co., Ltd. Kracie Pharmaceutical, Ltd.	21900AMX00630000 Jul 2007 Jul 2007	5.94 (18 tablets)	4.8	JP Sodium Lauryl Sulfate, JP Magnesium Stearate, JP Light Anhydrous Silicic Acid, JP Microcrystalline Cellulose, JP Croscarmellose Sodium	Tablets	(EKT-8)	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)	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
7	Revised: Apr 2016 (6th version)	Matsuura Daisaikoto Extract Granules Matsuura Yakugyo Co., Ltd.	(61AM)4175 Oct 1986 Oct 1986	6.0	viscous extract 7.2*	Hypromellose, Macrogol 6000, Lactose Hydrate, Dextrin, Corn Starch	Granules	8, Matsuura	A	before or between meals, 2 or 3 times	500g 2g x 84 packets 2g x 300 packets	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
8	Revised: Feb 2022 (1st version of new form)	OHSUGI Daisaikoto Extract Granules G Ohsugi Pharmaceutical Co., Ltd.	16100AMZ04821000 - Oct 1987	7.5	3.9	Lactose Hydrate, Corn Starch, Magnesium Stearate	Granules	SG-08	A	before or between meals, 2 or 3 times	500g[bottle] 735g (2.5g x 294 packets) 210g (2.5g x 84 packets)	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
9	Revised: Feb 2022 (1st version of new form)	OHSUGI Daisaikoto Extract T Tablets Ohsugi Pharmaceutical Co., Ltd.	16100AMZ04182000 - Oct 1986	5.94 (18 tablets)	4.0	Microcrystalline Cellulose, Magnesium Aluminometasilicate, Carmellose Calcium, Magnesium Stearate, Hypromellose, Titanium Oxide, Food Yellow No.5, Food Blue No.1, Food Red No.3	Tablets (Film-coated tablets)	SG-08T	A	before or between meals, 2 or 3 times	1,764 tablets (6 tablets x 294 packets) 504 tablets (6 tablets x 84 packets)	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
10	Revised: Aug 2015 (4th version)	SANWA Daisaikoto Extract Fine Granules Sanwa Shoyaku Co., Ltd.	(61AM)3624 Oct 1986 Nov 1986	9.0	5.8	Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregelatinized Starch, Light Anhydrous Silicic Acid	Fine granules	S-31	C	before or between meals, 3 times	500g 3.0g x 300 packets	6.0	4.0	2.0	/	3.0	3.0	3.0	2.0	1.0
11	Revised: Nov 2011 (6th version)	Taikodo Daisaikoto Extract Granules Taikoseido Pharmaceutical Co., Ltd.	(61AM)3850 Oct 1986 Nov 1986	6.0	4.26	JP Lactose Hydrate, JP Magnesium Stearate	Granules	TM-8	A	before or between meals, 3 times	500g 2.0g x 84 packets 2.0g x 315 packets	6.0	4.0	2.0	/	3.0	3.0	3.0	2.0	1.0
12	Revised: Aug 2017 (8th version)	TEIKOKU Daisaikoto Extract Granules Teikoku Kampo Seiyaku Co., Ltd. Teikoku Seiyaku Co., Ltd.	(61AM)3674 Oct 1987 Oct 1987	9.0	4.29	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate	Granules	TEIKOKU 8	A	before meals, 3 times	500g 3.0g x 42 packets 3.0g x 252 packets	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0
13	Revised: Oct 2005 (6th version)	Toyo Daisaikoto Extract Fine Granules Toyo Yakuko Co., Ltd.	(61AMY)0405 Oct 1986 Jan 1987	6.0	4.0	Corn Starch	Fine granules	TY-077	A	on empty stomach, 3 times	500g 2.0g x 252 packets	6.0	3.0	/	4.0	3.0	3.0	3.0	2.0	1.0
14	Revised: Oct 2014 (9th version)	TSUMURA Daisaikoto Extract Granules for Ethical Use Tsumura & Co.	(61AM)3261 Oct 1986 Oct 1986	7.5	4.5	JP Magnesium Stearate, JP Lactose Hydrate, Sucrose Esters of Fatty Acids	Granules	TSUMURA/8	D	before or between meals, 2 or 3 times	500g 2.5g x 42 packets 2.5g x 189 packets	6.0	4.0	1.0	/	3.0	3.0	3.0	2.0	1.0

*: correspond to 3.6g of dry extract

Table of Indications

A	The following symptoms of those patients with solid and comparatively strong constitution who are likely to have constipation: Gastritis, chronic constipation, symptoms associated with hypertension (shoulder stiffness, headache, and constipation), shoulder stiffness, and obesity
B	The following symptoms of those patients with sensation of liver pressure or epigastric tenderness, pain or pressure in the chest or flank, constipation or diarrhea accompanied by timidity, shoulder stiffness, fatigue, and decreased appetite: Hypertension, arteriosclerosis, chronic constipation, obesity, jaundice, cholelithiasis, cholecystitis, gastrointestinal disease, bronchial asthma, insomnia, neurasthenia, impotence, hemorrhoids, and hemiplegia
C	The following symptoms of those patients who have pressure or pain in the chest or flank, epigastric tenderness and discomfort, and constipation. Or those patients with diarrhea, timidity, anorexia and fatigue, etc.: Cholecystitis, cholelithiasis, jaundice, gastrointestinal catarrh, arteriosclerosis, hypertension, cerebral hemorrhage, hemiplegia, obesity, asthma, neurasthenia, insomnia, chronic constipation, hemorrhoids, and intercostal neuralgia
D	The following symptoms of those patients with comparatively strong constitution having a tendency to constipation, right upper abdominal tenderness accompanied by fullness and discomfort, timidity, shoulder stiffness, etc.: Cholelithiasis, cholecystitis, jaundice, hepatic dysfunction, hypertension, cerebral hemorrhage, uricaria, hyperchylia, acute gastrointestinal catarrh, nausea, vomiting, anorexia, hemorrhoid, diabetes mellitus, neurosis, and insomnia