

020 Daisaikoto

	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								
												Bupleurum Root	Pinellia Tuber	Ginger	Fresh Ginger	Scutellaria Root	Pony Root	Jujube	Immature Orange	Rhubarb
1	Revised: Oct 2022 (1st version)	Honzo Daisaikoto Extract Granules-M Honzo Pharmaceutical Co., Ltd.	16100AMZ04154000 Oct 1986	7.5	3.4	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Aluminometasilicate, Magnesium Stearate	Granules	H08	A	before or between meals, 3 times	500g [loose,bottle] 735g(2.5g x 294 packets) [sachets] 105g(2.5g x 42 packets) [sachets]	6.0	4.0	1.5		3.0	3.0	3.0	2.0	2.0
2	Revised: Dec 2023 (1st version)	JPS Daisaikoto Extract Granules for Ethical Use JPS Pharmaceutical Co., Ltd.	16100AMZ04127000 Nov 1986	7.5	4.5	Mg 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)	JUNKOU Daisaikoto FC Extract Fine Granules for Ethical Use Kohwayakutuu 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) [sachets]	6.0	3.0	1.0		3.0	3.0	3.0	2.0	1.0
4	Revised: Jan 2023 (1st version)	Kotaro Daisaikoto Extract Fine Granules Kotaro Pharmaceutical Co., Ltd.	16100AMZ03827000 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 [bottle,loose] 3.0g x 42 packets [sachets] 3.0g x 168 packets [sachets]	6.0	4.0	1.0		3.0	3.0	3.0	2.0	2.0
5	Revised: Oct 2023 (1st version)	Kracie Daisaikoto Extract Fine Granules Kracie, Ltd. Kracie Pharmaceutical, Ltd.	16100AMZ03517000 Oct 1986	6.0	5.4	JP Magnesium Stearate, JP Light Anhydrous Silicic Acid, JP Microcrystalline Cellulose, Hydrated Silicon Dioxide	Fine granules	KB-8 (3.0g per sachet) EK-8 (2.0g per sachet)	A	before or between meals, 2 or 3 times	(KB-8) 3.0g x 28 packets [sachets] 3.0g x 168 packets [sachets] (EK-8) 2.0g x 42 packets [sachets] 2.0g x 294 packets [sachets] 500g[bottle]	6.0	4.0	1.0		3.0	3.0	3.0	2.0	1.0
6	Revised: Oct 2023 (1st version)	Kracie Daisaikoto Extract Tablets Omiedo Pharmaceutical Industry Co., Ltd. Kracie Pharmaceutical, Ltd.	21900AMX00630000 Oct 1986	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) [sachets] 1,764 tablets (3 tablets x 6 packets x 98 sheets) [sachets]	6.0	4.0	1.0		3.0	3.0	3.0	2.0	1.0
7	Revised: Feb 2022 (1st version)	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)[sachets] 210g (2.5g x 84 packets)[sachets]	6.0	4.0	1.0		3.0	3.0	3.0	2.0	1.0
8	Revised: Feb 2022 (1st version)	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)[sachets] 504 tablets (6 tablets x 84 packets)[sachets]	6.0	4.0	1.0		3.0	3.0	3.0	2.0	1.0
9	Revised: May 2022 (1st version)	SANWA Daisaikoto Extract Fine Granules Sanwa Shoyaku Co., Ltd.	16100AMZ03624000 Nov 1986	9.0	5.8	Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregeatinized Starch, Light Anhydrous Silicic Acid	Fine granules	S-31	C	before or between meals, 3 times	500g[bottle] 3.0g x 300 packets[sachets]	6.0	4.0	2.0		3.0	3.0	3.0	2.0	1.0
10	Revised: Feb 2024 (1st version)	Taikodo Daisaikoto Extract Granules Taikoseido Pharmaceutical Co., Ltd.	16100AMZ03850000 Nov 1986	6.0	4.26	JP Lactose Hydrate, JP Magnesium Stearate	Granules	Tai TM-8	A	before or between meals, 3 times	500g[bottle] 2.0g x 84 packets[sachets] 2.0g x 315 packets[sachets]	6.0	4.0	2.0		3.0	3.0	3.0	2.0	1.0
11	Revised: Nov 2023 (1st version)	Toyo Daisaikoto Extract Fine Granules Toyo Yakuko Co., Ltd.	16100AMY00405000 Jan 1987	6.0	4.0	Corn Starch (excipient)	Fine granules	TY-077	A	on empty stomach, 3 times	500g[bottle] 2.0g x 252 packets[sachets]	6.0	3.0		4.0	3.0	3.0	3.0	2.0	1.0
12	Revised: Dec 2023 (1st version)	TSUMURA Daisaikoto Extract Granules for Ethical Use Tsumura & Co.	16100AMZ03261000 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 [bottle] 2.5g x 42 packets [sachets] 2.5g x 189 packets [sachets]	6.0	4.0	1.0		3.0	3.0	3.0	2.0	1.0

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 tinnitus, 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, tinnitus, 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, tinnitus, 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