

092 Otsujito

	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					
												Japanese Angelica Root	Bupleurum Root	Scutellaria Root	Glycyrrhiza	Cimicifuga Rhizome	Rhubarb
1	Revised: May 2007 (5th version)	Honzo Otsujito Extract Granules-M Honzo Pharmaceutical Co., Ltd.	(61AM)4155 Oct 1986 Oct 1986	7.5	3.3	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Aluminometasilicate, Magnesium Stearate	Granules	H03	A	before or between meals, 3 times	500g 2.5g x 294 packets 2.5g x 42 packets	6.0	5.0	3.0	2.0	1.5	1.0
2	Revised: Feb 2015 (5th version)	JPS Otsujito Extract Granules for Ethical Use JPS Pharmaceutical Co., Ltd.	62AM-0093 Oct 1987 Oct 1987	7.5	3.2	Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose	Granules	(J-03)	A	before or between meals, 2 or 3 times	500g 750g (2.5g x 300 packets) 105g (2.5g x 42 packets)	6.0	5.0	3.0	2.0	1.5	1.0
3	Revised: Feb 2022 (1st version of new form)	JUNKOU Otsujito FC Extract Fine Granules for Ethical Use Kohwayakutau Inc. Ohsugi Pharmaceutical Co., Ltd.	16100AMY00379000 - Oct 1986	6.0	3.55	Corn Starch, Lactose Hydrate	Fine granules	FC 03	A	before or between meals, 2 or 3 times	168g (2.0g x 84 packets)	6.0	5.0	3.0	2.0	1.5	1.0
4	Revised: Feb 2008 (6th version)	Kotaro Otsujito Extract Fine Granules Kotaro Pharmaceutical Co., Ltd.	(61AM)3822 Oct 1986 Oct 1986	9.0	5.3	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate	Fine granules	N3	B	before or between meals, 2 or 3 times	500g 3.0g x 168 packets (504g) 3.0g x 42 packets (126g)	6.0	5.0	3.0	2.0	1.5	1.0
5	Revised: Mar 2015 (3rd version)	Kracie Otsujito Extract Fine Granules Kracie Pharma, Ltd. Kracie Pharmaceutical, Ltd.	(61AM)3502 Jul 2007 Jul 2007	6.0	4.2	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide	Fine granules	KB-3 3.0g EK-3 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	5.0	3.0	2.0	1.5	1.0
6	Revised: Jan 2022 (1st version of new form)	OHSUGI Otsujito Extract Granules G Ohsugi Pharmaceutical Co., Ltd.	16100AMZ04806000 - Oct 1987	7.5	3.6	Lactose Hydrate, Corn Starch, Magnesium Stearate	Granules	SG-03	A	before or between meals, 2 or 3 times	500g [bottle] 735g (2.5g x 294packets) 210g (2.5g x 84packets)	6.0	5.0	3.0	2.0	1.5	1.0
7	Revised: Sep 2015 (4th version)	SANWA Otsujito Extract Fine Granules Sanwa Shoyaku Co., Ltd.	(61AM)3612 Oct 1986 Nov 1986	7.5	3.6	Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregelatinized Starch, Light Anhydrous Silicic Acid	Fine granules	S-23	C	before or between meals, 3 times	500g 2.5g x 300 packets	6.0	5.0	3.0	2.0	1.5	1.0
8	Revised: May 2011 (5th version)	Taikodo Otsujito Extract Granules Taikoseido Pharmaceutical Co., Ltd.	(61AM)3910 Oct 1986 Nov 1986	7.5	4.15	JP Lactose Hydrate, JP Magnesium Stearate	Granules	TM-3	A	before or between meals, 3 times	500g 2.5g x 84 packets 2.5g x 252 packets	6.0	5.0	3.0	2.0	1.5	1.0
9	Revised: Aug 2017 (8th version)	TEIKOKU Otsujito Extract Granules Teikoku Kampo Seiyaku Co., Ltd. Teikoku Seiyaku Co., Ltd.	(61AM)3673 Jul 1988 Jul 1988	9.0	4.27	Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate	Granules	TEIKOKU 3	A	before meals, 3 times	500g 3.0g x 42 packets 3.0g x 252 packets	6.0	5.0	3.0	3.0	1.0	1.0
10	Revised: Mar 2013 (6th version)	TSUMURA Otsujito Extract Granules for Ethical Use Tsumura & Co.	(61AM)1149 Oct 1986 Oct 1986	7.5	4.0	JP Magnesium Stearate, JP Lactose Hydrate	Granules	TSUMURA/3	D	before or between meals, 2 or 3 times	500g 2.5g x 42 packets 2.5g x 189 packets	6.0	5.0	3.0	2.0	1.0	0.5

Table of Indications

A	The following symptoms of those patients with discharged hard stools and a tendency to constipation: Hemorrhoids, anal fissure and constipation
B	Hemorrhoids, anal prolapse, anal hemorrhage, and hemorrhoidal pain
C	The following symptoms of those patients with a tendency to constipation, anal pain and a little hemorrhage occasionally: Hemorrhoids, anal prolapse, anal hemorrhage, and pruritus vulvae
D	The following symptoms of those patients with a moderately strong constitution without very severe symptoms or debility: Anal fissure and hemorrhoids