

048 Kakkonto

| No. | Date of Making or Revision of Package Insert | Product Name<br>Manufacturer<br>Distributor   | Approval No.<br>Date of Listing in the<br>NHI Reimbursement<br>Price<br>Date of Initial<br>Marketing in Japan | Dose for<br>One Day<br>(g) | Extract<br>Content in<br>One Day<br>Dose (g) | Inactive Ingredients  | Dosage<br>Form                      | ID Code<br>(Item Number,<br>etc.) | Indications | Daily Dosage and<br>Administration<br>(Adult) | Packaging  | Component Ratio |                 |        |                  |                  |               |             |        |                 |
|-----|--|---|---|----------------------------|--|---|-------------------------------------|-----------------------------------|-------------|---|--|-----------------|-----------------|--------|------------------|------------------|---------------|-------------|--------|-----------------|
|     |  |   |   |                            |  |   |                                     |                                   |             |   |  | Peanut<br>Root  | Ephedra<br>Herb | Jujube | Cinnamon<br>Bark | Cinnamon<br>Twig | Peony<br>Root | Glycyrrhiza | Ginger | Fresh<br>Ginger |
| 1   | Revised: Nov 2007<br>(5th version)           | <b>Honzo Kakkonto Extract Granules-M</b><br>Honzo Pharmaceutical Co., Ltd.  | (61AM)4136<br>Oct 1986<br>Oct 1986  | 7.5                        | 4.3  | Lactose Hydrate, Microcrystalline Cellulose, Magnesium Aluminometasilicate, Magnesium Stearate  | Granules                            | H01                               | A           | before or between meals,<br>3 times           | 500g<br>2.5g x 294 packets<br>2.5g x 42 packets  | 8.0             | 4.0             | 4.0    | 3.0              | /                | 3.0           | 2.0         | 1.0    | /               |
| 2   | Revised: Jul 2007<br>(5th version)           | <b>JPS Kakkonto Extract Granules for Ethical Use</b><br>JPS Pharmaceutical Co., Ltd.                                    | 61AM-4761<br>Oct 1987<br>Oct 1987   | 7.5                        | 5.0  | Magnesium Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate  | Granules                            | (J-01)                            | A           | before or between meals,<br>2 or 3 times      | 500g<br>750g (2.5g x 300 packets)<br>105g (2.5g x 42 packets)  | 8.0             | 4.0             | 4.0    | 3.0              | /                | 3.0           | 2.0         | 1.0    | /               |
| 3   | Revised: Feb 2017<br>(3rd version)           | <b>JUNKOU Kakkonto FC Extract Fine Granules for Ethical Use</b><br>Kohwayakutuu Inc.<br>Ohsugi Pharmaceutical Co., Ltd. | 16100AMY00370000<br>Oct 1986<br>Oct 1986  | 6.0                        | 3.5  | Corn Starch, Lactose Hydrate  | Fine granules                       | FC 01                             | A           | before or between meals,<br>2 or 3 times      | 168g (2.0g x 84 packets)   | 8.0             | 4.0             | 4.0    | 3.0              | /                | 3.0           | 2.0         | 1.0    | /               |
| 4   | Revised: Nov 2007<br>(7th version)           | <b>Kotaro Kakkonto Extract Fine Granules</b><br>Kotaro Pharmaceutical Co., Ltd.   | (61AM)3812<br>Oct 1986<br>Oct 1986  | 7.5                        | 4.8  | Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate   | Fine granules                       | N1                                | B           | before or between meals,<br>2 or 3 times      | 500g<br>2.5g x 189 packets<br>(472.5g)<br>2.5g x 42 packets (105g)   | 4.0             | 4.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 5   | Revised: Jul 2010<br>(2nd version)           | <b>Kracie Kakkonto Extract Fine Granules</b><br>Kracie Pharma, Ltd.<br>Kracie Pharmaceutical, Ltd.                      | (61AM)3513<br>Jul 2007<br>Jul 2007  | 7.5                        | 5.2  | JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide  | Fine granules                       | KB-1 3.75g<br>EK-1 2.5g           | A           | before or between meals,<br>2 or 3 times      | 3.75g x 28 packets<br>3.75g x 168 packets<br>2.5g x 42 packets<br>2.5g x 294 packets<br>500g               | 8.0             | 4.0             | 4.0    | 3.0              | /                | 3.0           | 2.0         | 1.0    | /               |
| 6   | Revised: Jul 2010<br>(2nd version)           | <b>Kracie Kakkonto Extract Tablets T</b><br>Ominedo Pharmaceutical Industry Co., Ltd.<br>Kracie Pharmaceutical, Ltd.    | 21900AMX00624000<br>Jul 2007<br>Jul 2007  | 5.94<br>(18 tablets)       | 3.2  | JP Magnesium Stearate, JP Talk, JP Carmellose Calcium, JP Light Anhydrous Silicic Acid, JP Microcrystalline Cellulose, Magnesium Hydroxide-Aluminium Hydroxide Co-Precipitate   | Tablets                             | (EKT-1)                           | A           | before or between meals,<br>2 or 3 times      | 252 tablets (3 tablets x 6<br>packets x 14 sheets)<br>1,764 tablets (3 tablets x 6<br>packets x 98 sheets) | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 7   | Revised: Oct 2005<br>(3rd version)           | <b>Matsuura Kakkonto Extract Granules</b><br>Matsuura Yakugyo Co., Ltd.   | (61AM)4045<br>Oct 1986<br>Oct 1986  | 6.0                        | Viscous<br>extract<br>6.6*                   | Hypromellose, Magnesium Stearate, Lactose Hydrate, Dextrin, Corn Starch   | Granules                            | 1, Matsuura                       | A           | before or between meals,<br>2 or 3 times      | 500g<br>2g x 84 packets<br>2g x 300 packets  | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 8   | Oct 2005<br>(1st version)                    | <b>OHSUGI Kakkonto Extract Granules G</b><br>Ohsugi Pharmaceutical Co., Ltd.  | (61AM)3880<br>Oct 1986<br>Oct 1986  | 7.5                        | 3.3  | Lactose Hydrate, Corn Starch, Magnesium Stearate  | Granules                            | SG-01                             | A           | before or between meals,<br>2 or 3 times      | 500g<br>735g (2.5g x 294 packets)<br>210g (2.5g x 84 packets)  | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 9   | Jan 2019<br>(1st version)                    | <b>OHSUGI Kakkonto Extract T Tablets</b><br>Ohsugi Pharmaceutical Co., Ltd.   | (62AM)0179<br>Oct 1987<br>Oct 1987  | 4.65<br>(15 tablets)       | 3.3  | Microcrystalline Cellulose, Magnesium Aluminometasilicate, Carmellose Calcium, Magnesium Stearate, Hypromellose, Titanium Oxide, Food Yellow No.5 Aluminium Lake, Food Blue No.1 Aluminium Lake, Food Red No.3 Aluminium Lake | Tablets<br>(Film-coated<br>tablets) | SG-01T                            | A           | before or between meals,<br>2 or 3 times      | 1,470 tablets (5 tablets x<br>294 packets)<br>420 tablets (5 tablets x 84<br>packets)                      | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 10  | Revised: Jul 2017<br>(4th version)           | <b>SANWA Kakkonto Extract Fine Granules</b><br>Sanwa Shoyaku Co., Ltd.  | (61AM)3596<br>Oct 1986<br>Nov 1986  | 7.5                        | 4.1  | Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregelatinized Starch, Light Anhydrous Silicic Acid  | Fine granules                       | S-17                              | C           | before or between meals,<br>3 times           | 500g<br>2.5g x 300 packets   | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 11  | Revised: Nov 2010<br>(6th version)           | <b>Taikodo Kakkonto Extract Granules</b><br>Taikoseido Pharmaceutical Co., Ltd.   | (61AM)4223<br>Oct 1986<br>Nov 1986  | 7.5                        | 4.15   | JP Lactose Hydrate, JP Magnesium Stearate   | Granules                            | TM-1                              | A           | before or between meals,<br>3 times           | 500g<br>2.5g x 84 packets<br>2.5g x 252 packets  | 8.0             | 4.0             | 4.0    | 3.0              | /                | 3.0           | 2.0         | 1.0    | /               |
| 12  | Revised: Aug 2017<br>(7th version)           | <b>TEIKOKU Kakkonto Extract Granules</b><br>Teikoku Kampo Seiyaku Co., Ltd.<br>Teikoku Seiyaku Co.,Ltd.                 | (61AM)3864<br>Oct 1987<br>Oct 1987  | 7.5                        | 3.19   | Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate   | Granules                            | TEIKOKU 1                         | A           | before meals,<br>3 times                      | 500g<br>2.5g x 42 packets<br>2.5g x 252 packets  | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 1.0    | /               |
| 13  | Revised: Jan 2014<br>(7th version)           | <b>Toyo Kakkonto Extract Fine Granules</b><br>Toyo Yakuko Co., Ltd.   | (61AMY)0399<br>Oct 1986<br>Dec 1986   | 6.0                        | 3.6  | Corn Starch   | Fine granules                       | TY-013                            | A           | on empty stomach,<br>3 times                  | 500g<br>2.0g x 252 packets   | 4.0             | 3.0             | 3.0    | /                | 2.0              | 2.0           | 2.0         | /      | 3.0             |
| 14  | Revised: Aug 2007<br>(7th version)           | <b>TSUMURA Kakkonto Extract Granules for Ethical Use</b><br>Tsumura & Co.   | (61AM)3292<br>Oct 1986<br>Oct 1986  | 7.5                        | 3.75   | JP Magnesium Stearate, JP Lactose Hydrate, Sucrose Esters of Fatty Acids  | Granules                            | TSUMURA/1                         | D           | before or between meals,<br>2 or 3 times      | 500g<br>5kg (500g x 10)<br>2.5g x 42 packets<br>2.5g x 189 packets   | 4.0             | 3.0             | 3.0    | 2.0              | /                | 2.0           | 2.0         | 2.0    | /               |

\*: correspond to 3.3g of dry extract

Table of Indications

|   |  |
|---|--|
| A | Common cold, coryza, headache, shoulder stiffness, myalgia, and pains in the arms and shoulders  |
| C | The following symptoms of those patients with comparatively strong constitution who have headache, fever, rigor and shoulder or back stiffness without spontaneous sweating:<br>Common cold, coryza, tonsillitis, otitis media, empyema, conjunctivitis, mastitis, shoulder stiffness, and branchial neuralgia   |
| D | The following symptoms of those patients with comparatively strong constitution having headache, fever, rigor, and shoulder stiffness without spontaneous sweating:<br>Common cold, coryza, the initial stage of febrile diseases, inflammatory diseases (conjunctivitis, keratitis, otitis media, tonsillitis, mastitis, and lymphadenitis), shoulder stiffness, neuralgia in the upper body, and urticaria |