

018 Daiobotampito

|   | Date of Making or Revision of Package Insert | Product Name<br>Manufacturer<br>Distributor   | Approval No.<br>Date of Listing in the NHI Reimbursement Price<br>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 |             |              |                          |                        |
|---|--|---|--|----------------------|-------------------------------------|---|---------------|-----------------------------|-------------|---|--|-----------------|-------------|--------------|--------------------------|------------------------|
|   |  |   |  |                      |                                     |   |               |                             |             |   |  | Rhubarb         | Moutan Bark | Peach Kernel | Anhydrous Sodium Sulfate | Sodium Sulfate Hydrate |
| 1 | Revised: Oct 2016 (6th version)              | <b>Kotaro Daiobotampito Extract Fine Granules</b><br>Kotaro Pharmaceutical Co., Ltd.                          | (61AM)3826<br>Oct 1986<br>Oct 1986   | 6.0                  | 3.8                                 | Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate | Fine granules | N33                         | B           | before or between meals, 2 or 3 times   | 500g<br>2.0g x 231 packets (462g)<br>2.0g x 42 packets (84g) | 2.0             | 4.0         | 4.0          | 1.8                      | 6.0                    |
| 2 | Revised: Aug 2017 (7th version)              | <b>TEIKOKU Daiobotampito Extract Granules</b><br>Teikoku Kampo Seiyaku Co., Ltd.<br>Teikoku Seiyaku Co., Ltd. | (61AM)3680<br>Jul 1988<br>Jul 1988   | 7.5                  | 2.32                                | Lactose Hydrate, Microcrystalline Cellulose, Magnesium Stearate                           | Granules      | TEIKOKU 33                  | A           | before meals, 3 times                   | 500g<br>2.5g x 42 packets<br>2.5g x 252 packets              | 2.0             | 4.0         | 4.0          | 4.0                      | 6.0                    |
| 3 | Revised: Mar 2013 (5th version)              | <b>TSUMURA Daiobotampito Extract Granules for Ethical Use</b><br>Tsumura & Co.                                | (61AM)3321<br>Oct 1986<br>Oct 1986   | 7.5                  | 3.5                                 | JP Light Anhydrous Silicic Acid, JP Magnesium Stearate, JP Lactose Hydrate                | Granules      | TSUMURA/33                  | A           | before or between meals, 2 or 3 times   | 500g<br>2.5g x 42 packets<br>2.5g x 189 packets              | 2.0             | 4.0         | 4.0          | 1.8                      | 6.0                    |

**Table of Indications**

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| A | The following symptoms of those patients with a comparatively strong constitution and lower abdominal pain who are likely to have constipation:<br>Menstrual irregularity, dysmenorrhea, constipation, and hemorrhoid  |
| B | The following symptoms of those patients with cecal tenderness and fecal impaction, hard feces, red-purple or dark red skin, and tendency to congestion or bleeding:<br>Chronic constipation, arteriosclerosis, various disorders due to menstrual irregularity, climacteric disturbance, eczema, urticaria, acne, skin boils, and bladder catarrh |