ID Code	SG-03

October 2005
(1st version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Otsujito Extract Granules G

(Otsujito)

Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is specified on the container or the outer package.

Approval No.	(61AM) 4806
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

(1) The daily dose of this product, 7.5 g, contains 3.6 g of the dried extract (Otsujito extract) from the following mixed crude drugs.
JP Rhubarb ---------- 1 g
JP Glycyrrhiza ---------- 2 g
JP Bupleurum Root ---------- 5 g
JP Scutellaria Root ---------- 3 g
JP Cimicifuga Rhizome ---------- 1.5 g
JP Japanese Angelica Root ---------- 6 g
(JP: The Japanese Pharmacopeia)
The inactive ingredients contained are Lactose Hydrate, Corn Starch and Magnesium Stearate.

(2) This product is light grayish dark brown to light grayish and yellowish brown-colored granules, smells slightly, and tastes slightly sweet initially and then bitter slightly.
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INDICATIONS

The following symptoms of those patients with discharged hard stools and a tendency to constipation:
Hemorrhoids, anal fissure and constipation

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

PRECAUTIONS

(1) Careful Administration (Otsujito should be administered with care in the following patients.)

1) Patients with diarrhea or soft feces [These symptoms may be aggravated.]
2) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, abdominal pain, diarrhea, etc. may occur.]
3) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]
4) Patients with a remarkably declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

(2) Important Precautions.

1) When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into account. The patient's progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.
2) Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.
3) When this product is coadministered with other Kampo-products (Japanese traditional herbal medicines), etc.,attention should be paid to the duplication of the contained crude drugs. Special caution should be exercised when this product is coadministered with other products containing Rhubarb.
4) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

(3) Drug Interactions

Precautions for coadministration (Otsujito should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza (2) Preparations containing glycyrrhizinic acid or glycyrrhizinates	Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

(4) Adverse Reactions

This product has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

1) Clinically significant adverse reactions

① **Interstitial Pneumonia**: If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product should be discontinued, and examination such as chest X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones should be taken. Besides, the patient should be advised to discontinue this product immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.

② **Pseudoaldosteronism**: Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

③ **Myopathy**: Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

④ **Hepatic dysfunction and jaundice**: Hepatic dysfunction, with remarkable elevation of AST(GOT), ALT(GPT), Al-P and γ - GTP level, and/ or jaundice may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

2) Other adverse reactions

	Incidence Unknown
Hypersensitivity Note 1)	Rash, Redness, Urticaria, etc.
Gatrointestinal	Anorexia, Epigastric distress, Nausea, Abdominal pain, Diarrhea etc.

Note 1) If such symptoms are observed, administration should be discontinued.

(5) Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

(6) Use during Pregnancy, Delivery or Lactation

1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]
2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursed infants.]

(7) Pediatric Use

The safety of this product in children has not been established. [Insufficient clinical data]

PRECAUTIONS FOR HANDLING

- Store at dry and cool place, protected from direct sunlight.
- Since this product contains natural crude drugs, some differences may be noted in the color or taste, etc. However, there is no change in the effect.

PACKAGING

500 g
735 g (2.5 g x 294 packets)
210 g (2.5 g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
050-3776-0358