

November 2014
(3rd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Yokukansanryo Extract Granules TG (Yokukansan)

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.	(62AM) 0181
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, 7.5g, contains 3.7g of the dried extract (Yokukansanryo extract) from the following mixed crude drugs.

JP Japanese Angelica Root -----	3 g
JP Poria Sclerotium -----	4 g
JP Uncaria Hook -----	3 g
JP Bupleurum Root -----	2 g
JP Cnidium Rhizome -----	3 g
JP Glycyrrhiza -----	1.5 g
JP Atractylodes Rhizome -----	4 g

(JP: The Japanese Pharmacopeia)

The inactive ingredients contained are Lactose Hydrate, Corn Starch and Magnesium Stearate.

(2) This product is light brown-colored granules, smells slightly, and tastes slightly sweet and astringent.

INDICATIONS

The following symptoms of those patients with delicate constitution and nervousness:

Neurosis, insomnia, night cry in children, and peevishness in children

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 (Yokukansan should be administered with care in the following patients.)

- 1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, diarrhea, etc. may occur.]
- 2) Patients with anorexia, nausea or vomiting [These 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 any duplication of the contained crude drugs.

(3) Drug Interactions

Precautions for coadministration (Yokukansan 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, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.
- 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 **Heart failure:** Heart failure may occur. Adequately monitor the patient, and discontinue administration and take appropriate measures if fluid buildup, rapid weight gain, and signs and symptoms of heart failure (e.g., shortness of breath, increased cardiothoracic ratio, pleural effusion) are observed.
- ④ **Myopathy, rhabdomyolysis:** Myopathy and rhabdomyolysis may occur as a result of hypokalemia. Adequately monitor the patient, and discontinue administration and take appropriate measures such as administration of a potassium preparation if sluggishness, muscular weakness, myalgia, limb cramping/paralysis, elevated CK (CPK) levels, and elevated blood and urine myoglobin levels are observed.
- ⑤ **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with remarkable elevation of AST(GOT), ALT(GPT), ALP and γ -GTP etc. 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, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Diarrhea, etc.
Neuropsychiatric	Somnolent
Other	Malaise

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

The safety of this product in pregnant woman has not been established. Therefore, the product should be used in pregnant women, women who may possibly be pregnant only if the expected therapeutic benefit outweigh the possible risks associated with treatment.

(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

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

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., LTD.
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050-3776-0358