

**Kampo Formulations for Prescription 2018
- Information in Package Inserts of 148 Formulations -**

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**Usability Research Subcommittee
Ethical Kampo Products Committee
Japan Kampo Medicines Manufacturers Association (JKMA)**

Not for sale

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Introduction

The Japan Kampo Medicines Manufacturers Association (JKMA) occasionally receives inquiries about how many kinds of Kampo formulations for prescription are marketed and how many companies currently market them. There has been an increasing need recently for overviews of Japanese Kampo formulations for prescription in academic papers, and in publications of the World Health Organization (WHO), the International Organization for Standardization (ISO), etc.

In January 1995, JKMA's Planning Committee produced an in-house summary of the Kampo formulations for prescription currently approved entitled, *Summary of Kampo Formulations for Prescription*. The situation has changed considerably over the last few decades with many Kampo formulations for prescription being discontinued or marketed by a different company. However, the *Summary of Kampo Formulations for Prescription* has not been updated since 1995 and no materials give an overview of the current state of Kampo formulations for prescription. It is, therefore, difficult to give an accurate and simple explanation of the current situation, so incorrect descriptions occasionally appear in academic papers.

On November 11, 2011, JKMA's Usability Research Subcommittee took the initiative to summarize the database on the current state of Kampo formulations entitled Information in Package Inserts for Ethical Pharmaceuticals on the Pharmaceutical and Medical Devices Agency (PMDA) website. Information is reviewed and revised every two years.

【Table】 Year of publication and investigation date of Information on package inserts of 148 Formulations

Year of publication	Investigation date of information	Period of time
Fiscal 2012	November 11th, 2011	Until November 11th, 2011
Fiscal 2014	June 2nd, 2014	From November 12th, 2011 to June 2nd, 2014
Fiscal 2016	May 11th, 2016	From June 3rd, 2014 to May 11th, 2016
Fiscal 2018	April 9th, 2018	From May 12th, 2016 to April 9th, 2018

The latest edition (Fiscal 2018) is a reevaluation and revision of the information that was changed until April 9, 2018. Given that information in the package inserts are provided by Kampo manufacturers who vouch for their accuracy, and that this document provides the latest and most accurate information updated through April 2018, we hope that it will help facilitate correct understanding of the current status of Kampo formulations for prescription.

Any citation or excerpt from this document must include a notation that the information has been updated as of April 2018.

The Usability Research Subcommittee plans to conduct regular reviews of this document so as to ensure that it contains the most up-to-date information possible. Readers who discover any errors are asked to advise the JKMA.

Preparation

Listing of Kampo Formulations for Prescription

- (1) The Kampo formulations for prescription listed here are from the *Information in Package Inserts for Ethical Pharmaceuticals* published on the Pharmaceuticals and Medical Devices Agency (PMDA) website (<https://www.info.pmda.go.jp/>) (accessed 9 April 2018) and those that are classified as “Kampo formulation (Number 875200)” based on Japan Standard Commodity Classification.
- (2) If a product with an identical name is marketed by several distributors, it will be handled as separate products in this document, even if they are fundamentally identical. However, a product that is only packaged differently (i.e., bottled or as individual sachets) is handled as an identical product, even if the different packaging types have separate package inserts.
- (3) Products listed in the “Information in the Package Inserts for Ethical Pharmaceuticals” on the PMDA website at the time of the Usability Research Subcommittee’s investigation but confirmed as “interim products” (products which will be removed from the National Health Insurance drug price list before Mar 31, 2018) according to the Ministry of Health, Labour and Welfare Notification issued on March 5, 2017 are excluded from this list. There is no such products in this time investigation.

Policies on Listing Information in Package Inserts

- (1) The package insert files in *Information in Package Inserts for Ethical Pharmaceuticals* on the PMDA website are in two file formats, Standard Generalized Markup Language (SGML) and Portable Document Format (PDF); this document was essentially prepared on the basis of the PDF version.
- (2) Precautions for Use are not listed here because they are revised frequently.
- (3) Indications are classified by pattern using an alphanumeric code. Indication patterns are listed at the end in the table of each Kampo formulation.
- (4) Japanese Pharmacopoeia denotations for the crude drugs in the Component Ratio section have been abbreviated, even if they are identified in the package insert. Inactive ingredients with indication of Japanese Pharmacopoeia are listed in package inserts as they appear.

Listing of Detailed Information

The list of Kampo formulations shows product names in alphabetical order.

(1) Date of Making or Revision of Package Insert

Only the most up-to-date information has been included.

(2) Product Name, Manufacturer, and Distributor

The product name appears at the top of the box and the names of the manufacturer and distributor appear at the bottom of the box. If the manufacturer is the distributor, only the name of the manufacturer has been listed. If the sales agency is different from the distributor, the listing appears as Sales Agency/Distributor.

(3) Approval No., Date of Listing in the NHI Reimbursement Price, Date of Initial Marketing in Japan

The Approval No. for each product appears as it does in its package insert (PDF version).

The Date of Listing in the NHI Reimbursement Price and Date of Initial Marketing in Japan are replaced with the Western calendar format (A.D. or C.E.) if the dates are written with the Japanese era names in the package insert.

The extract products among the Kampo formulations for prescription are substitute products according to *How to Treat Ethical Kampo Extract Products*, Ministry of Health and Welfare Notification 120, issued by the Second Evaluation and Registration Division Chief as of May 31 1985 (commonly known as the Maru-Kan Notification). Therefore, the Approval No., Date of Listing in the NHI Reimbursement Price, and Date of Initial Marketing in Japan are the number and dates as of the date of substitute product approval. It should be noted that although a large number of Kampo extract formulations went through the approval process, listing on the NHI reimbursement price list, and began to be marketed in Japan prior to substitute product approval (late 1970s), this document does not include information from the time of initial approval.

In addition, the date of listing on the NHI reimbursement price list and date of initial marketing in Japan may not be the dates of substitute product approval, depending on the company and product circumstances. For example, Kanebo Pharmaceuticals, Ltd. changed its name to Kracie Pharma, Ltd. in 2007, so the date of listing on the NHI reimbursement price list and date of initial marketing in Japan for Kracie Pharma, Ltd. products follow the date of the company's name change (and the approval numbers did not change).

(4) Daily Dosage

The daily formulation dosage appears in grams to one decimal place. Any dosage indicated to two or more decimal places includes the last significant digit. Dosages in milligrams have been converted to grams. Dosages for tablets (including film-coated tablets), capsules, and pills also appear the numbers of tablets, capsules, or pills in addition to dosage weight.

(5) Extract Contained in Daily Dosage

The daily extract dosage appears in grams to one decimal place. Any dosage indicated to two

or more decimal places includes the last significant digit. Dosages in milligrams have been converted to grams.

If a “non-extract crude drug” (e.g., Koi in daikenchuto) is added to an “extract” as an active ingredient, the extract quantity appears in the table (column for Extract Contained in daily dosage) and an explanatory note appears separately. A “zero (0)” appears in this table (column for non-extract preparations [preparations using only powdered crude drug]) and an explanatory note appears separately.

(6) Inactive Ingredients

This appears according to the package insert (PDF) for the product. Any Japanese Pharmacopoeia entry appears as is.

(7) Dosage Form

This is the dosage form as it appears in the product’s package insert: granules, fine granules, tablets, film-coated tablets, pills, powders, ointment, and capsules.

The dosage form indicated in the product name may differ from the dosage form that appears in the package insert. For example, the dosage form of Taikodo Ryutanshakanto Extract Fine Granules is described in the package insert as powders. (So it appears in this document as powders.)

(8) Identification Code (Item Number, etc.)

This is the identification (ID) code or number that appears in the package insert. Logo-like product codes (e.g., Taikoseido Pharmaceutical Co., Ltd.’s *Tai*) have been omitted. Any such code that appears as a product number, rather than an identification code or number, appears in brackets.

(9) Indications

The indications for each product as printed in the package insert (PDF) are classified by pattern.

If the printed indications have essentially the same meaning, they are deemed to be the same indications. While their meanings may vary, indications that are basically the same (e.g., “constipation” and “constipation syndrome”, and the same diseases but names listed in different order) are given the same branch number.

The pattern numbers A/B/C and A-1/A-2/A-3 are assigned in the order of decreasing number of package inserts.

(10) Dosage and Administration (adult; per day)

This is a simplified description based on the information in the package insert.

(11) Packaging

In general, the information on the package is according to the information that appears in the product’s package insert (PDF).

(12) Component Ratio

Crude drug names are arranged in the order listed in *The guide book of the approval*

standards for OTC Kampo products (Revised edition) (supervision of Hiroyuki Goda, Takashi Hakamazuka and the Japan Kampo Manufacturers Association [Jihosha, 2013]) Relevant or same crude drugs with different notations were arranged to be shown next to each other.

The following are examples of related crude drugs with different notations.

Donkey Glue and gelatin; Cherry Bark and Quercus Bark; Processed Aconite Root, Powdered Processed Aconite Root and Powdered processed Aconite Root 2; Orange Fruit and Immature Orange; Cinnamon Bark and Cinnamon Twig; Ginger, Fresh Ginger, and Processed Ginger; Atractylodes Lancea Rhizome and Powdered Atractylodes Lancea Rhizome; Alisma Rhizome and Powdered Alisma Rhizome; Polyporus Sclerotium and Powdered Polyporus Sclerotium; Atractylodes Rhizome and Atractylodes Lancea Rhizome; Poria Sclerotium and Powdered Poria Sclerotium; Sodium Sulfate Hydrate and Anhydrous Sodium Sulfate; Saposhnikovia Root and Rhizome, and Glehnia Root and Rhizome

Daily dosages of crude drugs appear in grams to one decimal place. Dosages in milligrams have been converted to grams.

(13) Other

Items that require supplemental remarks are described in the margin.

Kampo Formulations for Prescription – Current State

Number of Items of Kampo Formulations for Prescription (No. of Approvals) – 653

Including:

Formulations for internal use – 649

Non-extract formulations for internal use – 3

Honzo Goreisan Extract Granules-R

OHSUGI Shireito Extract Fine Granules for Ethical Use

UCHIDA Hachimigan Pills Medical

Formulations for external use – 1

TSUMURA Shiunko Ointment

Number of Products of Kampo Formulations for Prescription (No. of package inserts) – 682

Including:

Formulations for internal use – 678

Non-extract formulations for internal use – 3

Honzo Goreisan Extract Granules-R

OHSUGI Shireito Extract Fine Granules for Ethical Use

UCHIDA Hachimigan Pills Medical(distributed by Kracie
Pharmaceutical, Ltd.)

Formulations for external use – 1

TSUMURA Shiunko Ointment

Number of Manufacturers of Kampo Formulations for Prescription – 15

Honzo Pharmaceutical Co., Ltd., Kotaro Pharmaceutical Co., Ltd., Kohwa Yakutuu Inc., Kracie
Pharma, Ltd., Matsuura Yakugyo Co., Ltd., Ohsugi Pharmaceutical Co., Ltd., Ominedo
Pharmaceutical Industry Co., Ltd., Sanwa Shoyaku Co., Ltd., JPS Pharmaceutical Co., Ltd.,
Taikoseido Pharmaceutical Co., Ltd., Takasago Pharmaceutical Industry Co., Ltd., Teikoku
Kampo Seiyaku Co., Ltd., Toyo Yakuko Co., Ltd., Tsumura & Co.

Number of Distributors of Kampo Formulations for Prescription – 13

Fuso Pharmaceutical Industries Ltd., Honzo Pharmaceutical Co., Ltd., JPS Pharmaceutical Co., Ltd., Kotaro Pharmaceutical Co., Ltd., Kracie Pharma, Ltd., Matsuura Yakugyo Co., Ltd., Ohsugi Pharmaceutical Co., Ltd., Ohki Pharmaceutical Co., Ltd., Sanwa Shoyaku Co., Ltd., Taikoseido Pharmaceutical Co., Ltd., Toyo Yakuko Co., Ltd., Tsumura & Co.

Based on information in package inserts for Kampo formulations for prescription listed in *Information in Package Inserts for Ethical Pharmaceuticals* published on the Pharmaceuticals and Medical Devices Agency (PMDA) website (<https://www.info.pmda.go.jp/>) (accessed 9th April 2018).