

## NATURAL HEALTH PRODUCT

### KELP PRODUCTS

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

#### Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

**Date** October 28, 2022

#### Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Ascophyllum nodosum</i>	▶ Knuppetang ▶ Norwegian kelp	<i>Ascophyllum nodosum</i>	▶ Thallus ▶ Whole	Dry
<i>Fucus vesiculosus</i>	▶ Black tang ▶ Bladder fucus ▶ Kelpware ▶ Seawrack	<i>Fucus vesiculosus</i>	▶ Thallus ▶ Whole	Dry
<i>Laminaria digitata</i>	▶ Horsetail kelp ▶ Kelp ▶ Silketare	<i>Laminaria digitata</i>	▶ Thallus ▶ Whole	Dry
<i>Laminaria japonica</i>	▶ Hai dai ▶ Japanese kelp ▶ Makombu ▶ Sea tangle	<i>Laminaria japonica</i>	▶ Thallus ▶ Whole	Dry

References: Proper names: Guiry and Guiry 2018a,b; Common names: TGA 2016, The Biodiversity Committee of Chinese Academy of Science 2013; Source information: Guiry and Guiry 2018a,b.

#### Route of administration

Oral

## Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

## Use(s) or Purpose(s)

### *All products*

- ▶ Source of/Provides antioxidants (Murphy et al. 2013; CNF 2012; Kang et al. 2012; Veena et al. 2008; Veena et al. 2007; Zhang et al. 2007; Jin et al. 2004).
- ▶ Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Murphy et al. 2013; CNF 2012; Kang et al. 2012; Veena et al. 2008; Veena et al. 2007; Zhang et al. 2007; Jin et al. 2004).

### *Products providing 0.8 g or more of *Fucus vesiculosus* per day*

- ▶ Traditionally used in Herbal Medicine as an alterative for the glandular system (Hoffman 2003; Duke 2002; Grieve 1931a,b; Felter and Lloyd 1898).
- ▶ Used in Herbal Medicine to support normal thyroid function (Bradley 1992; Grieve 1931a,b; Ellingwood 1919).

### *Products standardized to iodine*

As per the Natural and Non-prescription Health Products Directorate (NNHPD) Multi-vitamin/mineral Supplements monograph.

## Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

## Dose(s)

### Subpopulation(s)

Adults 18 years and older

## Quantity(ies)

### *Antioxidants*

Methods of preparation: Dry, Powdered, Non-standardized ethanolic extracts (Dry extract, Tincture, Fluid extract)

Not to exceed 1 gram of kelp per day (Barnes et al 2007; Mills and Bone 2005; Kolb et al 2004; Duke 2002; BHP 1996; Bradley 1992).

### *Fucus vesiculosus: alterative, support normal thyroid function*

0.8 - 1 gram of *Fucus vesiculosus* per day (Mills and Bone 2005; Bradley 1992).

### *Iodine claims (Multi-vitamin/mineral Supplements monograph)*

Methods of preparation: Dry standardized, Powdered standardized, Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Medicinal ingredient(s) must provide the minimum amount of iodine outlined on the NNHPD Multi-vitamin/mineral Supplements monograph. Iodine should be indicated on the PLA form as a potency constituent.

### Note

The total amount of iodine provided by the product must not exceed 800 micrograms iodine per day (IOM 2006).

## Direction(s) for use

No statement required.

## Duration(s) of use

No statement required.

## Risk information

### Caution(s) and warning(s)

#### *All products*

- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (Gardner and McGuffin 2013; Ren et al 2013; Zhao et al 2012; Brinker 2010; Gruenwald et al 2007; Duke 2002).

- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (Brinker 2010; Barnes 2002).

### Contraindication(s)

No statement required.

### Known adverse reaction(s)

No statement required.

### Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations* (NHPR).

### Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

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