

Kelp Products

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Extracted: 2025-08-26T06:37:40.283046

Kelp Products (PDF Version - 109 KB) 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 ingredient. Notes Text in parentheses is additional optional information which can be included on the 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 on the label. Date October 25, 2024 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) Ascophyllum nodosum Knotted wrack Egg wrack Kuppetang Norwegian kelp Ascophyllum nodosum Thallus Whole Dry Fucus vesiculosus Black tang Bladder fucus Bladderwrack Kelpware Seawrack Fucus vesiculosus Thallus Whole Dry Laminaria digitata Horsetail kelp Kelp Silketare Laminaria digitata Thallus Whole Dry Saccharina japonica Hai dai Japanese kelp Makombu Sea tangle Saccharina japonica Thallus Whole Dry References: Proper name: Guiry and Guiry 2018a,b; Common names: TGA 2020; 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 antioxidants/Provides antioxidants (CNF 2024; Murphya et al. 2013; 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 (CNF 2024; Murphya et al. 2013; 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 alternative 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 For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Kelp is traditionally used in Herbal Medicine as an alternative for the glandular system). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. 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: alternative, 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 current 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 Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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). Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 . 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details.

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DOSAGE FORM(S)

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.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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). Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Ascophyllum nodosum	Knotted wrack Egg wrack Kuppertang Norwegian seaweed	Ascophyllum nodosum	Thallus Whole	Dry
Fucus vesiculosus	Black tang Bladder fucus Bladderwrack Kelp Fucus vesiculosus	Fucus vesiculosus	Thallus Whole	Dry
Laminaria digitata	Horsetail kelp Kelp Silketare	Laminaria digitata	Thallus Whole	Dry
Saccharina japonica	Hai dai Japanese kelp Makombu Sea tangle	Saccharina japonica	Thallus Whole	Dry