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

March 31, 2015

Medicinal Ingredients

Table 1 Medicinal ingredients. 1

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Ascophyllum nodosum</em></td>
<td>Norwegian Kelp</td>
<td></td>
</tr>
<tr>
<td><em>Fucus vesiculosus</em></td>
<td>► Bladder fucus</td>
<td>► Thallus</td>
</tr>
<tr>
<td></td>
<td>► Kelpware</td>
<td>► Whole</td>
</tr>
<tr>
<td></td>
<td>► Seawrack</td>
<td></td>
</tr>
<tr>
<td><em>Laminaria digitata</em></td>
<td>Kelp</td>
<td></td>
</tr>
<tr>
<td><em>Laminaria japonica</em></td>
<td>► Japanese kelp</td>
<td></td>
</tr>
<tr>
<td></td>
<td>► Makombu</td>
<td></td>
</tr>
</tbody>
</table>

1 The following references have been consulted:

Gardner and McGuffin 2013; Guiry and Guiry 2013a,b; The Biodiversity Committee of Chinese Academy of Science 2013; Guiry and Guiry 2012a,b; Seeley and Schlesinger 2012; Brinker 2010; Barnes et al. 2007; Sweetman 2007; TGA 1999.

Route(s) of administration

Oral
Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)

Statement(s) to the effect of

All products

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

All products standardized to iodine

As per the Natural and Non-Prescription Health Products Directorate (NNHPD) Iodine monograph

Products containing ≥ 0.8 g of Fucus vesiculosus

- 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).

Dose(s)

Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)
Quantity(ies)

Table 2  Acceptable Method of Preparation and Dosing.¹

<table>
<thead>
<tr>
<th>Medicinal Ingredient(s)</th>
<th>Method(s) of Preparation</th>
<th>Dose(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Ascophyllum nodosum</em></td>
<td>Dry, Powder, Non-standardized ethanolic extracts (fluid extract, tincture)</td>
<td>Up to 1 gram per day</td>
</tr>
<tr>
<td><em>Fucus vesiculosus</em></td>
<td></td>
<td>Up to 1 gram per day</td>
</tr>
<tr>
<td><em>Laminaria digitata</em></td>
<td></td>
<td>Up to 1 gram per day</td>
</tr>
<tr>
<td><em>Laminaria japonica</em></td>
<td></td>
<td>Up to 1 gram per day</td>
</tr>
</tbody>
</table>

¹ The following references have been consulted:


Additional notes

Iodine

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

*For iodine monograph claims*

Medicinal ingredient(s) must provide the minimum amount of Iodine outlined on the NNHPD Iodine monograph.

Directions for use

No statement required.

Duration of use

No statement required.

Risk information  Statement(s) to the effect of

Caution(s) and warning(s)

All products
If you are taking blood thinners, consult a health care practitioner prior to use (Gardner and McGuffin 2013; Ren et al 2013; Zhao et al 2012; Brinker 2010; Gruenwald et al 2007; Duke 2002).

If you are pregnant or breastfeeding, consult a health care practitioner prior to use (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.

Specifications

The finished product specifications must be established in accordance with the requirements described in the NNHPD Quality of Natural Health Products Guide.

The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited


Felter HW, Lloyd JU. King’s American Dispensatory. Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].


Veena CK, Josephine A, Preetha SP, Varalakshmi P. Effect of sulphated polysaccharides on erythrocyte changes due to oxidative and nitrosative stress in experimental hyperoxaluria. Human & Experimental Toxicology 2007;26:923-932.


References reviewed


Garber DW, Henkin Y, Osterlund LC, Woolley TW, Segrest JP. Thyroid function and other clinical chemistry parameters in subjects eating iodine-enriched eggs. Food and Chemical Toxicology 1993;31(4):247-51.


Myers S. A combined phase I and II open label study on the effects of a seaweed extract nutrient complex on osteoarthritis. Biologics 2010;4:33-44.


Wren RC. Potter's Cyclopedia of Botanical Drugs and Preparations. London (GB): Potter and Clark; 1907.