NATURAL HEALTH PRODUCT

SELENIUM

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 PLA and product label at the applicant’s discretion.
- The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant.

Date: February 9, 2016

Proper name(s):

Selenium (Sweetman 2015; O’Neil et al. 2001)

Common name(s):

Selenium (Sweetman 2015; O’Neil et al. 2001)

Source material(s):

- Selenium acid (Sweetman 2015)
- Selenium aspartate (NIH 2015)
- Selenium citrate (NIH 2015)
- Selenium dioxide, monohydrate (Sweetman 2015)
- Selenium fumarate (Richards 2008)
- Selenium glycinate (Richards 2008)
- Selenium hydrolyzed animal protein (HAP) chelate (Albion 2015)
- Selenium hydrolyzed vegetable protein (HVP) chelate (NIH 2015)
- Selenium malate (Richards 2008)
- Selenium succinate (Richards 2008)
- Selenium-enriched yeast (EFSA 2008)
- Selenocysteine (TGA 2007)
- Selenomethionine (TGA 2007)
- Sodium hydrogen selenite (EFSA 2008)
- Sodium selenate (TGA 2007)
- Sodium selenite (TGA 2007)
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:

General:

- Source of selenium, a factor in the maintenance of good health (IOM 2006; IOM 2000).
- Source of selenium, a factor in normal growth and development (CFIA 2015).
- Source of selenium, to support biological functions which play a key role in the maintenance of good health (IOM 2006; IOM 2000).

Specific:

- Source of/An antioxidant for the maintenance of good health (CFIA 2015; IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- Source of/An antioxidant that helps protect against oxidative stress (CFIA 2015; IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- Source of/An antioxidant that helps (to) a) fight/ b) protect (cells) against/ c) reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (CFIA 2015; IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).
- Helps to maintain normal function of the thyroid gland (EC 2015).

Dose-specific:

For products providing daily doses of selenium at or above the Recommended Dietary Allowance (RDA) (adjusted for the life stage groups), the following use or purpose is acceptable:

- Helps to prevent selenium deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 2000).

Notes:

- See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.
- Selenium deficiency is rare in North America (Groff and Gropper 2000).
Dose(s):

Table 1: Dose information for selenium presented as dose per day

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Selenium (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum¹</td>
</tr>
<tr>
<td>Adults ≥ 19 y</td>
<td>3.5</td>
</tr>
</tbody>
</table>

¹Based on approximately 5% of the highest RDA (IOM 2006). See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.

²Maximum dose based on the Tolerable Upper Intake Level (UL) which applies to total selenium intake from food and supplements. Maximum dose was obtained by subtracting the average dietary intake of selenium from UL (IOM 2006).

³Includes pregnant and breastfeeding women.

Duration of use:

No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

For products providing doses of selenium at 200 µg, per day, the following statement is required:

If you have a history of non-melanoma skin cancer, consult a health care practitioner prior to use (Duffield-Lillico et al. 2003).

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 Natural and Non-Prescription Health Products Directorate Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

References:


Appendix 1: Definitions

**Recommended Dietary Allowances (RDA):** The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group (IOM 2006).

**Tolerable Upper Intake Level (UL):** The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase (IOM 2006).

Appendix 2: RDA Values

The RDA values for selenium (provided below) for the purpose of this monograph are intended to:
- provide targets for setting appropriate supplement dosage levels;
- provide the minimum dose for the use of the dose specific use or purpose: “Helps to prevent selenium deficiency”;
- facilitate the optional labelling of % RDA values.

Table 2: Recommended Dietary Allowance for selenium based on life stage group (IOM 2006)

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Selenium (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults ≥ 19 y</td>
<td>55</td>
</tr>
<tr>
<td>Pregnancy 19-50 y</td>
<td>60</td>
</tr>
<tr>
<td>Breastfeeding 19-50 y</td>
<td>70</td>
</tr>
</tbody>
</table>