CALCIUM

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

Note: Text in parentheses is additional optional information which can be included on the PLA and product labels at the applicants’ discretion. The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: June 23, 2009

Proper name(s): Calcium (Sweetman 2007; O’Neil et al. 2006)

Common name(s): Calcium (Sweetman 2007; O’Neil et al. 2006)

Source material(s):
- Bone meal*
  (HC 2007)
- Calcium acetate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
- Calcium ascorbate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
- Calcium bisglycinate
  (Albion 2000)
- Calcium carbonate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
- Calcium chloride
  (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Calcium chloride dihydrate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
- Calcium chloride hexahydrate
  (Sweetman 2007; O’Neil et al. 2006)
- Calcium citrate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
- Calcium citrate malate
  (Patrick 1999)
- Calcium citrate tetrahydrate
  (Sweetman 2007; O’Neil et al. 2006)
• Calcium fumarate
  (HC 2007)
• Calcium gluconate
  (Sweetman 2007)
• Calcium gluconate monohydrate
  (Sweetman 2007)
• Calcium gluconate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
• Calcium gluconate monohydrate
  (Sweetman 2007; IOM 2003)
• Calcium glutarate
  (HC 2007)
• Calcium glycerophosphate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
• Calcium hydrolyzed animal protein (HAP) chelate
  (Albion 1996; Albion 1993)**
• Calcium hydrolyzed vegetable protein (HVP) chelate
  (Albion 1996; Albion 1993)**
• Calcium hydroxide
  (IOM 2003)
• Calcium lactate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
• Calcium lactate gluconate
  (Sweetman 2007)
• Calcium lactate pentahydrate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
• Calcium lactate trihydrate
  (Sweetman 2007; IOM 2003)
• Calcium lactobionate dihydrate
  (Sweetman 2007; IOM 2003)
• Calcium levulinate
  (Sweetman 2007; O’Neil et al. 2006)
• Calcium levulinate dihydrate
  (Sweetman 2007; O’Neil et al. 2006)
• Calcium malate
  (HC 2007)
• Calcium oxide
  (IOM 2003)
• Calcium phosphate dibasic
  (Sweetman 2007; IOM 2003)
• Calcium phosphate monobasic
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
• Calcium phosphate tribasic
  (Sweetman 2007; IOM 2003; O’Neil et al. 2006)
Calcium pidolate
(Sweetman 2007)

Calcium pyrophosphate
(IOM 2003)

Calcium silicate
(Sweetman 2007; IOM 2003; O’Neil et al. 2006)

Calcium sodium lactate
(Sweetman 2007)

Calcium succinate
(O’Neil et al. 2006)

Calcium sulfate
(IOM 2003)

Calcium sulfate dihydrate
(IOM 2003)

Coral
(HC 2007)

Dolomite
(Sweetman 2007; O’Neil et al. 2006)

Oyster shell
(HC 2007)

* When bone meal is used as a source material for calcium, it must be sourced from a non-human animal that is not susceptible to Transmissible Spongiform Encephalopathy (TSE) diseases, including Bovine Spongiform Encephalopathy (BSE) (HC 2006).

** When calcium HAP or HVP chelate are used as a source material, the products should be indicated for an adult subpopulation only.

** Route(s) of administration:** Oral

**Dosage form(s):** Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. 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:** A factor in the maintenance of good health (IOM 2006; IOM 1997).
Specific:

- Helps in the development and maintenance of bones and teeth (Optional: “especially in childhood, adolescence and young adulthood”) (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997).

- Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may help prevent bone loss/osteoporosis (in peri- and postmenopausal women) (in later life) (FDA 2008; NAMS 2006; Shils et al. 2006; Groff and Gropper 2000; NIH 2000; Brown and Josse 2002; Tang et al. 2007).

  Note: “may reduce the risk of developing osteoporosis” is an acceptable alternative to “may help prevent bone loss/osteoporosis”.

Dose-specific:

For products providing daily doses of calcium at or above the Adequate Intake (AI) (adjusted for the life stage groups), the following use or purpose is acceptable:

- Helps to prevent calcium deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1997).

See Appendix 1 for definitions and Table 2 in Appendix 2 for AI values.

Dose(s):

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

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Calcium (mg/day)</th>
<th>Minimum¹</th>
<th>Maximum²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3 y</td>
<td></td>
<td>65</td>
<td>1,500</td>
</tr>
<tr>
<td>4-8 y</td>
<td></td>
<td>65</td>
<td>1,500</td>
</tr>
<tr>
<td>Adolescents</td>
<td></td>
<td>65</td>
<td>1,500</td>
</tr>
<tr>
<td>9-13 y</td>
<td></td>
<td>65</td>
<td>1,500</td>
</tr>
<tr>
<td>14-18 y</td>
<td></td>
<td>65</td>
<td>1,500</td>
</tr>
<tr>
<td>Adults³</td>
<td></td>
<td>≥ 19 y</td>
<td>65</td>
</tr>
</tbody>
</table>

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

² Maximum dose based on the Tolerable Upper Intake Level (UL) less average dietary intake (adapted from IOM 2006).

³ Includes pregnant and breastfeeding women.

Direction(s) for use:

Statement(s) to the effect of:

Take a few hours before or after taking other medications (Sweetman 2007; ASHP 2005).
Duration(s) of use: No statement required.

Risk information:

Caution(s) and warning(s): No statement required.

Contraindication(s): No statement required.

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD Natural Health Products Ingredients Database and must meet the limitations outlined in the database.

Specifications:

- The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.
- The medicinal ingredient may comply with the specifications outlined in the applicable calcium monographs published in the USA (USP), British (BP) and European (Ph. Eur.) Pharmacopoeias.

References cited:


References reviewed:


**Appendix 1: Definitions**

**Adequate Intake (AI):** The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate. An AI is used when an RDA cannot be determined (IOM 2006).

**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: AI Values**

The AI values for calcium are provided below. For the purpose of this monograph, these values 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 calcium deficiency”;
- facilitate the optional labelling of % AI values.

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Calcium (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td></td>
</tr>
<tr>
<td>1-3 y</td>
<td>500</td>
</tr>
<tr>
<td>4-8 y</td>
<td>800</td>
</tr>
<tr>
<td>Adolescents</td>
<td></td>
</tr>
<tr>
<td>9-18 y</td>
<td>1,300</td>
</tr>
<tr>
<td>Adults</td>
<td></td>
</tr>
<tr>
<td>19-50 y</td>
<td>1,000</td>
</tr>
<tr>
<td>≥ 51 y</td>
<td>1,200</td>
</tr>
<tr>
<td>Pregnancy</td>
<td></td>
</tr>
<tr>
<td>14-18 y</td>
<td>1,300</td>
</tr>
<tr>
<td>19-50 y</td>
<td>1,000</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td></td>
</tr>
<tr>
<td>14-18 y</td>
<td>1,300</td>
</tr>
<tr>
<td>19-50 y</td>
<td>1,000</td>
</tr>
</tbody>
</table>