VITAMIN B$_{12}$

Date: November 8, 2007

Proper name(s): Vitamin B$_{12}$ (Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Common name(s): Cyanocobalamin, vitamin B$_{12}$ (Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Source material(s):
- Cyanocobalamin/Vitamin B$_{12}$ (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Hydroxocobalamin (Van Der Kuy et al. 2002; Chalmers et al. 2000; EC 2000; Zeitlin et al. 1985; Yamagata et al. 1966)
- Methylcobalamin (Sweetman 2007; O’Neil et al. 2001)

Note: The slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

Route(s) of administration: Oral

Dosage form(s): Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewable 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 food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s): Statement(s) to the effect of:

General claim: A factor in the maintenance of good health (IOM 2006; IOM 1998).
Specific claims:

- Helps the body to metabolize carbohydrates (Shils et al. 2006; Groff and Gropper 2000; IOM 1998).
- Helps the body to metabolize fats and proteins (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1998).
- Helps to form red blood cells (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1998).

Dose-specific claim:

For products providing daily doses of vitamin B₁₂ at or above the Recommended Dietary Allowance (RDA) (adjusted for the life stage groups), the following use or purpose is acceptable:

Helps to prevent vitamin B₁₂ deficiency (IOM 2006; Shils et al. 2006; Groff and Gropper 2000; IOM 1998).

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

Dose(s):

Table 1: Dose information for vitamin B₁₂ presented as dose per day

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Vitamin B₁₂ (µg/day)</th>
<th>Minimum¹</th>
<th>Maximum²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0.09</td>
<td>1,000</td>
</tr>
<tr>
<td>Children</td>
<td>1-3 y</td>
<td>0.09</td>
<td>1,000</td>
</tr>
<tr>
<td></td>
<td>4-8 y</td>
<td>0.09</td>
<td>1,000</td>
</tr>
<tr>
<td>Adolescents</td>
<td>9-13 y</td>
<td>0.09</td>
<td>1,000</td>
</tr>
<tr>
<td></td>
<td>14-18 y</td>
<td>0.14</td>
<td>1,000</td>
</tr>
<tr>
<td>Adults³</td>
<td>≥ 19 y</td>
<td>0.14</td>
<td>1,000</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 supported by the following references: HC 2006 and FSA 2003.
³Includes pregnant and breastfeeding women.

Duration of use: No statement required.

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

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 List of Acceptable
Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications: Must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.

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).

Appendix 2: RDA Values

The RDA values for vitamin B\textsubscript{12} 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 vitamin B\textsubscript{12} deficiency”;
- facilitate the optional labelling of % RDA values.

Table 2: Recommended Dietary Allowance values for vitamin B\textsubscript{12} based on life stage group (IOM 2006)

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Vitamin B\textsubscript{12} (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>1-3 y</td>
</tr>
<tr>
<td></td>
<td>4-8 y</td>
</tr>
<tr>
<td></td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>1.2</td>
</tr>
<tr>
<td>Adolescents</td>
<td>9-13 y</td>
</tr>
<tr>
<td></td>
<td>14-18 y</td>
</tr>
<tr>
<td></td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td>2.4</td>
</tr>
<tr>
<td>Adults</td>
<td>≥ 19 y</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>14-50 y</td>
</tr>
<tr>
<td></td>
<td>2.6</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>14-50 y</td>
</tr>
<tr>
<td></td>
<td>2.8</td>
</tr>
</tbody>
</table>