EVENING PRIMROSE OIL

Note: Vitamin E is an optional medicinal ingredient in evening primrose oil products. However, no use or purpose statements may be associated with vitamin E. See Appendix 1 for vitamin E proper name, common name, source material, and dose information.

Date: July 16, 2008

Proper name(s): *Oenothera biennis* L. (Onagraceae) (USDA 2005)

Common name(s): Evening primrose (McGuffin et al. 2000), evening primrose oil (Sweetman 2007)

Source material(s): Seed oil (Sweetman 2007; WHO 2002)

Route(s) of administration: Oral

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

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

- Source of essential fatty acids (Sweetman 2007; IOM 2006) for the maintenance of good health
- Source of omega-6 fatty acids (EP 2008; IOM 2006; Mills and Bone 2005; WHO 2002) for the maintenance of good health
- Source of linoleic acid (EP 2008; IOM 2006; Mills and Bone 2005; WHO 2002) for the maintenance of good health

Dose(s): 1,300-6,000 mg, per day (Sweetman 2007; IOM 2006; Keen 1993)
Optional potencies:

- 7-14% gamma-linolenic/gamolenic acid (GLA) (EP 2008; Mills and Bone 2005; WHO 2002);

Duration 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 *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.
- For products providing vitamin E at doses lower than the minima specified in Table 2 of Appendix 1, vitamin E must be declared as a non-medicinal ingredient.

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 Refined Evening Primrose Oil Monograph published in the British Pharmacopoeia or the Evening Primrose Oil, Refined Monograph published in the European Pharmacopoeia.
- For products indicating one or more of the optional potencies listed in the dose section, an assay must be performed in order to confirm the potency(ies).
References cited:


References reviewed:


Appendix 1: Vitamin E

Proper name(s), common name(s), and source material(s)

Table 1: Vitamin E proper name(s), common name(s) and source material(s)

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin E</td>
<td>Alpha (α)-tocopherol</td>
<td>All racemic (all rac)-α-tocopherol/ dl-α-tocopherol (Sweetman 2007; IOM 2003)</td>
</tr>
<tr>
<td>(Sweetman 2007; IOM 2003; O’Neil et al. 2001)</td>
<td></td>
<td>All rac-α-tocopheryl acetate/ dl-α-tocopheryl acetate (Sweetman 2007; IOM 2003)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All rac-α-tocopheryl succinate/ dl-α-tocopheryl acid succinate/ dl-α-tocopheryl succinate (Sweetman 2007)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RRR-α-tocopherol/ d-α-tocopherol (Sweetman 2007; IOM 2003; O’Neil et al. 2001)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RRR-α-tocopheryl acetate/ d-α-tocopheryl acetate (Sweetman 2007; IOM 2003)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RRR-α-tocopheryl succinate/ d-α-tocopheryl acid succinate/ d-α-tocopheryl succinate (Sweetman 2007; IOM 2003)</td>
</tr>
</tbody>
</table>

Quantity:

The quantity of vitamin E must always be provided in terms of α-tocopherol (AT) (i.e. mg RRR-α-tocopherol), irrespective of the source material used.

IUs may be provided as optional additional information on the PLA form in the "potency" field and on product labels.

Table 2: Dose information for vitamin E presented as dose per day (IOM 2006)

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Vitamin E (mg AT/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Adults</td>
<td>≥ 19 y</td>
</tr>
</tbody>
</table>
Conversion factors:

Table 3: Conversion of vitamin E source material quantity into vitamin E quantity in terms of alpha-\(\alpha\)-tocopherol (AT) and vitamin E activity in terms of International Units (IU) (IOM 2006)

<table>
<thead>
<tr>
<th>Source material (1 mg)</th>
<th>Vitamin E quantity (mg AT)</th>
<th>Vitamin E activity (IU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(RRR)-(\alpha)-Tocopherol</td>
<td>1.00</td>
<td>1.49</td>
</tr>
<tr>
<td>(RRR)-(\alpha)-Tocopheryl acetate</td>
<td>0.91</td>
<td>1.36</td>
</tr>
<tr>
<td>(RRR)-(\alpha)-Tocopheryl succinate</td>
<td>0.81</td>
<td>1.21</td>
</tr>
<tr>
<td>All (rac)-(\alpha)-tocopherol</td>
<td>0.50</td>
<td>1.10</td>
</tr>
<tr>
<td>All (rac)-(\alpha)-tocopheryl acetate</td>
<td>0.46</td>
<td>1.00</td>
</tr>
<tr>
<td>All (rac)-(\alpha)-tocopheryl succinate</td>
<td>0.41</td>
<td>0.89</td>
</tr>
</tbody>
</table>

Table 4: Conversion of vitamin E source material activity into vitamin E quantity in terms of alpha-\(\alpha\)-tocopherol (AT) (IOM 2006)

<table>
<thead>
<tr>
<th>Source material (1 IU)</th>
<th>Vitamin E quantity (mg AT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(RRR)-(\alpha)-Tocopherol</td>
<td>0.67</td>
</tr>
<tr>
<td>(RRR)-(\alpha)-Tocopheryl acetate</td>
<td>0.67</td>
</tr>
<tr>
<td>(RRR)-(\alpha)-Tocopheryl succinate</td>
<td>0.67</td>
</tr>
<tr>
<td>All (rac)-(\alpha)-tocopherol</td>
<td>0.45</td>
</tr>
<tr>
<td>All (rac)-(\alpha)-tocopheryl acetate</td>
<td>0.45</td>
</tr>
<tr>
<td>All (rac)-(\alpha)-tocopheryl succinate</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Examples using the vitamin E conversion factors:

a) Converting vitamin E activity into quantity of AT (mg)

Convert 400 IU of \(RRR\)-\(\alpha\)-tocopheryl succinate activity into mg AT:

\[= 400 \text{ IU} \times 0.67 \text{ mg AT/IU} \]
\[= 268 \text{ mg AT}\]

b) Converting vitamin E source material quantity into quantity of AT (mg)

Convert 200 mg of all \(rac\)-\(\alpha\)-tocopheryl acetate into mg AT:

\[= 200 \text{ mg} \times 0.46 \text{ mg AT/mg} \]
\[= 92 \text{ mg AT}\]