NATURAL HEALTH PRODUCT

FLAXSEED OIL

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.

Notes:
- 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.
- Vitamin E is an optional medicinal ingredient in flaxseed oil products. However, no use or purpose statements may be associated with vitamin E. See Appendix 2 for vitamin E proper name, common name, source material, and dose information.

Date: July 18, 2017

Proper name(s):
Linum usitatissimum L. (Linaceae) (USDA 2004)

Common name(s):
- Flaxseed oil (Hoffman 2003)
- Linseed oil (Ph. Eur. 2008; Sweetman 2007)
- Flax oil (Hendler and Rorvik 2001)

Source material(s):
Seed (Sweetman 2007)

Route(s) of administration:
Oral

Dosage form(s):
This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:

- **Children 2 years**: The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoa et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoa et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

**Use(s) or Purpose(s):**

- Source of essential fatty acids (IOM 2006) for the maintenance of good health
- Source of omega-3 fatty acids (IOM 2006) for the maintenance of good health
- Source of alpha-linolenic acid (ALA) (IOM 2006) for the maintenance of good health
- Source of omega-6 fatty acids (IOM 2006) for the maintenance of good health
- Source of linoleic acid (LA) (IOM 2006) for the maintenance of good health

**Dose(s):**

Table 1: Dose information of *Linum usitatissimum* L. oil presented as dose per day, based on uses or purposes and subpopulations.

<table>
<thead>
<tr>
<th>Use(s) or Purpose(s)</th>
<th>Subpopulations$^{1,2,3}$</th>
<th>Oil g/day</th>
<th>Oil ml/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source of essential fatty acids, omega-3 fatty acids, and/or ALA</td>
<td>Children 2-4 y</td>
<td>0.04</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>Children and adolescents 5-9 y</td>
<td>0.06</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>Adolescents 10-14 y</td>
<td>0.12</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Adults, and adolescents ≥ 15 y</td>
<td>0.23</td>
<td>1</td>
</tr>
<tr>
<td>Source of omega-6 fatty acids and/or LA</td>
<td>Children 2-4 y</td>
<td>1.28</td>
<td>1.33</td>
</tr>
<tr>
<td></td>
<td>Children and adolescents 5-9 y</td>
<td>1.93</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Adolescents 10-14 y</td>
<td>3.85</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Adults, and adolescents ≥ 15 y</td>
<td>7.70</td>
<td>8</td>
</tr>
</tbody>
</table>

$^1$ Children and adolescent doses were calculated as a proportion of the adult dose (JC 2008). The use of Flaxseed oil in children and adolescents is supported by Bove 2001.

$^2$ Adult dose supported by the following references: IOM 2006; Schwab et al. 2006; Nordström et al. 1995; Kelley et al. 1993; Fischer et al. 1984.

$^3$ Includes pregnant and breastfeeding women (Mills et al. 2006).

If potencies are declared, the only acceptable potencies are as follows:


The following potency is considered as additional information and can be included on the label: 11-35% oleic acid (Ph. Eur. 2008)

See Appendix 1 for examples of dosages according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**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.

**Storage condition(s):**

For all products, except those encapsulated: Refrigerate after opening (Nykter et al. 2006; Lukaszewicz et al. 2004).

**Non-medicinal ingredients:**

- Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.
- For products providing vitamin E at doses lower than the minima specified in Table 2 of Appendix 2, vitamin E must be declared as a non-medicinal ingredient.

**Specifications:**
The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.

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

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).

The medicinal ingredient may comply with the specifications outlined in the Linseed or Linseed Oil, Virgin, monographs published in the European Pharmacopoeia, or the Linseed or Virgin Linseed Oil monographs published in the British Pharmacopoeia.

References cited:


References reviewed:


Sanders TA, Lewis F, Slaughter S, Griffin BA, Griffin M, Davies I, Millward DJ, Cooper JA, Miller GJ. 2006. Effect of varying the ratio of n-6 to n-3 fatty acids by increasing the dietary intake of alpha-linolenic acid, eicosapentaenoic and docosahexaenoic acid or both on fibrinogen and clotting factors VII and XII in persons aged 45-70 y: the OPTILIP Study. American Journal of Clinical Nutrition 84(3):513-522.


Appendix 1: Examples of dosages

- 230 mg (~1 ml), per day (provides approximately 5% of the IOM’s AI for alpha-linolenic acid) (IOM 2006)
- 7.7 g (~8 ml), per day (provides approximately 5% of the IOM’s AI for linoleic acid) (IOM 2006)
- 28 g (~30 ml), per day (Schwab et al 2006)
- 30 g (~32 ml), per day (Nordström 1995; Fischer 1984)
- 32 g (~34 ml), per day (Kelley 1993)
Appendix 2: 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></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><em>RRR</em>-α-tocopheryl acetate/ d-α-tocopheryl acetate (Sweetman 2007; IOM 2003)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>RRR</em>-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 Product Licence Application 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>Children</td>
<td>1-8 y</td>
</tr>
<tr>
<td>Adolescents</td>
<td>9-13 y</td>
</tr>
<tr>
<td></td>
<td>14-18 y</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-(α)-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><em>RRR</em>-α-Tocopherol</td>
<td>1.00</td>
<td>1.49</td>
</tr>
<tr>
<td><em>RRR</em>-α-Tocopheryl acetate</td>
<td>0.91</td>
<td>1.36</td>
</tr>
<tr>
<td><em>RRR</em>-α-Tocopheryl succinate</td>
<td>0.81</td>
<td>1.21</td>
</tr>
<tr>
<td>All <em>rac</em>-α-tocopherol</td>
<td>0.50</td>
<td>1.10</td>
</tr>
<tr>
<td>All <em>rac</em>-α-tocopheryl acetate</td>
<td>0.45</td>
<td>1.00</td>
</tr>
<tr>
<td>All <em>rac</em>-α-tocopheryl succinate</td>
<td>0.40</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-(α)-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><em>RRR</em>-α-Tocopherol</td>
<td>0.67</td>
</tr>
<tr>
<td><em>RRR</em>-α-Tocopheryl acetate</td>
<td>0.67</td>
</tr>
<tr>
<td><em>RRR</em>-α-Tocopheryl succinate</td>
<td>0.67</td>
</tr>
<tr>
<td>All <em>rac</em>-α-tocopherol</td>
<td>0.45</td>
</tr>
<tr>
<td>All <em>rac</em>-α-tocopheryl acetate</td>
<td>0.45</td>
</tr>
<tr>
<td>All <em>rac</em>-α-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*-α-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*-α-tocopheryl acetate into mg AT:

\[= 200 \text{ mg} \times 0.45 \text{ mg AT/mg} \]
\[= 90 \text{ mg AT} \]