

Drugs and Health Products

Iron

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

June 23, 2009

Proper name(s)

Iron (Sweetman 2007; O'Neil *et al.* 2006)

Common name(s)

Iron (Sweetman 2007; O'Neil *et al.* 2006)

Source material(s)

- Ferritin (Sweetman 2007; O'Neil *et al.* 2006)
- Ferrocholate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron, carbonyl (not pentacarbonyl) (IOM 2003)
- Iron-dextrin complex (IPCS 1998)
- Iron, electrolytic (IOM 2003)
- Iron hydrolyzed animal protein (HAP) chelate (Albion 2003; Albion 1997; Albion 1996; Albion 1993)
- Iron hydrolyzed vegetable protein (HVP) chelate (Albion 2003; Albion 1997; Albion 1996; Albion 1993)
- Iron, reduced (Sweetman 2007; IOM 2003)
- Iron-sorbitol-citric acid complex (IPCS 1998)
- Iron (II) ascorbate/Ferrous ascorbate (Sweetman 2007)
- Iron (II) aspartate/Ferrous aspartate (Sweetman 2007; O'Neil *et al.* 2001)
- Iron (II) aspartate tetrahydrate/Ferrous aspartate tetrahydrate (Sweetman 2007)
- Iron (II) bisglycinate/Ferrous bisglycinate (Allen 2002; Albion 2000)
- Iron (II) carbonate/Ferrous carbonate (O'Neil *et al.* 2001)
- Iron (II) chloride/Ferrous chloride (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) chloride tetrahydrate/Ferrous chloride tetrahydrate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) citrate/Ferrous citrate (IOM 2003; O'Neil *et al.* 2006)
- Iron (II) fumarate/Ferrous fumarate (Sweetman 2007; IOM 2003; O'Neil *et al.* 2006)
- Iron (II) gluceptate/Ferrous gluceptate (Sweetman 2007)
- Iron (II) gluconate/Ferrous gluconate (Sweetman 2007; IOM 2003; O'Neil *et al.* 2006)
- Iron (II) gluconate dihydrate/Ferrous gluconate dihydrate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) glutarate/Ferrous glutarate (HC 2008)
- Iron (II) glycine sulfate/Ferrous glycine sulfate (Sweetman 2007)
- Iron (II) lactate/Ferrous lactate (Sweetman 2007; IOM 2003; O'Neil *et al.* 2006)
- Iron (II) lactate trihydrate/Ferrous lactate trihydrate (Sweetman 2007; O'Neil *et al.* 2006)

- Iron (II) malate/Ferrous malate (HC 2008)
- Iron (II) oxalate/Ferrous oxalate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) oxalate dihydrate/Ferrous oxalate dihydrate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) succinate/Ferrous succinate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) sulfate/Ferrous sulfate (Sweetman 2007; IOM 2003; O'Neil *et al.* 2006)
- Iron (II) sulfate dried (monohydrate)/Ferrous sulfate dried (monohydrate) (Sweetman 2007; IOM 2003; O'Neil *et al.* 2006)
- Iron (II) sulfate heptahydrate/Ferrous sulfate heptahydrate (Sweetman 2007; O'Neil *et al.* 2006)
- Iron (II) tartrate/Ferrous tartrate (Sweetman 2007)
- Iron (III) ammonium citrate/Ferric ammonium citrate (Sweetman 2007; IOM 2003)
- Iron (III) citrate/Ferric citrate (IOM 2003; O'Neil *et al.* 2006)
- Iron (III) glycerophosphate/Ferric glycerophosphate (HC 2008)
- Iron (III) phosphate/Ferric phosphate (IOM 2003)
- Iron (III) pyrophosphate/Ferric pyrophosphate (Sweetman 2007; IOM 2003; O'Neil *et al.* 2006)
- Iron (III) sulfate/Ferric sulfate (O'Neil *et al.* 2006)
- Saccharated iron oxide (IPCS 1998)

Note: When iron HAP or HVP chelate is 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 (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 foods or food-like dosage forms such as beverages, bars or chewing gums.

Use(s) or Purpose(s)

Statement(s) to the effect of:

General

A factor in the maintenance of good health (IOM 2006; IOM 2001)..

Specific

Helps to form red blood cells and helps in their proper function (IOM 2006; Shils *et al.* 2006; IOM 2001; Groff and Gropper 2000).

Dose-specific

For products providing daily doses of iron at or above the Recommended Dietary Allowance (RDA) or Adequate Intake (AI) (adjusted for the life stage groups), either of the following use or purpose statements are acceptable provided that they are used verbatim:

- "Helps to prevent iron deficiency" (IOM 2006; Shils *et al.* 2006; IOM 2001; Groff and Gropper 2000).
- "Helps to prevent iron deficiency anaemia" (IOM 2006; Shils *et al.* 2006; IOM 2001; Groff and Gropper 2000).

For products providing daily doses of iron between 16-20 mg:

Helps pregnant women meet the (Institute of Medicine's)recommended intake for iron, when taken in conjunction with a healthy diet (IOM 2006; IOM 2001).

Notes:

- For products providing a daily dose of iron above 35 mg, per day, the Specific use or purpose and/or the Dose-specific use or purpose indicated above are required.
- See [Appendix 1](#) for definitions and Table 2 in [Appendix 2](#) for RDA and AI values.

Dose(s)**Table 1** Dose information for iron presented as dose per day

Life stage group		Iron (mg/day)	
		Minimum ¹	Maximum ²
Infants	0-12 mo	0.6	40
Children	1-3 y	0.6	40
	4-8 y	0.6	40
Adolescents	9-13 y	0.6	40
	14-18 y	1.4	45
Adults ³	≥ 19 y	1.4	45

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

² Maximum dose based on the Tolerable Upper Intake Level (UL) which applies to total iron intake from food and supplements (IOM 2006)

³ Includes pregnant and breastfeeding women.

Directions for use

Statement(s) to the effect of:

- Take with food.
- Take a few hours before or after taking other medications (Sweetman 2007; ASHP 2005).

Duration of use

No statement required.

Risk information

Statement(s) to the effect of:

Caution(s) and warning(s)

If the package contains more than the equivalent of 250 mg of elemental iron: Keep out of reach of children. There is enough drug in this package to seriously harm a child. (Note: This must be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour) (As per Section 97 of the *Natural Health Product Regulations*, citing Sections C.01.029 and C.01.031 of the *Food and Drug Regulations* (JC 2009a,b)).

Contraindication(s)

No statement required.

Known adverse reaction(s)

For products targeted to pregnant women, providing iron at doses 16-35 mg per day, the following statement is required:

Taking a daily prenatal multi-vitamin mineral supplement along with this product may result in constipation, diarrhoea, and/or vomiting due to the high intake of iron (IOM 2006; IOM 2001).

For all products providing iron at doses greater than 35 mg, per day, the following statement is required:

Some people may experience constipation, diarrhoea, and/or vomiting (IOM 2006; IOM 2001).

Non-medicinal ingredients

Must be chosen from the current NNHPD [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 NNHPD [Compendium of Monographs](#).
- The medicinal ingredient may comply with the specifications outlined in the applicable iron monographs published in the USA (USP), British (BP) and European (Ph.Eur.) Pharmacopoeias.

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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; used when an RDA cannot be determined.

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 and AI Values

The AI (as indicated by an asterisk) and RDA values for iron 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 iron deficiency";
- facilitate the optional labelling of % RDA and AI values.

Table 2 Recommended Dietary Allowance and Adequate Intake* values for iron based on life stage group (IOM 2006)

Life stage group		Iron (mg/day)
Infants	0-6 mo	0.27*
	7-12 mo	11
Children	1-3 y	7
	4-8 y	10
Adolescent males	9-13 y	8
	14-18 y	11
Adult males	≥ 19 y	8
Adolescent females	9-13 y	8
	14-18 y	15
Adult females	19-50 y	18
	≥ 51 y	8
Pregnancy	14-50 y	27
Breastfeeding	14-18 y	10
	19-50 y	9

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