

Arginine, L-

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L-ARGININE (PDF Version - 121 KB) 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 label at the applicant's discretion. The solidus (/) indicates that either term and/or statement may be selected on the label. Date July 25, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source Information Proper name(s) Common name(s) Source Information Source ingredient(s) Preparation(s) (S)-2-Amino-5-[(aminoiminomethyl) amino] pentanoic acid L-Arginine L-Arginine DL-Arginine L-Arginine L-Arginine alpha-ketoglutarate L-Arginine ketoisocaproic acid L-Arginine monohydrochloride Synthetic References: Proper names: NIH 2023; RSC 2023; Common name: NIH 2023; RSC 2023; Source information: NIH 2023; USP-NF 2023; BP 2009; Ph. Eur. 2007. Route of administration Oral Dosage form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.. Use(s) or Purpose(s) May help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases (CVD) (Doutreleau et al. 2010; Doutreleau et al. 2006; Lim et al. 2004; Palloschi et al. 2004; Bode- Böger et al. 2003; Lekakis et al. 2002; Sydow et al. 2002; Nagaya et al. 2001; Bednarz et al. 2000; Hambrecht et al. 2000; Tangphao et al. 1999; Lerman et al. 1998; Clarkson et al. 1996; Rector et al. 1996). L-Arginine is (a non-essential amino acid) involved in protein synthesis (Shils et al. 2006; IOM 2005; Groff and Gropper 2000). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Improvement in exercise capacity in individuals with stable CVD 6 - 21 grams of L-Arginine, per day; Not to exceed 8 grams per single dose (Doutreleau et al. 2010; Shao and Hathcock 2008; Doutreleau et al. 2006; Evans et al. 2004; Lim et al. 2004; Palloschi et al. 2004; Bode-Bogër et al. 2003; Bednarz et al. 2000; Hambrecht et al. 2000; Lerman et al. 1998; Adams et al. 1997; Ceremu■y■ski et al. 1997; Clarkson et al. 1996; Rector et al. 1996). Protein synthesis 0.21 - 21 grams of L-Arginine, per day; Not to exceed 8 grams per single dose (Shao and Hathcock 2008; IOM 2005; Evans et al. 2004; Bode-Bogër et al. 2003; Sydow et al. 2002). Direction(s) for use No statement required. Duration(s) of use Products providing 3 g or more of L-Arginine, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 8 weeks if you have a cardiovascular disease (Salmani et al. 2021; Sydow et al. 2002; Hambrecht et al. 2000; Clarkson et al.1996; Rector et al. 1996). Products providing more than 9 g and up to 14 g of L-Arginine, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 months (De Nicola et al. 1999). Products providing more than 14 g of L-Arginine, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 12 weeks (Tangphao et al. 1999). Note: Durations of use can be combined on the label (e.g., Ask a health care practitioner for use beyond 6 months, or beyond 8 weeks if you have a cardiovascular disease). Risk information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are pregnant or breastfeeding. Improvement in exercise capacity in individuals with stable CVD Ask a health care practitioner/health care provider/health care professional/doctor/ physician if your symptoms worsen. Products providing more than 0.42 g of L-Arginine, per day Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have a cardiovascular disease and are attempting an increase in physical activity (Doutreleau et al. 2010; Doutreleau et al. 2006; Schulman et al. 2006; Goldman and Ausiello 2004; Nagaya et al. 2001; Bednarz et al. 2000; Ceremu■y■ski et al. 1997; Rector et al. 1996). Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners (Huynh et al. 2002; Parker et al. 2002; Siani et al. 2000; Adams et al. 1995). Contraindication(s) Products providing more than 9 g of L-Arginine, per day Do not use if you have had a heart attack/myocardial infarction (Sun et al. 2009; Schulman et al. 2006; Bednarz et al. 2005). Known adverse reaction(s) Products providing more than 9 g of L-Arginine, per day When using this product you may experience gastrointestinal

discomfort/disturbances (Grimble 2007; Evans et al. 2004; IOM 2005; Clarkson et al. 1996). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Adams MR, McCredie R, Jessup W, Robinson J, Sullivan D, Celermajer DS. 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MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications..

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are pregnant or breastfeeding. Improvement in exercise capacity in individuals with stable CVD Ask a health care practitioner/health care provider/health care professional/doctor/ physician if your symptoms worsen. Products providing more than 0.42 g of L-Arginine, per day Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have a cardiovascular disease and are attempting an increase in physical activity (Doutreleau et al. 2010; Doutreleau et al. 2006; Schulman et al. 2006; Goldman and Ausiello 2004; Nagaya et al. 2001; Bednarz et al. 2000; Ceremu■y■ski et al. 1997; Rector et al. 1996).Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners (Huynh et al. 2002; Parker et al. 2002; Siani et al. 2000; Adams et al. 1995). Contraindication(s) Products providing more than 9 g of L-Arginine, per day Do not use if you have had a heart attack/myocardial infarction (Sun et al. 2009; Schulman et al. 2006; Bednarz et al. 2005). Known adverse reaction(s) Products providing more than 9 g of L-Arginine, per day When using this product you may experience gastrointestinal discomfort/disturbances (Grimble 2007; Evans et al. 2004; IOM 2005; Clarkson et al. 1996).

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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.

Proper name(s)	Common name(s)	Source Information	
Source ingredient(s)	Preparation(s)		
(S)-2-Amino-5-[(aminoiminomethyl) amino] pentanoic acid	L-Arginine	DL-ArginineL-ArginineL-Arginine alpha-ketoglutarate	Synthetic

Arginine ketoiso