Creatine monohydrate

Creatine Monohydrate Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 36 K) 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 statements are synonymous. Either term or statement may be selected by the applicant. Date June 28, 2024 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) N-(Aminoiminomethyl)-N-methylglycine monohydrate Creatine monohydrate Creatine monohydrate References: Proper name: RSC 2023, US NLM 2023; Common name: RSC 2023, US NLM 2023; Source information: RSC 2023, Weiss and Krommer 1998. 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. Note Liquids and solutions are not permitted due to lack of stability of the finished product (Dash and Sawhney 2002). Use(s) or Purpose(s) Increases body/(lean)muscle mass/size when used in conjunction with a resistance training regimen (Brose et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997). Improves strength/power/performance in repetitive bouts of brief, highly-intense physical activity (e.g. sprints, jumping, resistance training) (by increasing [muscle/intramuscular] [creatine/phosphocreatine/energy] levels) (Okudan and Gökbel 2005; Brose et al. 2003; Preen et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997; Hultman et al. 1996). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Table 2. Dose(s) for creatine monohydrate (with loading phase) Loading Phase Maintenance Phase Min/day Max/day Max/single dose Min/day Max/day Option 1 15 g 20 g 5 g 2 g 5 g Option 2 3 g 5 g N/A Table 3. Dose(s) for creatine monohydrate (no loading phase) Min/day Max/day Option 3 3 g 5 g References for Tables 2 and 3: Okudan and Gökbel 2005; Preen et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997; Hultman et al. 1996. Direction(s) for use and duration(s) of use Table 4. Direction(s) for use and duration(s) of use Option(s) 1 Direction(s) for use and duration(s) of use Option 1 - loading phase of 15-20 g/day Start with a loading phase of X g 2 per day for 5-7 days and follow with a maintenance phase (Y g 2 /day) Option 2 - loading phase of 3-5 g/day Start with a loading phase of X g 2 per day for a minimum of 4 weeks and follow with a maintenance phase (Y g 2 /day) Option 3 - no loading phase Use for a minimum of 4 weeks. 1 If more than one option is listed for a product, they should be separated with 'OR' for clarity. 2 The dose in grams can be replaced on the label with the number of dosage unit required to reach the loading dose (X g) and the maintenance dose (Y g) (e.g. X scoop(s); sachet(s); serving(s), etc). Risk information Caution(s) and warning(s) When using this product you may gain weight (Volek and Rawson 2004; Bemben et al. 2001; Mihic et al. 2000). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder (Pline and Smith 2005; Pritchard and Kalra 1998). Contraindication(s): No statement required. Known adverse reaction(s): No statement required. 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. The finished product and/or raw material specifications must meet the process-related impurity acceptance criteria outlined in the USP Creatine monograph (or any other internationally recognized pharmacopoeia). Note that the NNHPD will accept these process-related impurity acceptance criteria for either the finished product or the raw material; however,

the procedures described in the USP Creatine monograph are specific to the testing of creatine monohydrate as raw material. As per the NNHPD Quality of Natural Health Products Guide, if alternate methods are used for testing to meet pharmacopoeial specifications, the relevant pharmacopoeia should be consulted for information on whether or not the alternate methods are considered suitable. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Bemben MG, Bemben DA, Loftiss DD, Knehans AW. 2001. Creatine supplementation during resistance training in college football athletes. Medicine & Science in Sports & Exercise 33(10):1667-1673. Brose A, Parise G, Tarnopolsky MA. 2003. Creatine supplementation enhances isometric strength and body composition improvements following strength exercise training in older adults. The Journals of Gerontology Series A: Biological Science and Medical Science 58(1):11-19. 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Pharmacotherapy 21(5):647-651. Koshy KM, Griswold E, Schneeberger EE. 1999. Interstitial nephritis in a patient taking creatine. The New England Journal of Medicine 340(10):814-815. Kreider RB, Melton C, Rasmussen CJ, Greenwood M, Lancaster S, Cantler EC, Milnor P, Almada AL. 2003. Long-term creatine supplementation does not significantly affect clinical markers of health in athletes. Molecular and Cellular Biochemistry 244(1-2):95-104. McKenna MJ, Morton J, Selig SE, Snow RJ. 1999. Creatine supplementation increases muscle total creatine but not maximal intermittent exercise performance. Journal of Applied Physiology 87(6):2244-2252 McRae CA, Agarwal K, Mutimer D, Bassendine MF. 2002. Hepatitis associated with Chinese herbs. European Journal of Gastroenterology and Hepatology 14(5):559-562. Nissen SL and Sharp RL. 2003. Effects of dietary supplements on lean mass and strength gains with resistance exercise: a meta-analysis. Journal of Applied Physiology 94(2):651-659. Ostojic SM, Ahmetovic Z. 2008. Gastrointestinal distress after creatine supplementation in athletes: are side effects dose dependent? Research in Sports Medicine 16(1):15-22. Persky AM, Brazeau GA. 2001. Clinical pharmacology of the dietary supplement creatine monohydrate. Pharmacological Reviews 53(2):161-176. Poortmans JR, Auquier H, Renault V, Durussel A, Saugy M, Brisson GR. 1997. Effect of short-term creatine supplementation on renal responses in men. European Journal of Applied Physiology 76(6):566-567. Poortmans JR, Francaux M. 2000. Adverse effects of creatine supplementation: fact or fiction? SportsMedicine 30(3):155-170. Poortmans JR, Francaux M. 1999. Long-term oral creatine supplementation does not impair renal function in healthy athletes. Medicine & Science in Sports & Exercise 31(8):1108-1110. Powers ME, Arnold BL, Weltman AL, Perrin DH, Mistry D, Kahler DM, Kraemer W, Volek J. 2003. Creatine supplementation increases total body water without altering fluid distribution. Journal of Athletic Training 38(1):44-50. Prevost MC, Nelson AG, Morris GS. 1997. Creatine supplementation enhances intermittent work performance. Research Quarterly for Exercise and Sport 68(3):233-240. Rawson ES, Clarkson PM, Price TB, Miles MP. 2002. Differential response of muscle phosphocreatine to creatine supplementation in young and old subjects. Acta Physiologica Scandinavica 174(1):57-65. Rico-Sanz J, Mendez MTM. 2000. Creatine enhances oxygen uptake and performance during alternating intensity exercise. Medicine and Science in Sports and Exercise 32(2):379-385. Robinson TM, Sewell DA, Casey A, Steenge G, Greenhaff PL. 2000. Dietary creatine supplementation does not affect some haematological indices, or indices of muscle damage and hepatic and renal function. British Journal of Sports Medicine 34(4):284-288. Saab G, Marsh GD, Casselman MA, Thompson RT. 2002. Changes in human muscle transverse relaxation following short-term creatine supplementation. Experimental Physiology 87(3):383-389. Schilling BK, Stone MH, Utter A, Kearney JT, Johnson M, Coglianese R, Smith L, O'Bryant HS, Fry AC, Starks M, Keith R, Stone ME. 2001. Creatine supplementation and health variables: a retrospective study. Medicine & Science in Sports & Exercise 33(2):183-188. Shao A, Hathcock JN. 2006. Risk assessment for creatine monohydrate. Regulatory Toxicology and Pharmacology 45(3):242-251. Vahedi K, Domigo V, Amarenco P, Bousser MG. 2000. Ischaemic stroke in a sportsman who consumed MaHuang extract and creatine monohydrate for body building. Journal of Neurology, Neurosurgery, and Psychiatry 68(1):112-113. Volek JK, Kraemer WJ, Bush JA, Boetes M, Incledon T, Clark KL, Lynch JM. 1997. Creatine supplementation enhances muscular performance during high-intensity resistance exercise. Journal of the American Dietetic Association 97(7):765-770. Volek JS, Mazzetti SA, Farquhar WB, Barnes BR, Gómez AL, Kraemer WJ. 2001. Physiological responses to short-term exercise in the heat after creatine loading. Medicine & Science in Sports & Exercise 33(7):1101-1108. Watson G, Casa DJ, Fiala KA, Hile A, Roti MW, Healey JC, Armstrong LE, Maresh CM. 2006. Creatine use and exercise heat tolerance in dehydrated men. Journal of Athletic Training 41(1):18-29. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the currentNatural 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. NoteLiquids and solutions are not permitted due to lack of stability of the finished product (Dash and Sawhney 2002).

RISK INFORMATION

Caution(s) and warning(s) When using this product you may gain weight (Volek and Rawson 2004; Bemben et al. 2001; Mihic et al. 2000).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder (Pline and Smith 2005; Pritchard and Kalra 1998). Contraindication(s): No statement required. Known adverse reaction(s): No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the currentNatural 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 theNatural 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.The finished product and/or raw material specifications must meet the process-related impurity acceptance criteria outlined in the USP Creatine monograph (or any other internationally recognized pharmacopoeia). Note that the NNHPD will accept these process-related impurity acceptance criteria for either the finished product or the raw material; however, the procedures described in the USP Creatine monograph are specific to the testing of creatine monohydrate as raw material. As per the NNHPD Quality of Natural Health Products Guide, if alternate methods are used for testing to meet pharmacopoeial specifications, the relevant pharmacopoeia should be consulted for information on whether or not the alternate methods are considered suitable.

Proper name(s)	Common name(s)	Source information
Source ingredient(s)		
N-(Aminoiminomethyl)-N-methylglycine monohydrate	Creatine monohydrate	Creatine monohydrate

	Loading Phase	Maintenance Phase			
Min/day	Max/day	Max/single dose	Min/day	Max/day	
Option 1	15 g	20 g	5 g	2 g	5 g

Option 2	3 g	5 g	N/A		

	Min/day	Max/day
Option 3	3 g	5 g

Option(s)1	Direction(s) for use and duration(s) of use
Option 1 - loading phase of 15-20 g/day	Start with a loading phase of X g2per day for 5-7 days and follow with a mai g2/day)
Option 2 - loading phase of 3-5 g/day	Start with a loading phase of X g2per day for a minimum of 4 weeks and foll phase (Y g2/day)
Option 3 - no loading phase	Use for a minimum of 4 weeks.