Hydrolyzed collagen

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Hydrolyzed Collagen 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 - 132 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 For the purpose of this monograph, hydrolyzed collagen has no jelling power and is soluble in cold water (Schrieber and Gareis 2007; Moskowitz 2000).The average molecular weight of hydrolyzed collagen is approximately 4 kDa (i.e. 2-6 kDa) (Moskowitz 2000; Oesser et al . 1999). 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 March 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 material(s) Part(s) Hydrolyzed collagen Collagen hydrolysate Hydrolyzed collagen Bovine Bovine skin/hide split Porcine Bone Skin Fish Bone Skin Chicken Cartilage References: Proper name: NIH 2023, ICIDH 2008; Common names: NIH 2023, ICIDH 2008, Moskowitz 2000; Source information: Schauss et al 2012, FCC 7 2010, Schrieber and Gareis 2007, Baziwane and He 2003. 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) Source of (the) essential amino acid(s) (histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine) for the maintenance of good health/involved in (muscle) protein synthesis (CNF 2023; IOM 2005; Eastoe 1955). Source of (the) non-essential amino acid(s) (alanine, arginine, aspartic acid, glutamic acid, glycine, proline, serine, tyrosine) involved in (muscle) protein synthesis (CNF 2023; IOM 2005; Eastoe 1955). Source of (the essential amino acid) lysine to help in collagen formation/synthesis (derMarderosian and Beutler 2011; Baziwane and He 2003; Garrison and Somer 1995; Jansen 1962). Helps reduce joint pain associated with osteoarthritis (Bruyère et al. 2012; Benito-Ruiz et al. 2009; Clark et al. 2008). Helps reduce osteoarthritis-related joint pain (Bruyère et al. 2012; Benito-Ruiz et al. 2009; Clark et al. 2008). Helps manage/in the management of joint pain (Bruyère et al. 2012; Benito-Ruiz et al. 2009; Clark et al. 2008). Notes: The above uses can be combined on the product label (e.g. Source of essential amino acids for the maintenance of good health and non-essential amino acids involved in muscle protein synthesis). The terms 'Helps' or 'Helps to' can be used interchangeably on the label. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Source of (the) essential amino acid(s)(histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine) 2.6-10 grams hydrolyzed collagen, per day (IOM 2005; Moskowitz 2000). OR Essential amino acids Minimum dose (mg/day) 5% of the RDA 1 Maximum dose of hydrolyzed collagen (g/day) 2 L-Histidine 49 mg 10 g L-Isoleucine 66.5 mg L-Leucine 147 mg L-Lysine 133 mg L-Methionine 66.5 mg L-Phenylalanine 115.5 mg L-Threonine 70 mg L-Valine 84 mg 1 Minimum doses have been calculated as 5% of each specific amino acid Recommended Dietary Allowance with a reference weight of 70 kg (IOM 2005). 2 Maximum dose (Benito-Ruiz et al. 2009; IOM 2005; Moskowitz 2000). Source of (the) non-essential amino acid(s) (alanine, arginine, aspartic acid, glutamic acid, glycine, proline, serine, tyrosine) 2.6-10 grams hydrolyzed collagen, per day (IOM 2005; Moskowitz 2000). OR Non-Essential amino acids Minimum dose (mg/day) 5% of the RDA 1 Maximum dose of hydrolyzed collagen (g/day) 2 L-Alanine 181.5 mg 10 g L-Arginine 208.5 mg L-Aspartic acid 325 mg L-Glutamic acid 750 mg Glycine 160 mg L-Proline 259.5 mg L-Serine 175.5 mg L-Tyrosine 139 mg 1 Minimum doses have been calculated as 5% of each specific amino acid Mean Intake (IOM 2005) 2 Maximum dose (Benito-Ruiz et al. 2009; IOM 2005; Moskowitz 2000). Source of lysine Essential amino acids Minimum dose(mg/day) 5% of the RDA 1 Maximum dose of hydrolyzed collagen (g/day) 2 L-Lysine 133 mg 10 g 1 Minimum doses have been calculated as 5% of Recommended Dietary Allowance with a reference weight of 70 kg (IOM 2005). 2 Maximum dose (Benito-Ruiz et al. 2009; IOM 2005; Moskowitz 2000). Joint pain 1.2-10 grams hydrolyzed collagen, per day (Bruyère et al. 2012; Benito-Ruiz et al. 2009; Clark et al. 2008). Direction(s) for use No statement required. Duration(s) of use Joint pain Use for at

least 5 months to see beneficial effects (Bruyère et al . 2012; Benito-Ruiz et al . 2009; Clark et al . 2008). Risk information Caution(s) and warning(s) Joint pain Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen. Products providing more than 2.8 g hydrolyzed collagen, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Shils et al. 2006; Goldman and Ausiello 2004). Contraindication(s) No statement required. Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Moskowitz 2000). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database 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. All products (information for industry; optional for labelling depending on the packaging) To be protected from heat and moisture (Ph.Eur. 2023). Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products (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 Baziwane D, He Q. Gelatin: The paramount food additive. Food Reviews International 2003;19(4):423-435. Benito-Ruiz P, Camacho-Zambrano MM, Carrillo-Arcentales JN, Mestanza-Peralta MA, Vallejo-Flores CA, Vargas-López SV, Villacís-Tamayo RA, Zurita-Gavilanes LA. A randomized controlled trial on the efficacy and safety of a food ingredient, collagen hydrolysate, for improving joint comfort. 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MEDICINAL INGREDIENT(S)

Must be chosen from the currentNatural Health Products Ingredients Databaseand 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.

DOSE(S)

Source of (the) non-essential amino acid(s) (alanine, arginine, aspartic acid, glutamic acid, glycine, proline, serine, tyrosine) 2.6-10 grams hydrolyzed collagen, per day (IOM 2005; Moskowitz 2000). OR Non-Essential amino acidsMinimum dose (mg/day)5% of the RDA1Maximum dose of hydrolyzed collagen (g/day)2L-Alanine181.5 mg10 gL-Arginine208.5 mgL-Aspartic acid325 mgL-Glutamic acid750 mgGlycine160 mgL-Proline259.5 mgL-Serine175.5 mgL-Tyrosine139 mg 1Minimum doses have been calculated as 5% of each specific amino acid Mean Intake (IOM 2005)2Maximum dose (Benito-Ruiz et al. 2009; IOM 2005; Moskowitz 2000). Source of lysine Essential amino acidsMinimum dose(mg/day)5% of the RDA1Maximum dose of hydrolyzed collagen (g/day)2L-Lysine133 mg10 g 1Minimum doses have been calculated as 5% of Recommended Dietary Allowance with a reference weight of 70 kg (IOM 2005).2Maximum dose (Benito-Ruiz et al. 2009; IOM 2005; Moskowitz 2000). Joint pain 1.2-10 grams hydrolyzed collagen, per day (Bruyère et al. 2012; Benito-Ruiz et al. 2009; Clark et al. 2008). Direction(s) for use No statement required. Duration(s) of use Joint pain Use for at least 5 months to see beneficial effects (Bruyère et al . 2012; Benito-Ruiz et al . 2009; Clark et al . 2008).

RISK INFORMATION

Caution(s) and warning(s) Joint pain Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen. Products providing more than 2.8 g hydrolyzed collagen, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Shils et al. 2006; Goldman and Ausiello 2004). Contraindication(s) No statement required. Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Moskowitz 2000).

NON-MEDICINAL INGREDIENTS

Must be chosen from the currentNatural Health Products Ingredients Databaseand 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. All products (information for industry; optional for labelling depending on the packaging) To be protected from heat and moisture (Ph.Eur. 2023).

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in theNatural and Non-Prescription Health Products (NNHPD)Quality of Natural Health Products Guide.The medicinal ingredient must comply with the requirements outlined in theNHPID.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Hydrolyzed collagen	Collagen hydrolysateHydrolyzed collagen	Bovine	Bovine skin/hide split
Porcine	BoneSkin		
Fish	BoneSkin		
Chicken	Cartilage		

Essential amino acids	Minimum dose (mg/day)5% of the RDA	Maximum dose of hydrolyzed collagen (g/day)2
L-Histidine	49 mg	10 g
L-Isoleucine	66.5 mg	
L-Leucine	147 mg	
L-Lysine	133 mg	
L-Methionine	66.5 mg	
L-Phenylalanine	115.5 mg	
L-Threonine	70 mg	
L-Valine	84 mg	

Non-Essential amino acids	Minimum dose (mg/day)5% of the RDA	Maximum dose of hydrolyzed collagen (g/da
L-Alanine	181.5 mg	10 g

L-Arginine	208.5 mg	
L-Aspartic acid	325 mg	
L-Glutamic acid	750 mg	
Glycine	160 mg	
L-Proline	259.5 mg	
L-Serine	175.5 mg	
L-Tyrosine	139 mg	

Essential amino acids	Minimum dose(mg/day)5% of the RDA	Maximum dose of hydrolyzed collagen (g/day)2
L-Lysine	133 mg	10 g