

NATURAL HEALTH PRODUCT

HYDROLYZED COLLAGEN

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications 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	<ul style="list-style-type: none"> • Collagen hydrolysate • Hydrolyzed collagen 	Bovine	Bovine skin/hide split
		Porcine	<ul style="list-style-type: none"> • Bone • Skin
		Fish	<ul style="list-style-type: none"> • 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	10
L-Isoleucine	66.5	
L-Leucine	147	
L-Lysine	133	
L-Methionine	66.5	
L-Phenylalanine	115.5	
L-Threonine	70	
L-Valine	84	

¹Minimum doses have been calculated as 5% of each specific amino acid Recommended Dietary Allowance with a reference weight of 70 kg (IOM 2005).

²Maximum 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 Mean Intake ¹	Maximum dose of hydrolyzed collagen (g/day) ²
L-Alanine	181.5	10
L-Arginine	208.5	
L-Aspartic acid	325	
L-Glutamic acid	750	
Glycine	160	
L-Proline	259.5	
L-Serine	175.5	
L-Tyrosine	139	

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 acids	Minimum dose (mg/day) 5% of the RDA ¹	Maximum dose of hydrolyzed collagen (g/day) ²
L-Lysine	133	10

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 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*.

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.

Product Facts	
Medicinal ingredient in each scoop	
Hydrolyzed collagen (Porcine – bone)	XX g
Providing XX mg of Lysine ¹	
Uses	
<ul style="list-style-type: none"> • Source of essential amino acids for the maintenance of good health. • Source of non-essential amino acids involved in muscle protein synthesis. • Source of the essential amino acid lysine to help in collagen formation. • Helps reduce joint pain associated with osteoarthritis. • Helps manage joint pain. 	
Warnings	
If applicable²:	
Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Ask a health care practitioner before use if you are pregnant or breastfeeding³.	
When using this product you may experience gastrointestinal discomfort.	
Ask a health care practitioner if symptoms worsen⁴.	
Directions	
Adults 18 years and older: • Take X scoop(s), X time(s) a day • Use for at least 5 months to see beneficial effects ⁴ .	
Other information	
(Add storage information)	
Non-medicinal ingredients	
List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

¹ Potency of other amino acids may be listed (optional).

² This section can be removed from the table if the product contains no allergen or aspartame.

³ Products providing more than 2.8 g hydrolyzed collagen, per day.

⁴ The qualifier ‘For joint pain:’ may be included on the label to inform consumers.

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