

NATURAL HEALTH PRODUCT

GLUCOSAMINE HYDROCHLORIDE

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 July 1, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)			Preparation(s)
			Common name(s)	Proper name(s)	Organism group(s) ¹	
2-Amino-2-deoxy-beta-D-glucopyranose hydrochloride	<ul style="list-style-type: none"> ▶ Glucosamine HCl ▶ Glucosamine hydrochloride 	Glucosamine hydrochloride	N/A	<ul style="list-style-type: none"> ▶ Crab ▶ Krill ▶ Lobster ▶ Prawn ▶ Shrimp 	Exoskeleton	Isolate
			<ul style="list-style-type: none"> ▶ <i>Aspergillus flavus</i> var. <i>oryzae</i> ▶ <i>Aspergillus melleus</i> ▶ <i>Aspergillus niger</i> ▶ <i>Aspergillus niger</i> var. <i>awamori</i> ▶ <i>Monascus pilosus</i> ▶ <i>Monascus purpureus</i> ▶ <i>Rhizopus oryzae</i> 	N/A	Whole	Fermented

References: Proper name: USP 32 2009, Kralovec and Barrow 2008, Sweetman 2007; Common names: USP 32 2009, Kralovec and Barrow 2008, Sweetman 2007; Source information: ITIS 2008; Kralovec and Barrow 2008.

¹The specific organisms used as source material(s) must be indicated in the Animal Tissue Form (ATF); simply indicating “crustaceans” is insufficient.

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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Helps to maintain healthy cartilage/joint health (Towheed and Anastassiades 2007; Braham et al. 2003; Houpt et al. 1999).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

1,500 - 2,000 milligrams of Glucosamine hydrochloride, per day (Braham et al. 2003; Houpt et al. 1999).

Direction(s) for use

No statement required.

Duration(s) of use

Use for at least 1 month to see beneficial effects (Mehta et al. 2007; Usha and Naidu 2004; Houpt et al. 1999; Qiu et al. 1998).

Risk information

Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (Sivojelezova et al. 2007).

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

No statement required.

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.

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