Glucosamine sulfate

Glucosamine Sulfate (PDF Version - 98 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 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 11, 2022 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) Source material(s) Organism group(s) 1 Part(s) Preparation(s) 2-Amino-2-deoxy-D-glucose sulfate Glucosamine sulfate Glucosamine Sulfate Potassium Chloride Glucosamine Sulfate Sodium Chloride N/A Crab Krill Lobster Prawn Shrimp Exoskeleton N/A Aspergillus flavus var. oryzae Aspergillus melleus Aspergillus niger Aspergillus niger var. awamori Monascus pilosus Monascus purpureus Rhizopus oryzae N/A Whole Fermented References: Proper name: NLM 2018; Common name: USP 32 2009, Sweetman 2007, Towheed and Anastassiades 2007; Source information: ITIS 2008, Kralovec and Barrow 2008. 1 The 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 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) Helps to relieve joint pain associated with osteoarthritis (Herrero-Beaumont et al. 2007; Usha and Naidu 2004; Pavelka et al. 2002; Reginster et al. 2001; Thie et al. 2001). Helps to relieve pain associated with osteoarthritis of the knee (Herrero-Beaumont et al. 2007; Usha and Naidu 2004; Pavelka et al. 2002; Reginster et al. 2001). Helps to protect against the deterioration of cartilage (Pavelka et al. 2002; Reginster et al. 2001). A factor in maintaining healthy cartilage and/or joint health (Towheed and Anastassiades 2007; Pavelka et al. 2002; Reginster et al. 2001) The following combined use(s) or purpose(s) is/are also acceptable: Helps protect against the deterioration of cartilage and relieve joint pain associated with osteoarthritis (Herrero-Beaumont et al. 2007; Usha and Naidu 2004; Pavelka et al. 2002; Reginster et al. 2001; Thie et al. 2001 Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 1,500 milligrams of glucosamine sulfate, per day (Herrero-Beaumont et al. 2007; Pavelka et al. 2002; Reginster et al. 2001) Direction(s) for use No statement required. Duration of Use Use for at least 4 weeks 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. Storage Condition(s) Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR). Non Medicinal Ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. 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. References Cited Herrero-Beaumont G, Ivorra JAR, Trabado MC, Blanco FJ, Benito P, Martín-Mola E, Paulino J, Marenco JL, Porto A, Laffon A, Araújo D, Figueroa M, Branco J. 2007. Glucosamine sulfate in the treatment of knee osteoarthritis symptoms- a randomized, double-blind, placebo-controlled study using acetaminophen as a side comparator. Arthritis and Rheumatism 56(2):555-567. Houpt JB, McMillan R, Wein C, Paget-Dellio SD. 1999. Effect of glucosamine hydrochloride in the treatment of pain of osteoarthritis of the knee. Journal of rheumatology 26(11):2423-2430. ITIS 2008: Integrated Taxonomic Information System. Taxon Based on Biological Information System [online]. Canadian Biodiversity Information Facility, Government of Canada. [Accessed 2018 June 19]. Available from: https://www.itis.gov/ Kralovec A, Barrow CJ. 2008. Glucosamine Production and Health Benefits. In: Marine Nutraceuticals and Functional Foods. Colin Barrow

and Fereidoon Shahidi, editors, pp198-227. Boca Raton (FL): CRC Press, Taylor and Francis Group. Mehta K, Gala J, Bhasale S, Naik S, Modak M, Thakur H, Deo N, Miller MJ. 2007. Comparison of glucosamine sulfate and a polyherbal supplement for the relief of osteoarthritis of the knee: a randomized controlled trial. BMC Complementary and alternative Medicine 31(7):34. NLM 2018: United States National Library of Medicine. ChemIDplus advanced [online]. Chemical name. RN: 000-00-0. Bethesda (MD): Specialized Information Services, United States National Library of Medicine, National Institutes of Health, United States Department of Health & Human Services. [Accessed 2018 June 19]. Available from: https://chem.nlm.nih.gov/chemidplus/ Pavelka K, Gatterova J, Olejarova M, Machacek S, Giacovelli G, Rovati LC. 2002. Glucosamine sulfate use and delay of progression of knee osteoarthritis: a 3-year, randomized, placebocontrolled, double-blind study. Archives of Internal Medicine 162(18):2113-2123. 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: Journal of the British Society for Allergy and Clinical Immunology 36(11):1457-1461. Williams HJ. 2006. Glucosamine, chondroitin sulfate, and the two in combination for painful knee osteoarthritis. The New England Journal of Medicine 354(8):795-808. Yu JG, Boies SM, and JM Olefsky. 2003. The effect of oral glucosamine sulphate on insulin sensitivity in human subjects. Diabetes Care 26(6): 1941-1942. Zachara NE, Hart GW. 2006. Cell signaling, the essential role of O-GlcNAc!. Biochimica et biophysica acta 1761(5-6):599-617. 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.

DOSE(S)

Nakamura H, Masuko K, Yudoh K, Kato T, Kamada T, Kawahara T. 2007. Effects of glucosamine administration on patients with rheumatoid arthritis. Rheumatology International 27(3):213-218. Nakamurai M, Barberi AJ, Antonetti DA, LaNoue KF, Robinson KA, Buse MG, Gardner TW. 2001. Excessive Hexosamines Block the Neuroprotective Effect of Insulin and Induce Apoptosis in retinal Neurons. The Journal of Biological Chemistry 270(23)43748-48755. Noack W, Fischer M, Förster KK, Rovati LC, Setnikar I.1994. Glucosamine sulfate in osteoarthritis of the knee. Osteoarthritis and Cartilage 2(1):51-59. Ossendza RA, Grandval P, Chinoune F, Rocher F, Chapel F, Bernardini D. 2007. Hépatite aiguë cholestatique à la Glucosamine forte®. Gastroentérologie clinique et biologique 31(4):449-450. Ostojic SM, Arsic M, Prodanovic S, Vukovic J, Zlatanovic M. 2007. Glucosamine administration in athletes: effects on recovery of acute knee injury. Research in Sports Medicine 15(2):113-124. Persiani S, Roda E, Rovati LC, Locatelli M, Giacovelli G, Roda A. 2005. Glucosamine oral bioavailability and plasma pharmacokinetics after increasing doses of crystalline glucosamine sulfate in man. Osteoarthritis and Cartilage 13(12):1041-1049. Rashad S, Revell P, Hemingway A, Low F, Rainsford K, Walker F. 1989. Effect of non-steroidal anti-inflammatory drugs on the course of osteoarthritis. The Lancet 14(2)(8668):914-915. Reginster JY. 2007. The efficacy of glucosamine sulfate in osteoarthritis: financial and nonfinancial conflict of interest. Arthritis and Rheumatism 56(7):2105-2110. Reichelt A, Förster KK, Fischer M, Rovati LC, Setnikar I.1994. Efficacy and safety of intramuscular glucosamine sulfate in osteoarthritis of the knee. A randomised, placebocontrolled, double-blind study. Arzneimittelforschung 44(1):75-80. Robertson LA, Kim AJ, Werstuck GH. 2006. Mechanisms linking diabetes mellitus to the development of atherosclerosis: a role for endoplasmic reticulum stress and glycogen synthase kinase-3. Canadian Journal of Physiology and Pharmacology 84(1):39-48. Rozendaal RM, Koes BW, van Osch GJ, Uitterlinden EJ, Garling EH, Willemsen SP, Ginai AZ, Verhaar JA, Weinans H, Bierma-Zeinstra SM. 2008. Effect of glucosamine sulfate on hip osteoarthritis: a randomized trial. Annals of Internal Medicine 148(4):268-277. Runkel DR, Cupp MJ. 1999. Glucosamine sulfate use in osteoarthritis. American journal of health-system pharmacy: American Journal of Health-System Pharmacy 56(3):267-269. Sandy JD, Gamett D, Thompson V, Verscharen C. 1998. Chondrocyte-mediated catabolism of aggrecan: aggrecanase-dependent cleavage induced by interleukin-1 or retinoic acid can be inhibited by glucosamine. The Biochemical Journal 335 (Pt 1):59-66. Schuster E, Dunn-Coleman N, Frisvad JC, Van Dijck PW. 2002. On the safety of Aspergillus niger--a review. Applied Microbiology and Biotechnology 59(4-5):426-435. Scroggie DA, Albright A, MD Harris. 2003. The effect of glucosamine-chondroitin supplementation on glycosylated haemoglobin levels in patients with type 2 diabetes mellitus: a placebo-controlled, double-blinded, randomized clinical trial. Archives of Internal Medicine 163(13): 1587-1590. Tannis AJ, Barban J, Conquer JA. 2004. Effect of glucosamine supplementation on fasting and

non-fasting plasma glucose and serum insulin concentrations in healthy individuals. Osteoarthritis and Cartilage 12(6):506-511. The Arthritis and Glucosamine Information Centre. Glucosamine Side effects. Raleigh (NC): DTC Health. [Accessed 2008 August 21]. Available from:http://www.glucosaminearthritis.org/glucosamine/glucosamine-side-effects.html Towheed TE, Maxwell L, Anastassiades TP, Shea B, Houpt J, Robinson V, Hochberg MC, Wells G. 2005. Glucosamine therapy for treating osteoarthritis. Cochrane database of systematic reviews (2):CD002946. Viad SC, LaValley MP, McAlindon TE, Felson DT. 2007. Glucosamine for pain in osteoarthritis: why do trial results differ? Arthritis and rheumatism 56(7):2267-2277. Villacis J, Rice TR, Bucci LR, El-Dahr JM, Wild L, Demerell D, Soteres D, Lehrer SB. 2006. Do shrimp-allergic individuals tolerate shrimp-derived glucosamine? Clinical and experimental allergy : Journal of the British Society for Allergy and Clinical Immunology 36(11):1457-1461. Williams HJ. 2006. Glucosamine, chondroitin sulfate, and the two in combination for painful knee osteoarthritis. The New England Journal of Medicine 354(8):795-808. Yu JG, Boies SM, and JM Olefsky. 2003. The effect of oral glucosamine sulphate on insulin sensitivity in human subjects. Diabetes Care 26(6): 1941-1942. Zachara NE, Hart GW. 2006. Cell signaling, the essential role of O-GlcNAc!. Biochimica et biophysica acta 1761(5-6):599-617.

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.

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.

REFERENCES

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

	Common name(s)	Source information		
	Source material(s)	Organism group(s)1	Part(s)	Preparation(s)
e sulfate	Glucosamine sulfate	Glucosamine Sulfate Potassium ChlorideGlucosamine Sulfate Sodium Chloride	N/A	Crab Krill Lobster Prawn Shrimp
aeAspergillus melleus	N/AAspergillus nigerAspergillus niger var. awamoriMonascus pilosusMonascus purpureus	Whole	Fermented	Rhizopus oryzae