Chondroitin Sulfate

CHONDROITIN SULFATE 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 - 59 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 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) Common name(s) Proper name(s) Part(s) 1 Chondroitin sulfate Chondroitin sulfate Sodium chondroitin sulfate Anas platyrhynchos Anser anser Bos taurus Cygnus olor Dromaius novaehollandiae Gallus gallus Meleagris gallopavo Numida meleagris Rhea Americana Struthio camelus Sus scrofa Cartilage References: Proper name: O'Neil et al. 2006; Common name: O'Neil et al. 2006; Source information: NIH 2019, USP 31 2008. 1 Cartilage must be derived from healthy and domestic animals used for food by humans (USP 31 2008). 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 any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) Helps to relieve (joint) pain associated with osteoarthritis (of the knee) (Mazières et al. 2007; Uebelhart et al. 2004; Mazières et al. 2001; Bourgeois et al. 1998; Bucsi and Poor 1998; Uebelhart et al. 1998). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 800 - 1,200 milligrams of Chondroitin sulfate, per day (Mazières et al. 2007; Hathcock and Shao 2006; Uebelhart et al. 2004; Mazières et al. 2001; Bourgeois et al. 1998; Bucsi and Poor 1998; Uebelhart et al. 1998) Direction(s) for use No statement required. Duration(s) of Use Use for at least 3 months to see beneficial effects (Bjordal et al. 2007). 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. 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. The medicinal ingredient must either: Comply with the specifications outlined in the Chondroitin Sulfate Sodium Monographs published in the British or European Pharmacopoeiae, or the United States Pharmacopoeia or; Be cited in an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File's registered owner. In order to minimize the risk of Transmissible Spongiform Encephalopathies (TSEs) from products sourced from bovine tissues, product licence applicants must have a veterinary certificate on file and must ensure that the following criteria has been met (EP 2008): Source animal is fit for human consumption; Source material can be traced back to the herd or animal; Avoidance of cross-contamination with high-infectivity tissues is ensured during sourcing; Manufacturing procedures that are known to reduce infectivity are implemented (e.g. procedures that are in accordance with those outlined in Chapter 5.2.8 of the European Pharmacopoeia). References Cited Bjordal JM, Klovning A, Ljunggren AE, Slørdal L. 2007. Short-term efficacy of pharmacotherapeutic interventions in osteoarthritic knee pain: A meta-analysis of randomised placebo-controlled trials. European Journal of Pain 11(2):125-138. Bourgeois P, Chales G, Dehais J, Delcambre B, Kuntz JL, Rosenberg S. 1998. 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MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

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. 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.

STORAGE CONDITION(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.The medicinal ingredient must either:Comply with the specifications outlined in theChondroitin Sulfate SodiumMonographs published in the British or European Pharmacopoeiae, or the United States Pharmacopoeia or;Be cited in an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File's registered owner.In order to minimize the risk of Transmissible Spongiform Encephalopathies (TSEs) from products sourced from bovine tissues, product licence applicants must have a veterinary certificate on file and must ensure that the following criteria has been met (EP 2008):Source animal is fit for human consumption;Source material can be traced back to the herd or animal;Avoidance of cross-contamination with high-infectivity tissues is ensured during sourcing;Manufacturing procedures that are known to reduce infectivity are implemented (e.g. procedures that are in accordance with those outlined in Chapter 5.2.8 of the European Pharmacopoeia).

REFERENCES

1Cartilage must be derived from healthy and domestic animals used for food by humans (USP 31 2008). Route of Administration Oral

name(s)	Common name(s)	Source ingredient(s)	Source material(s)	
name(s)	Proper name(s)	Part(s)1		
tin sulfate	Chondroitin sulfate	Sodium chondroitin sulfate	Anas platyrhynchosAnser anserBos taurusCygnu	Gal