CHONDROITIN SULFATE

Date: July 17, 2008

Proper name(s): Chondroitin sulfate (O'Neil et al. 2006)

Common name(s): Chondroitin sulfate (O'Neil et al. 2006)

Source material(s):

- Chondroitin sulfate sodium obtained from bovine (Bovidae) cartilage (NIH 2008; USP 31)
- Chondroitin sulfate sodium obtained from porcine (Suidae) cartilage (NIH 2008; USP 31)
- Chondroitin sulfate sodium obtained from avian (Phasianidae) cartilage (NIH 2008; USP 31)

Note: Cartilage must be derived from healthy and domestic animals used for food by humans (USP 31).

Route(s) of administration: Oral

Dosage form(s): Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons, or tablespoons are acceptable.
This monograph is not intended to include food-like dosage forms such as beverages, bars or chewing gums.

Use(s) or Purpose(s): Statement(s) to the effect of:

- Helps to relieve joint pain associated with osteoarthritis (Mazières et al. 2007; Uebelhart et al. 2004; Mazières et al. 2001; Bourgeois et al. 1998; Bucsi and Poor 1998; Uebelhart et al. 1998).
- Helps to relieve 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): 800-1,200 mg, 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)

Duration of use: Use for a minimum of 3 months to see beneficial effects (Bjordal et al. 2007).

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

- Consult a health care practitioner if symptoms worsen.
- Consult a health care practitioner 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 NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

Specifications:

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- The medicinal ingredient must either:
  i. Comply with the specifications outlined in the Chondroitin Sulfate Sodium Monographs published in the British or European Pharmacopoeiae, or the United States Pharmacopoeia or,
  ii. 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):
  i. Source animal is fit for human consumption;
  ii. Source material can be traced back to the herd or animal;
  iii. Avoidance of cross-contamination with high-infectivity tissues is ensured during sourcing;

iv. 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).

i. **Note**: This information is not to be submitted with the compendial Product Licence Application, although it may be requested at the NHPD's discretion.

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