NATURAL HEALTH PRODUCT

SERRAPEPTASE

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date February 7, 2014

Proper name(s)

- Serratiopeptidase (NHPID)
- Serrapeptase (NHPID)

Common name(s)

- Serratiopeptidase (NHPID)
- Serrapeptase (NHPID)

Source material(s)

*Serratia marcescens* Strain E-15 (Al-Khateeb and Nusair 2008)

Route(s) of administration

Oral

Dosage form(s)

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
**Proteolytic Enzyme**

The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.

*Reduction of symptoms associated with ear, nose and throat infections; Swelling and pain reduction; mucolytic enzyme*

The only acceptable pharmaceutical dosage forms include enteric coated capsules, tablets, granules or similar preparations (Bhagat et al. 2013; Balaji SM 2007; Chopra et al. 2009). The dosage form must be qualified with an additional term to describe the delayed release (e.g. enteric-coated capsules, gastro-resistant tablets, microencapsulated enzymes) (WHO 2011).

**Use(s) or Purpose(s)**

Statement(s) to the effect of

- Proteolytic Enzyme (Martindale 2011).
- Helps to reduce (symptoms such as) pain, quantity of secretion, inability to perceive smell and stuffy nose from ear, nose and/or throat infections (Mazzone et al 1990; Tachibana et al 1984).
- Helps reduce and/or relieve postoperative cheek swelling and/or pain after dental surgery (Al-Khateeb and Nusair 2008; Tachibana et al 1984).

**Dose(s)**

Statement(s) to the effect of

**Subpopulation(s)**

Adults (≥ 18 years)

**Quantity(ies)**

*Proteolytic Enzyme*

Not to exceed 120,000 serratiopeptidase units (SU), per day (Martindale 2011) and
Not to exceed 60 mg of enzyme preparation, per day (Martindale 2011)

*Reduction of symptoms associated with ear, nose and throat infections; mucolytic enzyme*

60,000-120,000 serratiopeptidase units (SU), per day (Chopra et al. 2009; Nakamura et al. 2003; Majima et al. 1990; Mazzone et al. 1990; Majima et al. 1988; Tachibana et al. 1984). and

Swelling and pain reduction

30,000-120,000 serratiopeptidase units (SU), per day (Chopra et al. 2009; Al-Khateeb and Nusair 2008; Tachibana et al. 1984).

and

15-60 mg of enzyme preparation, per day (Chopra et al. 2009; Al-Khateeb and Nusair 2008; Tachibana et al. 1984).

Note
Dose unit information must include the quantities of both the enzyme preparation (mg or ml) and its enzymatic activity (SU). When submitting by ePLA, please put the enzymatic activity quantity in the Quantity/Unit fields (field 77) and the quantity of enzyme preparation in mg or ml in the Additional Quantity/Unit fields.

Directions for use

Take 2 hours after a meal (Bhagat et al. 2013; Chopra et al. 2009; Mazzone et al. 1990).

Duration of use

Statement(s) to the effect of

Proteolytic enzyme; Reduction of symptoms associated with ear, nose and throat infections; mucolytic enzyme – for up to 30 mg of enzyme preparation and up to 60,000 serratiopeptidase units (SU), per day

Consult a health care practitioner for use beyond 4 weeks (Nakamura et al 2003; Majima et al 1990; Majima et al 1988;)

Swelling and pain reduction – between 31-60 mg of enzyme preparation and 60,001-120,000 serratiopeptidase units (SU), per day

Consult a health care practitioner for use beyond 7 days (Al-Khateeb and Nusair 2008; Tachibana et al. 1984).

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

- If symptoms persist or worsen, discontinue use and consult a health care practitioner.
- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- If you have a gastrointestinal lesion/ulcer, are taking anticoagulant/blood thinner or anti-inflammatory medication, or are having surgery, consult a health care practitioner prior to use (Bhagat et al. 2013; Chopra et al. 2009; Al-Khateeb and Nusair 2008; Mazzone et al. 1990).
**Contraindication(s)**

No statement required.

**Known adverse reaction(s)**

Hypersensitivity/allergy has been known to occur; in which case, discontinue use (Bhagat et al. 2013; Balagi 2007).

**Non-medicinal ingredients**

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).
- Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.
- No traces of any antibiotics or their residues, should be detectable in the finished product.
- The medicinal ingredient may comply with the specifications outlined in the Japanese Pharmacopia (JP XVI) : Serrapeptase.
- The specifications must include testing for enzymatic activity of the medicinal ingredient at appropriate stages of formulation and manufacturing using the assay outlined in the current Japanese Pharmacopia (JP XVI) : Serrapeptase.
- Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of their shelf life indicated on the product label.
References cited


References reviewed