Health Canada Santé Canada

NATURAL HEALTH PRODUCT

TRYPSIN

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

April 29, 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 material(s)	
		Proper name(s)	Part(s)
Trypsin	Trypsin	▸ *Bos taurus* ▸ *Sus scrofa*	Pancreas

References: Proper name: IUBMB 1972; Common name: IUBMB 1972; Source materials: FCC 8 2012; USP 35 2012; Bisby et al. 2011.

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)

Digestive enzyme

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 1,200,000 USP trypsin units of enzymatic activity, per day; and 400,000 USP trypsin units per single dose (USP 35 2012; Dörr et al. 2007; Martin et al. 2002; Dale et al. 2001).

Notes

- The Quantity per dosage unit must be the enzymatic activity (FCC or USP units). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity.
- One USP trypsin unit is the activity causing a change in the absorbance of 0.003/min under the conditions of the assay (FCC 8 2012).

Direction(s) for use

All products

Take with food/meal.

Enteric-coated products

Swallow whole/Do not crush or chew (CPS 2008).

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use.

Risk information

Caution(s) and warning(s)

- Consult a health care practitioner/health care provider/health care professional/doctor/

physician prior to use if you are pregnant, breastfeeding, have gastrointestinal lesion/ulcer or are having surgery.
- Consult a health care practitioner /health care provider/health care professional/doctor/ physician prior to use if you are taking an anticoagulant/blood thinner or anti-inflammatory medications.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Martindale 2011).

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

Store in a tightly closed, light-resistant container in a cool, dry place (Ph.Eur. 2012; USP 35 2012).

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.
- Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.
- 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 Food Chemicals Codex (FCC) or the current United States Pharmacopeia (USP): FCC: TRYPSIN ACTIVITY USP: Crystallized Trypsin.
- Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of the shelf life indicated on the product label.

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