Health Canada Santé Canada

NATURAL HEALTH PRODUCT

FUNGAL PROTEASE

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)
▸ Fungal protease ▸ Protease	▸ Acidic protease ▸ Acid protease ▸ Acid stable protease ▸ Aspergillus acid protease ▸ Fungal protease ▸ Protease ▸ Protease 3.0 ▸ Protease 4.5 ▸ Protease 6.0	▸ *Aspergillus flavus* var. *oryzae* ▸ *Aspergillus niger*	Whole

References: Proper names: FCC 8 2012; Common names: FCC 8 2012; Source materials: CABI 2012, FCC 8 2012, Bisby et al. 2010.

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 (Murray 1996)
- Digestive aid (Murray 1996)
- Helps digest proteins (Murray 1996)

The following combined use(s) or purpose(s) is/are also acceptable:

- Digestive aid to help digest proteins (Murray 1996).
- Digestive enzyme that helps digest proteins (Murray 1996).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 680,000 FCC HUT and/or 6,800 FCC SAP of enzymatic activity, per day (FCC 8 2012; Oben et al. 2008; Brown et al. 2004).

Notes

- The Quantity per dosage unit must be the enzymatic activity (FCC unit). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity.
- One hemoglobin unit on the tyrosine basis (HUT) of proteolytic (protease) activity is defined as that amount of enzyme that produces, in 1 minute under the conditions of the assay, a hydrolysate whose absorbance at 275 nm is the same as that of a solution containing 1.10 µg/mL of tyrosine in 0.006 N hydrochloric acid (FCC 8 2012).
- One spectrophotometric acid protease unit (SAP) is that activity that will liberate 1µmol of tyrosine per minute under the conditions of the assay (FCC 8 2012).
- For multi-ingredient products containing protease from *A. niger* and protease from *A. oryzae*, the maximum proteolytic activity from both sources cannot exceed 680,000 FCC HUT per day and/or 6,800 FCC SAP per day (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 lesions/ulcers or are having surgery.
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are taking anticoagulant/blood thinner or anti- inflammatory medications.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs.

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.
- 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 specifications must include testing for enzymatic activity of the medicinal ingredient at the appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): PROTEOLYTIC ACTIVITY, FUNGAL (HUT) PROTEOLYTIC ACTIVITY, FUNGAL (SAP).
- 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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