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

Date March 11, 2014

Proper name(s)

Fungal protease (FCC 8)

Common name(s)

- Fungal protease (FCC 8)
- Acidic protease/ acid protease/ acid stable protease
- Protease 3.0
- Protease 4.5
- Protease 6.0

Source material(s)

- *Aspergillus flavus* var. *oryzae* ((Ahlb.) Kurtzman MJ, Smiley, Robnett & Wicklow 1986 (Trichocomaceae)) (CABI 2012; FCC 8; Bisby et al. 2010)
- *Aspergillus niger* (van Tieghem 1867 (Trichocomaceae)) (CABI 2012; FCC 8; Bisby et al. 2010)

Route(s) of administration

Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)

Statement(s) to the effect of

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

Dose(s)

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:

- Enzyme preparation per dosage unit;

and

- Enzyme activity not to exceed the equivalent of 6.8×10^5 FCC HUT[1] and/or 6.8×10^3 FCC SAP[2] per day[3]. (FCC8; Oben et al. 2008; Brown et al. 2004).

Notes

1. FCC 8: 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.
2. FCC 8: one spectrophotometric acid protease unit (SAP) is that activity that will liberate 1µmol of tyrosine per minute under the conditions of the assay.
3. For multi-ingredient products containing protease from *A. niger* and protease from *A. oryzae*, the maximum proteolytic activity from both sources cannot exceed 6.8×10^5 FCC HUT per day and/or 6.8×10^3 FCC SAP per day(FCC 8).

Directions for use

All products

Take with food/meal.

Enteric-coated products

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

Duration of use

For prolonged use, consult a health care practitioner.

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- If you have gastrointestinal lesions/ulcers, are taking anticoagulant agents or anti-inflammatory agents or are having surgery, consult a health care practitioner prior to use.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Hypersensitivity/allergy has been known to occur, in which case discontinue use.

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.

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 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):

  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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