Protease, Fungal

Fungal Protease Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 80 KB) 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 any age category listed in this monograph for the specified route of administration are listed 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 ?g/mL of tyrosine in 0.006 N hydrochloric acid (FCC 8 2012). One spectrophotometric acid protease unit (SAP) is that activity that will liberate 1?mol 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. References Cited Bisby F, Roskov Y, Culham A, Orrell T, Nicolson D, Paglinawan L. Bailly N, Appeltans W, Kirk P, Bourgoin T, Baillargeon G, Ouvrard D, editors. Species 2000 & ITIS Catalogue of Life, 15th March 2012 [Internet]. Reading (GB): Species 2000. [Source database: Species Fungorum 9.0, Sep 2010; Accessed 2012 March 30]. Available from: http://www.catalogueoflife.org Brown SA, Coimbra M, Coberly DM, Chao JJ, Rohrich RJ. Oral nutritional supplementation accelerates skin wound healing: a randomized, placebo-controlled, double-arm, crossover study. Plastic and Reconstructive Surgery 2004;114(1):237-244. CABI 2012: Centre for Agriculture and Bioscience International. Index Fungorum [Internet]. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2012 March 30]. Available from: http://www.indexfungorum.org CPS 2008: Compendium of Pharmaceuticals and Specialties: The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008. FCC 8 2012: Food Chemicals Codex. Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2012. IUBMB 1992: IUBMB Enzyme Nomenclature [Internet]. London (GB): Queen Mary, University of London. [aspergillopepsin I: other name Aspergillus acid protease, CAS 9025-49-4, EC 3.4.23.18 created 1992; Accessed 2012 March 30]. Available from: http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/4/23/18.html Murray MT. Encyclopedia of Nutritional Supplements: The Essential Guide for Improving Your Health Naturally. New York (NY): Three Rivers Press; 1996. Oben J, Kothari SC, Anderson ML. An open label study to determine the effects of an oral proteolytic enzyme system on when protein concentrate metabolism in health males. Journal of the International Society of Sports Nutrition 2008;5:10. References Reviewed Cichoke AJ. Pancreatic Enzymes. In: Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. p. 1131-1146. Sweetman SC, editor. Martindale: The Complete Drug Reference [Internet]. London (GB): Pharmaceutical Press; 2011. [Pancreatic enzymes latest modification 09-Apr-2011; Accessed 2011 August 17]. Available from: http://www.medicinescomplete.com Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

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.

STORAGE CONDITION(S)

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.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)	
Proper name(s)	Part(s)		
Fungal proteaseProtease	Acidic proteaseAcid proteaseAcid stable protease	Aspergillus flavus acid protease	Fungal protease