FRUIT BROMELAIN

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 July 5, 2012

Proper name(s)

Fruit bromelain (IUBMB 1992)

Common name(s)

- Fruit bromelain (IUBMB 1992)
- Pineapple fruit bromelain (IUBMB 1992)
- Juice bromelain (IUBMB 1992)

Source material(s)

Pineapple (*Ananas comosus* (L.) Merr. var. *comosus* (Bromeliaceae)) Fruit (USDA 2011)

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 enzyme

Dose(s)

Subpopulation(s)

Adults (≥ 19 years)

Quantity(ies)

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

- Providing up to 600 mg per day enzyme preparation, not to exceed 300 mg per dose (Kerkhoffs et al. 2004; Walker et al. 2002; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978); and
- Enzyme activity providing up to 2.0 x 10^7 FCC PU per day, not to exceed 1.0 x 10^7 FCC PU per dose (Glade et al. 2001; Gutfreund et al. 1978).

Notes

- One papain unit (PU) is defined as that quantity of enzyme that liberates the equivalent of 1 µg of tyrosine per hour under the conditions of the assay (FCC 8).
- One gelatin digestion unit (GDU) is approximately equivalent to 1.5 x 10^4 FCC papain unit (1 GDU ≈ 1.5 x 10^4 FCC PU).
- For multi-ingredient products containing both papain and bromelain (fruit and/or stem), the combined proteolytic activity should not exceed the maximum proteolytic activity of 2.0 x 10^7 FCC PU per day.

Direction(s) for use

Take with food/meal.

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, anti-inflammatory agents or antibiotics or before having surgery, consult a health care practitioner prior to use (Martindale 2011; Brinker 2010; Blumenthal et al. 2000).

Contraindication(s)

No statement required.

Known adverse reaction(s)

- Hypersensitivity/allergy has been known to occur, in which case discontinue use (Martindale 2011; Brinker 2010; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmann 1979).
- Nausea, vomiting, and diarrhea have been known to occur, in which case discontinue use (and consult a health care practitioner) (Martindale 2011; Brien et al. 2006; Blumenthal et al. 2000).

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- 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):
  PLANT PROTEOLYTIC ACTIVITY.
- 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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