Health Canada Santé Canada

NATURAL HEALTH PRODUCT

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

Date November 25, 2022

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
Fruit bromelain	▶ Fruit bromelain ▶ Juice bromelain ▶ Pineapple fruit bromelain	▶ *Ananas comosus* var. *bracteatus* ▶ *Ananas comosus* var. *comosus*	Fruit

References: Proper name: IUBMB 1992; Common names: IUBMB 1992; Source information: USDA 2018.

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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s)

- Used in Herbal Medicine to help relieve minor pain, swelling and inflammation (Walker et al. 2002, Blumenthal 1998).
- Digestive enzyme.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Minor pain, swelling and inflammation relief

480,000 – 20,000,000 FCC PU of enzymatic activity per day; Not to exceed 10,000,000 FCC PU per single dose (Kerkhoffs et al. 2004; Walker et al. 2002; Glade et al. 2001; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978).

Digestive enzyme

Not to exceed 130,000,000 FCC PU of enzymatic activity per day and 45,000,000 FCC PU per single dose (Kerkhoffs et al. 2004; Walker et al. 2002; Glade et al. 2001; Singer et al. 2001; Klein and Kullich 2000; Gutfreund et al. 1978).

Notes

- Dose information must include the quantities of both the enzyme preparation and its enzymatic activity. The enzymatic activity quantity should be indicated in the Quantity/Unit field and its quantity of enzyme preparation in mg or ml in the Additional Quantity/Unit field.
- 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 130,000,000 FCC PU per day.
- One papain unit (PU) is defined as that quantity of enzyme that liberates the equivalent of 1 microgram of tyrosine per hour under the conditions of the assay (FCC 8 2012).
- One gelatin digestion unit (GDU) is approximately equivalent to 15,000 FCC papain unit (1 GDU ≈ 15,000 FCC PU).

Direction(s) for use

Digestive enzyme (optional for minor pain, swelling and inflammation relief)

Take with food/meal.

Duration(s) of use

Products providing up to 20,000,000 FCC PU of enzymatic activity per day

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

Products providing more than 20,000,000 FCC PU of enzymatic activity per day

For occasional use only.

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 or breastfeeding.
- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have gastrointestinal lesions/ulcers or are having surgery (Martindale 2011; Brinker 2010; Blumenthal et al. 2000).
- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking anticoagulant agents, anti-inflammatory agents or antibiotics (Martindale 2011; Brinker 2010; Blumenthal et al. 2000).

Contraindication(s)

No statement required.

Known adverse reaction(s)

- Stop use if hypersensitivity/allergy occurs (Martindale 2011; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmann 1979).
- Some people may experience gastrointestinal discomfort/disturbances (Martindale 2011; Brinker 2010; Brien et al. 2006; Murray and Pizzorno 2006; Blumenthal et al. 2000; Baur and Fruhmann 1979).

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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations* (NHPR).

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): 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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