Health Canada Santé Canada

NATURAL HEALTH PRODUCT

PAPAIN

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)
Papain	Papain	*Carica papaya*	▸ Fruit ▸ Leaf

References: Proper name: IUBMB 2000; Common name: IUBMB 2000; Source material: Merck 2012, USDA 2011, Morton 1987.

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 (Merck 2012)

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Not to exceed 7,200,000 FCC PU of enzymatic activity, per day; and 2,400,000 FCC PU per single dose (Martin et al. 2002; Dale et al. 2001).

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.
- 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 FCC papain unit is approximately equivalent to one USP papain unit (1 FCC PU ≈ 1 USP PU).

Direction(s) for use

Take with food/a meal.

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 a gastrointestinal lesion/ulcer or are having surgery (Martindale 2011).

- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use are taking an anticoagulant/blood thinner or anti-inflammatory medications (Martindale 2011).
- Consult a health care practitioner/ health care provider/health care professional/doctor/ physician prior to use if you have an allergy to latex or fruits (e.g. avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, and tomato) (US FDA 2008; APhA 2006; Brehler et al. 1997).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (HC 2011; Martindale 2011; US FDA 2008).

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 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 their shelf life indicated on the product label.

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