

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 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 on the label.

Date

June 27, 2025

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)
Papain	Papain	<i>Carica papaya</i>	- Fruit - Leaf

References: Proper name: IUBMB 2024; Common name: IUBMB 2024; Source information: RSC 2024; USDA 2024; 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compndial applications.

Note: Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when papain is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application.



Use(s) or Purpose(s)

Digestive enzyme (RSC 2024).

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 2024).
- One FCC papain unit is approximately equivalent to one USP papain unit (1 FCC PU $\approx$ 1 USP PU).

Direction(s) for use

Take with a meal/food.

Duration(s) of use

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

Risk information

Caution(s) and warning(s)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you are pregnant or breastfeeding.
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you have gastrointestinal lesions/ulcers or are having surgery (Brayfield and Cadart 2024).

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if** you are taking blood thinners or anti-inflammatory medications (Brayfield and Cadart 2024).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if** you have an allergy to latex or fruits (such as 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 (Brayfield and Cadart 2024; HC 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

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

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.



EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredient in each capsule	
Papain (<i>Carica papaya</i> – fruit)	XX FCC PU
Uses	
• Digestive enzyme.	
Warnings	
If applicable¹:	
Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Ask a health care practitioner before use if • you are pregnant, breastfeeding • you have gastrointestinal lesions/ulcers or are having surgery • you are taking blood thinners or anti-inflammatory medications • you have an allergy to latex or fruits (such as avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, and tomato).	
Stop use if allergy occurs.	
Directions	
Adults 18 years and older: • Take X capsule(s), X time(s) per day • Take with a meal • Ask a health care practitioner for prolonged use.	
Other information	
(Add storage information)	
Non-medicinal ingredients	
List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

¹This section can be removed from the table if the product contains no allergen or aspartame.

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