

NATURAL HEALTH PRODUCT

CAYENNE – *CAPSICUM ANNUUM*/CAPSAICIN Topical

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 either term and/or statement may be selected on the label.

Restrictions when this monograph is combined with other monographs (Class II and III applications):

- Counterirritants such as capsaicin/cayenne cannot be combined with other ingredients if the conditions of use are not compatible between monographs (e.g., products to be applied to irritated skin such as hydroquinone, medicated skin care, diaper rash products). These products must be submitted as a Class III application along with evidence to support their safety and efficacy.

Date

March 27, 2026

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 ingredient(s)	Source material(s)	Part(s)	Preparation(s)
<i>Capsicum annuum</i>	<ul style="list-style-type: none"> • Cayenne • Cayenne pepper • Chili pepper • Paprika • Red pepper 	N/A	<i>Capsicum annuum</i>	Fruit	Dry
<ul style="list-style-type: none"> • (6E)-N-[(4-Hydroxy-3-methoxyphenyl)methyl]-8-methyl-6-nonenamide • (E)-8-Methyl-N-vanillyl-6-nonenamide 	Capsaicin	Capsaicin ¹	<i>Capsicum annuum</i>	Fruit	N/A
		Capsaicin ²	N/A	N/A	N/A

References: Proper names: NIH 2024; USDA 2024; USP-NF 2024; Common names: NIH 2024; Gardner and

McGuffin 2013; Blumenthal et al. 2000; Source information: USP-NF 2024; Bradley 2006; Felter and Lloyd 1983.

¹Isolate

²Synthetic

Route of administration

Topical

Dosage form(s)

The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Cream; Emulsion; Fluid extract; Foam; Gel; Liniment; Liquid; Oil; Ointment; Salve; Solution; Spray; Spray, suspension; Suspension; Tincture; Topical liquid; Wipe.

Use(s) or Purpose(s)

Cayenne powder or extracts

Used in Herbal Medicine (as a rubefacient/counterirritant) to help (temporarily) relieve the symptoms of rheumatism and/or muscle and joint pain (Blumenthal et al. 2000; Lust 1987; BHP 1983; Ellingwood 1983; Felter 1983; Felter and Lloyd 1983; BPC 1934).

Cayenne extracts or Capsaicin (isolate; synthetic)

- Temporarily relieves aches and pains/soreness of muscles and joints (associated with one or more of the following: simple backache, lumbago, strains and sprains (involving muscles, tendons, and/or ligaments), and arthritis) (US FDA 2023; McCarthy et al. 1992; Deal et al. 1991).
- Temporarily relieves skin (cutaneous) pain associated with conditions such as post-herpetic neuralgia and/or diabetic neuropathy (Hautkappe et al. 1998; Watson et al. 1993; Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989).

Note: The above uses can be combined on the product label (e.g., Temporarily relieves aches and pains of muscles and joints and skin pain associated with conditions such as post-herpetic neuralgia or diabetic neuropathy).

Dose(s)

Subpopulation(s)

Children 2 to 11 years; Adolescents 12 to 17 years; Adults 18 years and older

Quantity(ies)

Cayenne powder or extracts

Herbal Medicine use

Methods of preparation: Powdered standardized, Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

The percentage of the medicinal ingredient in the product formulation and the percentage of the potency constituent, capsaicin, in the medicinal ingredient are not restricted as long as the concentration of capsaicin **in the finished product** is equivalent to:

0.01 – 0.05% capsaicin (BHP 1983).¹

Cayenne extracts

Relief of muscle and joint pain

Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

The percentage of the medicinal ingredient in the product formulation and the percentage of the potency constituent, capsaicin, in the medicinal ingredient are not restricted as long as the concentration of capsaicin **in the finished product** is equivalent to:

0.025 – 0.25% capsaicin (US FDA 2023; McCarthy et al. 1992; Deal et al. 1991).¹

Relief of skin (cutaneous) pain

Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

The percentage of the medicinal ingredient in the product formulation and the percentage of the potency constituent, capsaicin, in the medicinal ingredient are not restricted as long as the concentration of capsaicin **in the finished product** is equivalent to:

0.075% capsaicin (Watson 1993; Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989).¹

Capsaicin (isolate; synthetic)

Relief of muscle and joint pain

Methods of preparation: Isolate, Synthetic

0.025 – 0.25% capsaicin (US FDA 2023; McCarthy et al. 1992; Deal et al. 1991).

Relief of skin (cutaneous) pain

Methods of preparation: Isolate, Synthetic

0.075% capsaicin (Watson1993; Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989).

¹**Note:** For standardized Cayenne fruit powder or extract, the percentage of capsaicin in the finished product should also be included on the product label (e.g., Cayenne extract (*Capsicum annuum* - fruit) 30%, standardized to 0.1% capsaicin is equivalent to 0.03% capsaicin in the finished product).

Direction(s) for use

All products

- Apply thinly and evenly to affected area(s), up to 4 times per day (US FDA 2023).
- Rub and/or massage into skin until solution vanishes (US FDA 2023).
- Do not apply to wounds or damaged skin (US FDA 2023).
- Do not tightly bandage (US FDA 2023).
- Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn (Pray 2006; APhA 2002).
- Supervise children when they use this product (Ragucci et al. 2007; Love et al. 2004).

Products in spray or spray, suspension dosage form

Avoid inhaling or exposing others to spray (APhA 2002).

Combination rule

No permitted combinations between the ingredients listed in Table 1.

Duration(s) of use

Use for at least 1-2 weeks to see beneficial effects (APhA 2002; McCarthy et al. 1992; Deal et al.1991).

Risk information

Caution(s) and warning(s)

All products

- **For external use only** (US FDA 2023).
- **When using this product** avoid contact with the eyes and mucous membranes. If contact occurs, rinse thoroughly with water (US FDA 2023).

- **Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if** symptoms persist, worsen, or re-occur within a few days (US FDA 2023).
- **Keep out of the reach of children.** If swallowed, call a poison control centre or get medical help right away (CPS 2008).

Contraindication(s)

No statement required.

Known adverse reaction(s)

All products

Stop use if headache, redness, rashes, burning discomfort and/or hypersensitivity occur (Brayfield and Cadart 2024; Zhang et al. 2008; Hoffman 2003; APhA 2002; McCleane 2000).

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 Product Regulations*.

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.

EXAMPLE OF PRODUCT FACTS:

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

Product Facts	
Medicinal ingredient (w/w) Capsaicin	XX %
Uses	
<ul style="list-style-type: none"> Temporarily relieves aches and pains/soreness of muscles and joints associated with one or more of the following: simple backache, lumbago, strains and sprains (involving muscles, tendons, and/or ligaments), and arthritis. Temporarily relieves skin pain associated with conditions such as post-herpetic neuralgia or diabetic neuropathy. 	
Warnings	
If applicable¹:	
Allergens: food allergen, gluten (gluten source), sulphites	
For external use only	
When using this product avoid contact with the eyes and mucous membranes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a health care practitioner if symptoms persist, worsen, or re-occur within a few days.	
Stop use if headache, redness, rashes, burning discomfort and/or hypersensitivity occur.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions	
Adults, adolescents and children 2 years and older: <ul style="list-style-type: none"> Apply thinly and evenly to affected area, up to 4 times per day Rub or massage into skin until solution vanishes Do not apply to wounds or damaged skin Do not tightly bandage Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn Supervise children when they use this product Use for at least 1-2 weeks to see beneficial effects. 	
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.

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Version History

Publication date	Update type	Summary of main updates (from March 2026)
2026-03-27	Minor updates	<ul style="list-style-type: none"> • Introductory notes • Inclusion of a note about Class II and III restrictions • Additions of Dosage forms and removal of lotion • Adjustment of the claims • Addition of children and adolescent subpopulations • Additional methods of preparation • Increase of the maximum concentration for muscle and joint pain relief as per US FDA 2023 • Adjustments of the Directions for use statements to align with the Counterirritants monograph

Publication date	Update type	Summary of main updates (from March 2026)
		<ul style="list-style-type: none"> • Revision of the Duration of use section (applies to all claims) • Revisions to the Risk statements • Inclusion of the standard statement for storage conditions • Inclusion of a Product Facts Table example • Reference section • Inclusion of version history information
2021-03-19	Minor updates	—
2018-10-30	Validation (only includes topical)	—
2013-09-13	Minor updates (includes both oral/topical)	—
2013-05-13	Minor updates (includes both oral/topical)	—
2008-01-21	Initial release (includes both oral/topical)	—