

Cayenne - Capsicum annum/Capsaicin - Topical

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CAYENNE - CAPSICUM ANNUUM/CAPSAICIN Topical Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 81 KB) 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 March 19, 2021 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) Capsicum annum Cayenne Cayenne pepper Chili pepper Paprika Red Pepper N/A Capsicum annum Fruit Dried (6E)-N-[(4-Hydroxy-3-methoxyphenyl) methyl]-8-methyl-6-nonenamide (E)-8-Methyl-N-vanillyl-6-nonenamide Capsaicin Capsaicin 1 Capsicum annum Fruit N/A Capsaicin 2 N/A N/A N/A References: Proper name: USDA 2018; USP 36 2013, NLM 2012; Common names: Blumenthal et al. 2000, McGuffin et al. 2000, NLM 2012; Source information: USP 36 2013, Bradley 2006, Felter and Lloyd 1983. 1 Isolate 2 Synthetic Route of Administration Topical Dosage Form(s) The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Cream; Fluid extract; Gel; Liniment; Liquid; Lotion; Oil; Ointment; Salve; Solution; Tincture; Topical liquid. 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) Used for the (temporary) relief of muscle and joint pain associated with rheumatoid arthritis or osteoarthritis, and pain of tendons and ligaments (McCarthy et al. 1992; Deal et al. 1991). Used to relieve 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). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Cayenne powder or extracts Herbal Medicine use Methods of preparation: Powdered standardized, Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 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, joint, tendons and ligaments pain Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 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: 0.025-0.075% capsaicin (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, Infusion) 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 (Watson1993; Tandan et al. 1992; Scheffler et al. 1991; The Capsaicin Study Group 1991; Bernstein et al. 1989) 1 Capsaicin (isolate; synthetic) Relief of muscle, joint, tendons and ligaments pain Methods of preparation: Isolate, Synthetic 0.025-0.075% capsaicin (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) Note: 1 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 annum - fruit) 30%, standardized to 0.1% capsaicin is equivalent to 0.03 % capsaicin in the finished product Direction(s) for use Herbal Medicine use Apply as needed. Other uses Apply thinly and evenly to affected area up to 3-4 times per day. Rub and/or massage into skin until solution vanishes (US FDA 1979). Combination rule No permitted combinations. This

monograph only supports single ingredient products. Duration(s) of Use Herbal Medicine use No statement required. Other uses Use for at least 1-4 weeks to see beneficial effects (Berardi 2002; McCarthy et al. 1992; Deal et al.1991). Risk Information Caution(s) and warning(s) All products Keep out of the reach of children. Call a Poison Control Center immediately if overdose or accidental ingestion occurs (CPS 2008). For external use only. Avoid contact with the eyes and mucous membranes (US FDA 1983). Do not apply to wounds or damaged skin (US FDA 1983). Do not tightly bandage (US FDA 1983). 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; Berardi 2002). Contraindication(s) No statement required. Known adverse reaction(s) All products Stop use if headache, erythema, redness, rashes, burning discomfort or hypersensitivity occurs (Martindale 2010; Zhang et al. 2008; Hoffman 2003; Berardi 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 No statement required. 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. References Cited Berardi RR, DeSimone EM, Newton GGD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An interactive approach to self-care. 13 th edition. 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MEDICINAL INGREDIENT(S)

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.

RISK INFORMATION

Caution(s) and warning(s) All products Keep out of the reach of children. Call a Poison Control Center immediately if overdose or accidental ingestion occurs (CPS 2008). For external use only. Avoid contact with the eyes and mucous membranes (US FDA 1983). Do not apply to wounds or damaged skin (US FDA 1983). Do not tightly bandage (US FDA 1983). 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; Berardi 2002). Contraindication(s) No statement required. Known adverse reaction(s) All products Stop use if headache, erythema, redness, rashes, burning discomfort or hypersensitivity occurs (Martindale 2010; Zhang et al. 2008; Hoffman 2003; Berardi 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 No statement required.

STORAGE CONDITION(S)

No statement required.

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.

REFERENCES

1Isolate2Synthetic Route of Administration Topical

er name(s)	Common name(s)	Source information			
e ingredient(s)	Source material(s)	Part(s)	Preparation(s)		
cum annum	CayenneCayenne pepperChili pepperPaprikaN/A	Red Pepper	Capsicum annum	Fruit	
N-[4-Hydroxy-3-methoxyphenyl) methyl-6-nonenamide(E)-8-Methyl-N-vanillyl-6-nonenamide	Capsaicin	Capsaicin	Capsicum annum	Fruit	
aicin2	N/A	N/A	N/A		