Health Canada Santé Canada

NATURAL HEALTH PRODUCT

WART REMOVER

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 July 1, 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 ingredient(s)[1] Common name(s)
2-Hydroxybenzoic acid	Salicylic acid	Salicylic acid

[1]The ingredient must be pharmacopoeial grade.

References: Proper name: USP 29 2006, Gottschalk & McEwen 2004, O'Neil et al. 2001; Common name: USP 29 2006, Gottschalk & McEwen 2004, O'Neil et al. 2001; Source ingredient: USP 29 2006, Gottschalk & McEwen 2004, O'Neil et al. 2001.

Table 2. Proper name(s), Common name(s), Source material(s) – Complementary ingredient (safety only)

Proper name(s)	Common name(s)	Source ingredient(s)[1] Common name(s)
▸ 2-Hydroxy-2-methylacetic acid ▸ DL-Lactic acid	▸ DL-Lactic acid ▸ Lactic acid	Lactic acid

[1]The ingredient must be pharmacopoeial grade.

References: Proper names: USP 29 2006, Gottschalk & McEwen 2004, O'Neil et al. 2001; Common names: USP 29 2006, Gottschalk & McEwen 2004, O'Neil et al. 2001; Source ingredient: USP 29 2006, Gottschalk & McEwen 2004, O'Neil et al. 2001.

Route of administration

Topical (FDA 1990)

Dosage form(s)

Collodion-like solution; Karaya gum, glycol plaster; Plaster (FDA 1990).

Use(s) or Purpose(s)

- Wart remover (FDA 1990).
- For the removal of common warts (FDA 1990).
- For the removal of plantar warts on the bottom of the feet (FDA 1990).
- Common and/or plantar wart treatment (FDA 1990).

Dose(s)

Subpopulation(s)

Children 2-11 years, Adolescents 12-17 years and Adults 18 years and older

Quantity(ies)

Table 3. Doses of Salicylic acid associated with dosage forms

Dosage forms	Doses
Collodion-like solution	5 - 17%
Karaya gum, glycol plaster	15%
Other types of plasters	12 - 40%

Reference: FDA 1990.

Complementary Ingredient (Safety only)

Not to exceed 30% of lactic acid (Fiume 1998)

Direction(s) for use

Products formulated in a collodion-like solution (FDA 1990)

1. Wash affected area (**Optional:** May soak wart in warm water for five minutes) and dry thoroughly.
2. Apply one drop at a time to sufficiently cover each wart and let dry. Do not apply to surrounding skin.
3. Repeat procedure once or twice daily as needed (until wart is removed).

Products formulated in a karaya gum, glycol plaster (FDA 1990)

1. Wash affected area (**Optional:** May soak wart in warm water for five minutes) and dry thoroughly.
2. Gently smooth wart surface with emery file provided (FDA 1994).
3. Cut plaster to fit wart (if appropriate).
4. Apply a drop of warm water to the wart, keeping the surrounding skin dry (FDA 1994).
5. Apply medicated plaster at bedtime, leave in place for at least 8 hours.
6. Remove and discard plaster in morning.
7. Repeat every 24 hours as needed (until wart is removed).

Products formulated with other types of plaster (FDA 1990)

1. Wash affected area (**Optional:** May soak wart in warm water for five minutes) and dry thoroughly.
2. Cut plaster to fit wart (if appropriate).
3. Apply medicated plaster.
4. Repeat every 48 hours as needed (until wart is removed).

Duration(s) of use

Do not use this product beyond 12 weeks (FDA 1990).

Risk information

Caution(s) and warning(s)

All products

- For external use only (FDA 1990).
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician if discomfort persists (FDA 1990).

Products formulated in a collodion-like solution only

- Extremely flammable or flammable or combustible (FDA 1990).
- Keep away from fire or flame (FDA 1990).
- Cap bottle tightly and store at room temperature, in an upright position, away from heat (FDA 1990).
- Flush with water for 15 minutes if product gets into the eye (FDA 1990).
- Avoid inhaling vapours (FDA 1990).

Contraindication(s)

All products

- Do not use this product on irritated or reddened skin or any area that is infected (FDA 1990).
- Do not use this product if you have diabetes or poor blood circulation (FDA 1990).
- Do not use this product on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes (FDA 1990).

Known adverse reaction(s)

No statement required.

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

FDA 1994: The USA Department of Health and Human Services: Food and Drug Administration. 21 CFR Part 358. Wart remover drug products for over-the-counter human use, amendment of the final monograph; 1994. FR Citation: 59FR4015 [Accessed 2019 June 13]. Available at: https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-wart-remover-drug-products

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Gottschalck TE and McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook, 10th ed. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2004.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, & Biologicals, 13th ed. Whitehouse Station (NJ): Merck & Co., Inc.; 2001.

USP 29: The United States Pharmacopeia and the National Formulary (USP 29/NF 24). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2006.