

NATURAL HEALTH PRODUCT

CORN AND CALLUS 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

¹The ingredient must be pharmacopoeial grade.

References: Proper name: Gottschalck & McEwen 2004, O'Neil et al. 2001; Common name: Gottschalck & McEwen 2004, USP 29 2006, O'Neil et al. 2001; Source ingredient: NHPID 2019.

Route of administration

Topical (FDA 1990)

Dosage form(s)

Collodion-like solution; Plaster (FDA 1990).

Use(s) or Purpose(s)

- ▶ For the removal of corns and calluses (FDA 1990).
- ▶ Effectively removes corn and calluses (FDA 1990).
- ▶ Removes corns and calluses (FDA 1990).



Dose(s)

Subpopulation(s)

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

Quantity(ies)

Table 2. Doses of Salicylic acid associated with dosage forms

Dosage forms	Doses
Collodion-like solution	12 - 17.6%
Plaster	12 - 40%

Reference: FDA 1990.

Direction(s) for use

Products formulated in a plaster (FDA 1990)

1. Wash affected area and dry thoroughly.
2. Cut plaster to fit corn/callus (if appropriate).
3. Apply medicated plaster. (**Optional:** with sticky side adhering to skin).
4. After 2 days remove the medicated plaster. (**Optional:** Cover medicated plaster with enclosed cushion. After 48 hours, remove medicated plaster).
5. Repeat this procedure every 2 days as needed (until corn/callus is removed) for up to 14 days.
6. (**Optional:** To assist in removal of the corn/callus, at the end of the treatment period soak in warm water for 5 minutes).

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

1. Wash affected area and dry thoroughly.
2. With applicator/brush, apply a small amount to sufficiently cover each corn/callus. Let dry.
3. Repeat this procedure once or twice daily as needed (until corn/callus is removed) for up to 14 days. (**Optional:** Protective pads may be used to cushion corn/callus during treatment).
4. (**Optional:** To assist in removal of the corn/callus, at the end of the treatment period soak in warm water for 5 minutes).

Duration(s) of use

Do not use this product beyond 14 days (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 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).

Known adverse reaction(s)

No statement required.

Optional label information

For products which contain cushions the following additional information may be included on the product label:

“(Protective) Cushion helps to relieve painful shoe pressure and friction.”

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 1990: The USA Department of Health and Human Services: Food and Drug Administration. 55 CFR Part 157. Corn and Callus Remover Drug Products for Over-the-Counter Human Use, Final Monograph; 1990. FR Citation 55FR33258 [Accessed 2019 June 12]. Available at: <https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-corn-and-callus-remover-drug-products>

Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook, 10th ed. Washington (D.C.):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.