Corn & Callus Remover

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=cor_call⟨=eng

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CORN AND CALLUS REMOVER 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 - 49 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 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: 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) Wash affected area and dry thoroughly. Cut plaster to fit corn/callus (if appropriate). Apply medicated plaster. (Optional: with sticky side adhering to skin). After 2 days remove the medicated plaster. (Optional: Cover medicated plaster with enclosed cushion. After 48 hours, remove medicated plaster). Repeat this procedure every 2 days as needed (until corn/callus is removed) for up to 14 days. (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) Wash affected area and dry thoroughly. With applicator/brush, apply a small amount to sufficiently cover each corn/callus. Let dry. 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). (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, 10 th 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, 13 th 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. Date Modified 2008-12-19 Top of page Important Notices

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.

DOSAGE FORM(S)

Dosage formsDoses Collodion-like solution12 - 17.6%Plaster12 - 40%

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Dosage formsDoses Collodion-like solution12 - 17.6%Plaster12 - 40%

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.

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

Route of Administration Topical (FDA 1990)

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.		

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