Health Canada Santé Canada

NATURAL HEALTH PRODUCT

HYDROCORTISONE
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 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)	Preparation(s)
		Common name(s)	
(11beta)-11,17,21-Trihydroxypregn-4-ene-3,20-dione	▸ 17-Hydroxycorticosterone ▸ Cortisol ▸ Hydrocortisone	▸ Hydrocortisone ▸ Hydrocortisone acetate	Synthetic

References: Proper name: USP 37 2013, O'Neil et al. 2001; Common names: O'Neil et al. 2001; Source ingredients: O'Neil et al. 2001.

Route of administration

Topical

Dosage form(s)

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- For temporary relief of minor skin irritations (associated with redness, itching, dryness and scaling) (HC 1985).
- For temporary relief of minor skin irritations, rashes, itching and redness (due to eczema, insect bites, poison ivy, poison oak, poison sumac, seborrheic dermatitis, psoriasis, or contact dermatitis) (e.g. caused by soaps, detergents, cosmetics and/or jewellery)) (FDA 1986, 1983).
- For temporary relief of (external) feminine genital itching and/or (external) anal itching (due to hemorrhoids) (FDA 1983).
- Anti-pruritic (FDA 1983).
- Anti-itch (FDA 1983).

Dose(s)

Subpopulation(s)

Products for (external) feminine genital or anal itching

Adolescents 12 to 17 years and Adults 18 years and older (FDA 1990a, 1988, 1980)

All other products

Children 2 to 11 years, Adolescents 12 to 17 years and Adults 18 years and older (FDA 1990b)

Quantity(ies)

0.5 – 1.0% of Hydrocortisone (HC 1985; HC 2014)

Direction(s) for use

All products

Apply sparingly to the affected area not more than 3-4 times daily.

Products for anal itching

Gently cleanse, rinse thoroughly, and dry the affected area prior to application (FDA 1990a, 1988).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

- For external use only (HC 1985).
- Stop use and do not begin use of any other hydrocortisone product, except on the advice of a health care practitioner/health care provider/health care professional/doctor/physician, if symptoms worsen or persist more than 7 days or clear up and occur again within a few days (FDA 1991; FDA 1990b; HC 1985).

Products for anal itching

Consult a health care practitioner/health care provider/health care professional/doctor/physician promptly in case of bleeding (FDA 1990a, 1988).

Contraindication(s)

All products

- Do not use this product in or around the eyes or on large areas of the body (HC 1985).
- Do not use this product for the treatment of diaper rash, except on the advice of a health care practitioner/health care provider/health care professional/doctor/physician (Berardi et al. 2002; FDA 1990b).

Products for (external) feminine genital itching

Do not use this product to treat vulvar itching associated with a vaginal discharge, except on the advice of a health care practitioner/health care provider/health care professional/doctor/physician (HC 1985).

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

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FDA 1990a: USA Department of Health and Human Services: Food and Drug Administration. 55 CFR Part 346. Anorectal Drug Products for Over-the-Counter Human Use; Final Monograph; 1990. FR Citation: 55FR31776 [Accessed 2019 June 12]. Available at: https://www.fda.gov/drugs/status-otc-rulemakings/rulemaking-history-otc-anorectal-drug-products

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HC 1985: Health Canada. Information Letter No. 678, Recommendations of the Expert Advisory Committee on Dermatology Regarding the Availability of Over-the-Counter Topical Preparations Containing Hydrocortisone. Ottawa (ON): Health Canada; 1985.

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

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