Hydrocortisone Topical

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=hydrocortisone2⟨=eng

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HYDROCORTISONE - 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 - 74 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 label at the applicant's discretion. The solidus (/) indicates that either term and/or statement may be selected on the label. Restrictions when this monograph is combined with other monographs (Class II and III applications): Hydrocortisone cannot be combined with other ingredients if the conditions of use are not compatible between monographs (e.g., counterirritants, diaper rash products). These products may be submitted as a Class III application along with evidence to support their safety and efficacy. Date July 25, 2025 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) Preparation(s) (11beta)-11,17,21-Trihydroxypregn-4-ene-3,20-dione 17-Hydroxycorticosterone Cortisol Hydrocortisone Hydrocortisone Hydrocortisone acetate Synthetic References: Proper name: RSC 2024, USP-NF 2024; Common names: RSC 2024; Source information: RSC 2024. Route of Administration Topical Dosage Form(s) The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Cream; Lotion; Ointment; Spray. Use(s) or Purpose(s) For (the) temporary relief of itching associated with minor skin irritations, (inflammation) and rashes (due to eczema, insect bites, poison ivy, poison oak, poison sumac, seborrheic dermatitis, psoriasis, or contact with soaps, detergents, cosmetics or jewellery) (US FDA 2023). For (the) temporary relief of external feminine genital itching and/or external anal itching (due to hemorrhoids) (US FDA 2023). Antipruritic (US FDA 2023). Anti-itch (US FDA 2023). Note: The above uses can be combined on the product label (e.g., For temporary relief of itching associated with minor skin irritations and rashes and of external feminine genital itching). Dose(s) Subpopulation(s) Products for external feminine genital or anal itching Adolescents 12 to 17 years and Adults 18 years and older (US FDA 2023) All other products Children 2 to 11 years, Adolescents 12 to 17 years and Adults 18 years and older (US FDA 2023) Quantity(ies) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w) or percentage weight by volume (% w/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g. mg/mL). 0.25 - 1.0% of Hydrocortisone (US FDA 2023; HC 2014). Direction(s) for use All products Do not use around the eyes or on large areas of the body (HC 1985). All products (except for external anal itching) Apply to the affected area(s), up to 4 times per day (US FDA 2023). Products for external anal itching Cleanse the affected area with mild soap and warm water, rinse and dry (US FDA 2023). Apply to the affected area by patting gently (using a cleansing pad), up to 4 times per day (US FDA 2023). Do not put this product into the rectum (US FDA 2023). Products which include a subpopulation of children 2 - 11 years of age Supervise children when they use this product. Products in a spray form Avoid inhaling or exposing others to spray. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products For external use only (US FDA 2023; HC 1985). When using this product avoid contact with the eyes. If contact occurs, rinse thoroughly with water (US FDA 2023). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist for more than 7 days, worsen, or re-occur within a few days (US FDA 2023; HC 1985). Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) All products Do not use for the treatment of diaper rash (US FDA 2023; Berardi et al. 2002). Products for external feminine genital itching Do not use if you have a vaginal discharge (US FDA 2023; HC 1985). Known adverse reaction(s) Products for external anal itching Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience bleeding (US FDA 2023). 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self- care. 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Gottschalck TE, McEwen GN, editors. International Cosmetic Ingredient Dictionary and Handbook. 10th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2006. HC 2014: Notice: Prescription Drug List (PDL): Hydrocortisone. [Accessed 2025 June 30] Available at: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/pdl-ord/pdl_ldo_noi_adi_hydrocortisone-eng.pdf 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. RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2025 June 30]. Available from: https://merckindex.rsc.org/ US FDA 2023: United States Food and Drug Administration. Over-the-Counter Monograph M017: External Analgesics Drug Products for Over-the-Counter Human Use. Washington (DC): U.S. Food and Drug Administration, Department of Health and Human Services. [Accessed 2025 June 30]. Available from: https://dps-admin.fda.gov/omuf/sites/omuf/files/primary-documents/2023-05/Final%20Administrative%20Order%20OTC000033_M017-External%20Analgesic%20Drug%20Products%20for%20OTC%20Human%20Use.pdf USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2024. Report a problem on this page Date modified: 2019-03-01

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 Must be established in accordance with the requirements described in theNatural Health Products Regulations.

RISK INFORMATION

Caution(s) and warning(s) All products For external use only (US FDA 2023; HC 1985).When using this product avoid contact with the eyes. If contact occurs, rinse thoroughly with water (US FDA 2023).Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist for more than 7 days, worsen, or re-occur within a few days (US FDA 2023; HC 1985).Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) All products Do not use for the treatment of diaper rash (US FDA 2023; Berardi et al. 2002). Products for external feminine genital itching Do not use if you have a vaginal discharge (US FDA 2023; HC 1985). Known adverse reaction(s) Products for external anal itching Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience bleeding (US FDA 2023).

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 Must be established in accordance with the requirements described in theNatural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Topical

Proper name(s)	Common name(s)	Source information	
Source ingredient(s)	Preparation(s)		
(11beta)-11,17,21-Trihydroxypregn-4-ene-3,20-dione	17-HydroxycorticosteroneCortisolHydrocortisoneHydrocortisone acetate		Synthetic