



PRESCRIBING INFORMATION

PREVEX[®] HC

Hydrocortisone USP

Cream 1% (w/w)

Topical Corticosteroid

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4

Date of Revision:
October 28, 2015

Submission Control No: 215148

© 2015 GlaxoSmithKline Inc. All Rights Reserved
PREVEX is a registered trademark of Stiefel Laboratories, Inc., used under license by GlaxoSmithKline Inc.

TABLE OF CONTENTS

	PAGE
PART I: HEALTH PROFESSIONAL INFORMATION.....	3
SUMMARY PRODUCT INFORMATION.....	3
INDICATIONS AND CLINICAL USE	3
CONTRAINDICATIONS.....	4
WARNINGS AND PRECAUTIONS	4
ADVERSE REACTIONS	7
DRUG INTERACTIONS	8
DOSAGE AND ADMINISTRATION	9
OVERDOSAGE.....	10
ACTION AND CLINICAL PHARMACOLOGY.....	10
STORAGE AND STABILITY	11
DOSAGE FORMS, COMPOSITION AND PACKAGING.....	11
 PART II: SCIENTIFIC INFORMATION	 12
PHARMACEUTICAL INFORMATION	12
TOXICOLOGY.....	13
REFERENCES.....	14
 PART III: CONSUMER INFORMATION.....	 15

PREVEX[®] HC

Hydrocortisone USP

Cream 1% w/w

Topical Corticosteroid

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Topical use	Cream, 1% w/w	For a complete listing see DOSAGE FORMS, COMPOSITION AND PACKAGING section.

INDICATIONS AND CLINICAL USE

PREVEX[®] HC (hydrocortisone USP) Cream is indicated for temporary relief of minor skin irritations associated with redness, itching, dryness and scaling in patients 2 years and older.

Geriatrics (> 65 years of age): Safety and effectiveness of PREVEX[®] HC Cream in geriatric patients over 65 years of age have not been established. Some published studies of 1% hydrocortisone creams have reported that clinical outcomes in geriatric patients over 65 years of age were consistent with those of the general adult population (see WARNINGS AND PRECAUTIONS, Special Populations, Geriatrics (> 65 years of age)).

Pediatrics (<18 years of age): Safety and effectiveness of PREVEX[®] HC Cream in pediatric patients less than 18 years of age have not been established. Some published studies of 1% hydrocortisone creams have reported that clinical outcomes in pediatric patients less than 18 years of age were consistent with those of the general adult population (see WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics (<18 years of age)). PREVEX[®] HC should not be used in pediatric patients less than 2 years of age except on the advice of a physician.

CONTRAINDICATIONS

1. Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the PRESCRIBING INFORMATION.
2. Patients who are hypersensitive to other corticosteroids.
3. Patients with bacterial, tubercular, or fungal infections involving the skin, viral diseases (such as herpes simplex, chicken pox, and vaccinia), parasitic infections, skin manifestations relating to tuberculosis or syphilis, eruptions following vaccinations, rosacea, acne vulgaris, and pruritus without inflammation.
4. Topical application to the eye.

WARNINGS AND PRECAUTIONS

General

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

PREVEX[®] HC Cream should not be used under occlusion due to increased risk of systemic exposure and infection. Do not use for the treatment of diaper rash, except on the advice of a health care practitioner. When used under occlusive dressing, over extensive areas, on the face, scalp, axillae, or scrotum sufficient absorption may occur to result in adrenal suppression and other systemic effects (see WARNINGS AND PRECAUTIONS – Endocrine and Metabolism, Immune and Ophthalmologic).

Cardiovascular

Suitable precautions should be taken when using topical corticosteroids in patients with stasis dermatitis and other skin diseases associated with impaired circulation.

Use of corticosteroids around chronic leg ulcers may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Endocrine and Metabolism

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical corticosteroids. Hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids (see ADVERSE REACTIONS).

Conditions which augment systemic absorption include the formulation and potency of the topical corticosteroid, the application of topical corticosteroids over large body surface areas, application to intertriginous areas (such as the axillae), frequency of application, prolonged use, or the use of occlusive dressings. Other risk factors for increased systemic effects include increasing hydration of the stratum corneum, use on thin skin areas (such as the face), and use on broken skin or in conditions where the skin barrier may be impaired.

If patients must be treated over large body surface areas, they should be evaluated periodically for evidence of HPA axis suppression (see WARNINGS AND PRECAUTIONS – Monitoring and Laboratory Tests). If HPA axis suppression or Cushing’s syndrome is observed, an attempt should be made to withdraw the drug by reducing the frequency of application. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see ADVERSE REACTIONS).

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic corticosteroid supplementation, see the prescribing information for those products.

Pediatric patients may absorb larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface to body mass ratios as compared with adult patients (see WARNINGS AND PRECAUTIONS – Special Populations, Pediatrics).

Immune

Topical corticosteroids may increase the risk of infections including aggravation of cutaneous infection, masked infection, and secondary infections. In particular, bacterial infection is encouraged by the warm, moist conditions within skin-fold areas, or caused by occlusive dressings. If concomitant skin infections develop, PREVEX[®] HC Cream should be discontinued and antimicrobial therapy should be administered.

Ophthalmologic

Topical corticosteroids should be used with caution on lesions close to the eye because systemic absorption may cause increased intraocular pressure, cataract, or glaucoma.

Sensitivity

Local hypersensitivity reactions (see ADVERSE REACTIONS) may resemble symptoms of the condition under treatment. If hypersensitivity reactions occur, PREVEX[®] HC Cream should be discontinued and appropriate therapy should be initiated.

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing.

Skin

If significant irritation develops, PREVEX[®] HC Cream should be discontinued and appropriate therapy should be instituted.

Prolonged use of topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. Topical corticosteroids should be used with caution on lesions of the face, groin, and axillae as these areas are more prone to atrophic changes than other areas of the body. Frequent observation is important if these areas are to be treated. If skin atrophy is observed, treatment should be discontinued.

Special Populations

Pregnant Women: Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development (see TOXICOLOGY). Subcutaneous administration of hydrocortisone to mice at doses of ≥ 30 mg/kg/day, to rabbits at a dose of 675 μ g/kg/day, and the administration of a single intramuscular injection of ≥ 25 mg to hamsters during pregnancy produced fetal abnormalities including cleft palate. The relevance of this finding to human beings has not been established.

There are no adequate and well-controlled studies of PREVEX[®] HC Cream in pregnant women. Administration of PREVEX[®] HC Cream during pregnancy should only be considered if the expected benefit to the mother outweighs the potential risk to the fetus. The minimum quantity should be used for the minimum duration.

Nursing Mothers: The safe use of topical corticosteroids during lactation has not been established.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.

Because many drugs are excreted in human milk, caution should be exercised when PREVEX[®] HC Cream is administered to a nursing woman. Administration of PREVEX[®] HC Cream during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation, PREVEX[®] HC Cream should not be applied to the breasts to avoid accidental ingestion by the infant.

Pediatrics (<18 years of age): The safety of PREVEX[®] HC Cream has not been studied in pediatric patients.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment.

Adverse effects including striae have been reported with the use of topical corticosteroids in infants and children. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Chronic corticosteroid therapy may interfere with the growth and development of children.

There are no adequate and well-controlled studies of PREVEX[®] HC Cream in pediatric patients. Some published studies of 1% hydrocortisone creams have reported that clinical outcomes in pediatric patients less than 18 years of age were consistent with those of the general adult population.^{1, 2, 3, 5} Administration of topical corticosteroids to children under 18 years of age should be limited to the least amount and for the shortest duration compatible with an effective therapeutic regimen (see DOSAGE AND ADMINISTRATION).

PREVEX[®] HC should not be used in pediatric patients less than 2 years of age except on the advice of a physician.

Geriatrics (>65 years of age): The safety of PREVEX[®] HC Cream has not been studied in geriatric patients.

In general, topical corticosteroids should be used cautiously in elderly patients, reflecting their increased skin fragility and greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant disease or other drug therapy. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs.

There are no adequate and well-controlled studies of PREVEX[®] HC Cream in geriatric patients. Some published studies of 1% hydrocortisone creams have reported that clinical outcomes in geriatric patients over 65 years of age were consistent with those of the general adult population.^{1, 3, 4, 5} For geriatric patients over 65 years of age, the minimum quantity should be used for the minimum duration (see DOSAGE AND ADMINISTRATION).

Patients with renal / hepatic impairment: The safety of PREVEX[®] HC Cream has not been studied in patients with renal or hepatic impairment.

In case of systemic absorption, metabolism and elimination may be delayed leading to increased risk of systemic toxicity.

There are no adequate and well controlled studies of PREVEX[®] HC Cream in patients with renal or hepatic impairment. For patients with renal or hepatic impairment, the minimum quantity should be used for the minimum duration (see DOSAGE AND ADMINISTRATION).

Monitoring and Laboratory Tests

The cosyntropin (ACTH₁₋₂₄) stimulation test may be helpful in evaluating patients for HPA axis suppression.

ADVERSE REACTIONS

Post-Marketing Adverse Drug Reactions

The following adverse reactions have been identified during the post-approval use of PREVEX[®] HC Cream. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Endocrine Disorders: Hypothalamic-pituitary adrenal (HPA) axis suppression, cushingoid features (e.g. moon face, central obesity), increased weight /obesity, delayed weight gain/growth retardation in children, decreased endogenous cortisol levels, hyperglycemia/glucosuria, hypertension, osteoporosis, and steroid withdrawal syndrome.

Eye Disorders: Cataract, glaucoma.

General Disorders and Administrative Site Reactions: Application site irritation/pain.

Immune System Disorders: Local hypersensitivity.

Infections and Infestations: Secondary infection.

Skin and Subcutaneous Tissue Disorders: Contact dermatitis /dermatitis, erythema, rash, urticaria, pruritus, skin burning, skin pain, skin exfoliation, skin atrophy*, atrophy of subcutaneous tissues, skin dryness*, skin striae*, change in pigmentation*, hypertrichosis, telangiectasia*, and exacerbation of underlying symptoms. The following have been observed with the use of occlusive dressings: pustules, miliaria, folliculitis, and pyoderma.

*Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.

DRUG INTERACTIONS

Overview

No clinical trials were specifically designed to assess potential drug-drug, drug-food, drug-herb, or drug-laboratory interactions with PREVEX[®] HC Cream.

Co-administered drugs that can inhibit CYP3A4 (e.g., ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Drug-Drug Interactions

Interactions with other drugs have not been established.

Drug-Food Interactions

Interactions with food have not been established.

Drug-Herb Interactions

Interactions with herbal products have not been established.

Drug-Laboratory Interactions

Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Dosing Considerations

- Patients/caregivers should be instructed to use the minimum quantity of PREVEX[®] HC Cream for the shortest duration of time necessary to achieve the desired therapeutic benefit because of the potential for corticosteroids to suppress the hypothalamic-pituitary-adrenal (HPA) axis and cause skin atrophy (see WARNINGS AND PRECAUTIONS).
- If symptoms worsen or persist more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless directed by a health care practitioner.
- PREVEX[®] HC Cream is for topical use only and not for ophthalmic use.
- Pediatric patients may be more susceptible to local and systemic toxicity from equivalent doses of topical corticosteroids because of their larger skin surface to body weight ratios, and may require shorter courses of treatment than adults. PREVEX[®] HC should not be used in pediatric patients less than 2 years of age except on the advice of a physician.
- Geriatric patients may be more susceptible to percutaneous absorption and the potential effects of systemic absorption. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs.

Recommended Dose and Dosage Adjustment

Apply sparingly to affected areas once or twice a day for a maximum of 14 days. Use only enough to cover the affected area. Allow 15 minutes to dry completely. If symptoms worsen or persist more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless directed by a health care practitioner. If the condition resolves within 14 days, treatment with PREVEX[®] HC should be stopped. If, after 14 days of treatment, improvement is seen but further treatment is required, the patient should see a physician.

Avoid abrupt discontinuation of topical corticosteroids when control is achieved, as rebound of pre-existing dermatoses can occur. Continue an emollient as maintenance therapy.

Pediatrics (2-18 years of age): Care should be taken when using PREVEX[®] HC Cream in pediatric patients. The minimum quantity should be used for the shortest duration to achieve the desired therapeutic benefit (see WARNINGS AND PRECAUTIONS – Special Populations, Pediatrics (<18 years of age)).

Pediatrics (<2 years of age): PREVEX[®] HC should not be used in pediatric patients less than 2 years of age except on the advice of a physician.

Geriatrics (>65 years of age): PREVEX[®] HC Cream should be used with caution in geriatric patients due to increased risk of renal or hepatic impairment in this population. The minimum

quantity should be used for the shortest duration to achieve the desired therapeutic benefit (see WARNINGS AND PRECAUTIONS – Special Populations, Geriatrics (>65 years of age)).

Renal/Hepatic Impairment: In patients with renal or hepatic impairment, the minimum quantity should be used for the shortest duration to achieve the desired therapeutic benefit (see WARNINGS AND PRECAUTIONS — Special Populations, Patients with renal / hepatic impairment).

Missed Dose

In the event of missed dose, PREVEX[®] HC Cream should be applied as soon as possible after the missed dose is remembered. If this is close to the scheduled application time or the next dose, the patient should wait and apply the next scheduled dose. The usual schedule should be resumed thereafter.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see WARNINGS AND PRECAUTIONS). Excessive prolonged use or misuse may suppress hypothalamic-pituitary-adrenal (HPA) axis function, resulting in secondary adrenal insufficiency. If symptoms of HPA axis suppression occur, PREVEX[®] HC Cream should be withdrawn gradually by reducing the frequency of application. Further management should be as clinically indicated. If toxic effects occur, PREVEX[®] HC Cream treatment should be discontinued and symptomatic therapy should be administered.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

PREVEX[®] HC Cream belongs to a class of topical drugs called topical corticosteroids. It is considered to be a mild or low potency corticosteroid. Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity of topical corticosteroids is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Pharmacodynamics

The Pharmacodynamics of PREVEX[®] HC Cream have not been specifically investigated in any clinical studies. Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

Pharmacokinetics

The pharmacokinetics of PREVEX[®] HC Cream (absorption, distribution, excretion, and metabolism) have not been specifically investigated in any clinical studies. Pharmacokinetic properties of the drug class of topically applied corticosteroids remain incompletely understood.

Absorption: Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the product formulation, potency, vehicle, frequency and duration of application, as well as the integrity of the epidermal barrier, skin thickness, application to intertriginous areas (such as the axillae) and to large skin surface areas. Occlusion, hydration of the stratum corneum, inflammation and/or other disease processes in the skin may also increase percutaneous absorption.

Distribution: The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary because circulating levels are well below the level of detection.

Metabolism: Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are primarily metabolised in the liver.

Excretion: Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

STORAGE AND STABILITY

Store between 15°C and 25°C. Do not freeze. Keep out of the reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

PREVEX[®] HC Cream 1% is a white, smooth cream.

PREVEX[®] HC Cream 1% contains the medicinal ingredient hydrocortisone USP 1% w/w and the following non-medicinal ingredients: petrolatum, dimethicone, trisiloxane and microcrystalline wax.

PREVEX[®] HC Cream 1% is available in 30 g tubes.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

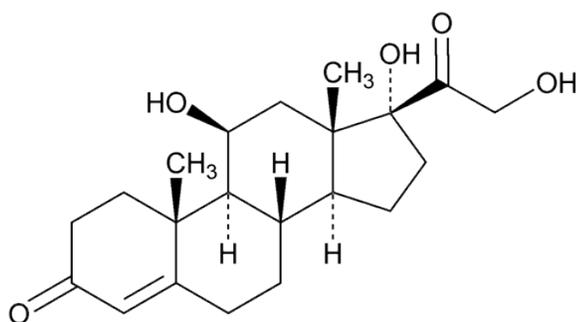
Common name: hydrocortisone

Chemical name: Pregn-4-ene-3,20-dione, 11,17,21-trihydroxy-, (11 β)-

Molecular formula: $C_{21}H_{30}O_5$

Molecular mass: 362.46

Structural formula:



Physicochemical properties: hydrocortisone is a white to practically white, odourless, crystalline powder.

TOXICOLOGY

Carcinogenesis

Long term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. Subcutaneous injection of hydrocortisone at 50 mg/kg once per week for 52 weeks was not carcinogenic in male rats.⁶

Genotoxicity

Hydrocortisone was not mutagenic in a bacterial mutagenicity assay (*Salmonella typhimurium*) in the absence or presence of metabolic activation, and was not genotoxic in an unscheduled DNA synthesis (UDS) assay in rat primary hepatocytes. Hydrocortisone was genotoxic in a chromosome aberration assay in human lymphocytes, and a mouse bone marrow micronucleus/sister chromatid exchange assay.

Fertility

The effect on fertility of Hydrocortisone has not been evaluated in animals.

Pregnancy

Subcutaneous administration of hydrocortisone to mice at doses of ≥ 30 mg/kg/day, to rabbits at a dose of 675 μ g/kg/day, and the administration of a single intramuscular injection of ≥ 25 mg to hamsters during pregnancy produced fetal abnormalities including cleft palate.

REFERENCES

1. Ashton RE, Catterall M, Morley N, Fairris G, Joseph DN. A double-blind comparison of 0.25% and 0.05% desoxymethasone, 0.1% betamethasone valerate and 1% hydrocortisone creams in the treatment of eczema. *J Int Med Res.* 1987;15(3):160-6.
2. British National Formulary for Children 2011-2012. Topical corticosteroids. BMJ Group, Pharmaceutical Press, RCPCH Publications Ltd. 2011; 13.4: 558-559.
3. Greenish BV, Johnstone RS, Peel MJ. Simple hydrocortisone creams for dermatitis in general practice. *Practitioner.* 1986;230(1416):579-81.
4. Pariser DM. Topical steroids: a guide for use in the elderly patient. *Geriatrics.* 1991;46(10):51-4, 57-60, 63.
5. Szarmach H, Weuta H, Stepka L. [Limitations of indications of clotrimazole-hydrocortisone and its components. A double-blind study]. *Arzneimittelforschung.* 1984;34(8):927-30.
6. Schmähl D. [Investigations on the influence of immunodepressive means on the chemical carcinogenesis in rats]. *Z Krebsforsch Klin Onkol.* 1974;81(3-4):211-5.

PART III: CONSUMER INFORMATION**PREVEX[®] HC****Hydrocortisone USP****Cream 1% (w/w)**

This leaflet is part III of a three-part "Prescribing Information" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PREVEX[®] HC. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

PREVEX[®] HC is used to help relieve redness, itching, dryness and scaling associated with minor skin irritations in patients 2 years of age and older.

What it does:

PREVEX[®] HC contains hydrocortisone which belongs to a group of medicines called steroids. Steroids help to reduce redness, swelling and irritation of the skin.

When it should not be used:

Do not use PREVEX[®] HC if you:

- are allergic to hydrocortisone, other corticosteroids, any component of the container, or to any of the other ingredients in PREVEX[®] HC (see **What the nonmedicinal ingredients are**).
- have bacterial, tubercular, fungal, parasitic, viral skin infections (e.g. herpes simplex, chicken pox, vaccinia), tuberculosis or syphilis skin lesions, or a skin reaction following a recent vaccination.
- have acne, rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules)), or itchy skin which is not inflamed.

Do not apply in or near the eye.

If you think any of these apply to you, don't use PREVEX[®] HC until you have checked with your doctor or pharmacist.

What the medicinal ingredient is:

Hydrocortisone

What the nonmedicinal ingredients are:

The nonmedicinal ingredients in PREVEX[®] HC Cream are petrolatum, dimethicone, trisiloxane and microcrystalline wax.

What dosage forms it comes in:

PREVEX[®] HC Cream 1% is available in a 30 g tube.

WARNINGS AND PRECAUTIONS

Topical corticosteroids when used over large areas, on sensitive areas such as the face, in skin-fold areas like the armpit and groin, on broken skin, for prolonged periods or under an airtight dressing are more likely to be absorbed into the bloodstream and cause side effects. Do not use for the treatment of diaper rash, except on the advice of a health care practitioner. Apply only enough to cover the affected areas. PREVEX[®] HC should not be applied over large areas unless advised by a physician.

Only use PREVEX[®] HC for as long as your doctor recommends.

Inform your doctor if you have previously used corticosteroids.

Before using PREVEX[®] HC, talk to your doctor or pharmacist if:

- you are pregnant or planning to become pregnant.
- you are breastfeeding. If you do use PREVEX[®] HC when breastfeeding, do not use on your breast area to ensure that the baby does not accidentally get it in their mouth.
- you have other inflammatory skin diseases in the leg as a result of impaired circulation (such as stasis dermatitis).
- you have problems with your kidney or liver. You may need to use a smaller amount of PREVEX[®] HC or use it less often.

While using PREVEX[®] HC, talk to your doctor or pharmacist if:

- you develop any skin infection
- you have an allergic reaction
- you develop significant skin irritation
- you experience skin thinning or softening
- your condition worsens or does not improve

While using PREVEX[®] HC:

- PREVEX[®] HC should be used with caution on the face, or in skin fold areas, such as the groin or the armpit.
- Avoid PREVEX[®] HC from getting in the eye, or other mucous membranes. In case of contact, wash with water. Absorption in the body may cause increased

pressure in the eye (glaucoma), or a cloudy lens in the eye (cataracts).

- Do not use occlusive dressings such as a bandage, nor cover the treated areas tightly.
- If you are over 65 years of age, use PREVEX[®] HC with caution. You may need to use a smaller amount of PREVEX[®] HC or use it less often
- Children absorb larger amounts of topical corticosteroids and therefore, may be more likely to develop side effects.
- If you have any skin disease around a leg ulcer, use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.

INTERACTIONS WITH THIS MEDICATION

Some medicines may affect how PREVEX[®] HC works, or make it more likely that you'll have side effects. Examples of these medicines include:

- Ritonavir (for HIV).
- Itraconazole (for fungal infections).

Tell your doctor or pharmacist about all your other medications, including medicines that you bought without prescription and natural health products.

PROPER USE OF THIS MEDICATION

For topical use only and not for use in the eyes.

PREVEX[®] HC should not be used in children less than 2 years of age unless recommended by a doctor.

Usual dose:

Apply sparingly to the affected areas once or twice a day for a maximum of 14 days. Use only enough to cover the affected area.

It is important to not stop using PREVEX[®] HC suddenly or your skin condition could flare up again. If symptoms worsen or persist more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless directed by a health care practitioner.

If you use PREVEX[®] HC regularly make sure you talk to your doctor before you stop using it.

How to Apply PREVEX[®] HC:

- Apply a thin layer and gently rub in, using only enough to cover the entire affected area.
- Wash your hands after use unless treating the hands.
- Excess product should not be returned to the container,

since it may cause contamination.

- A moisturizer should be used as maintenance therapy.

PREVEX[®] HC should be used for the minimum amount of time required to achieve the desired results, **but always use PREVEX[®] HC exactly as your doctor has told you.** Check with your doctor or pharmacist if you are not sure.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use PREVEX[®] HC, apply it as soon as you remember. If it is close to the time scheduled to apply your next dose, wait and apply your next scheduled dose and then continue as before. Do not apply extra PREVEX[®] HC to make up for missed doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines PREVEX[®] HC can have side effects although not everybody gets them. Side effects will affect your skin and may have an effect on other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

If your skin condition gets worse or your skin becomes swollen during treatment. You may be allergic to the medicine or need other treatment. Stop using PREVEX[®] HC and tell your doctor as soon as possible.

The following side effects have been reported in patients using PREVEX[®] HC and other corticosteroids:

- local hypersensitivity
- contact dermatitis/dermatitis (a type of eczema)
- redness
- rash
- hives
- itching
- skin burning
- skin pain
- skin dryness or flaking
- skin thinning or softening
- stretch marks
- changes in the colour of your skin
- increased body hair
- the appearance of blood vessels under the surface of your skin (telangiectasia)
- worsening of condition

- secondary infection
- application site irritation or pain

The following have been observed with the use of airtight dressings:

- pus-filled bumps (pustules), heat rash (miliaria), inflammation of the hair follicles (folliculitis), non-healing wounds (pyoderma)

Serious side effects such as Cushing's syndrome may be associated with absorption in the body of topical corticosteroids (for example, from long-term, improper or excessive use). Symptoms include: increased weight, moon face / rounding of the face and obesity. Other side effects may include weight loss, fatigue, nausea, diarrhea and abdominal pain (steroid withdrawal syndrome). Also, look out for delayed weight gain and slow growth in children.

Other symptoms that may only show in blood tests or when your doctor gives you a medical examination are: decreased hormone cortisol levels in your blood, increased sugar levels in your blood or urine, high blood pressure, cloudy lens in the eye (cataract), increased pressure in the eye (glaucoma), as well as weakening of the bones through gradual mineral loss (osteoporosis) and additional tests may be needed after your medical examination to confirm whether you have osteoporosis.

If any of the side effects listed becomes severe or troublesome, tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Allergic reactions: rash, hives, swelling of the skin.			✓
Cushing's syndrome: weight gain, moon face / rounding of the face and obesity.			✓

This is not a complete list of side effects. For any unexpected effects while taking PREVEX[®] HC contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15° and 25°C. Do not freeze. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca> or by contacting the sponsor,

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4
1-800-387-7374

This leaflet was prepared by GlaxoSmithKline Inc.
Last revised: October 28, 2015

© 2015 GlaxoSmithKline Inc. All Rights Reserved

PREVEX is a registered trademark of Stiefel Laboratories, Inc., used under license by GlaxoSmithKline Inc.