

PRESCRIBING INFORMATION

^{Pr}EURO-HYDROCORTISONE

Hydrocortisone Cream USP

2.5% (w/w)

Topical Corticosteroid

Euro-Pharm International Canada Inc.

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Control # 199865

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PREScribing INFORMATION

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Non-medicinal Ingredients
Topical use	Cream / 2.5% w/w	Ceteareth-20, Cetostearyl Alcohol, Germaben II (Diazolidinyl Urea, Methylparaben, Propylene Glycol, Propylparaben), Light Mineral Oil, Purified Water, White Petrolatum.

INDICATIONS AND CLINICAL USE

EURO-HYDROCORTISONE (Hydrocortisone USP) is indicated for topical therapy of corticosteroid responsive dermatoses for a maximum duration of 4 weeks, where an anti-inflammatory and antipruritic activity is required in the topical management of these conditions.

Geriatrics (> 65 years of age): Safety and effectiveness of Hydrocortisone in geriatric patients over 65 years of age have not been established (see WARNINGS AND PRECAUTIONS, Special Populations, Geriatrics (> 65 years of age)).

Pediatrics (<18 years of age): Safety and effectiveness of Hydrocortisone in pediatric patients less than 18 years of age have not been established (see WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics (<18 years of age)).

CONTRAINDICATIONS

- 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.
- Patients who are hypersensitive to other corticosteroids.
- 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.
- Topical application to the eye.

WARNINGS AND PRECAUTIONS

General

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

EURO-HYDROCORTISONE should not be used under occlusion due to increased risk of systemic exposure and infection. 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, EURO-HYDROCORTISONE 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, EURO-HYDROCORTISONE 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, EURO-HYDROCORTISONE 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 Hydrocortisone in pregnant women. Administration of EURO-HYDROCORTISONE 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 EURO-HYDROCORTISONE is administered to a nursing woman. Administration of EURO-HYDROCORTISONE during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant.

If used during lactation, EURO-HYDROCORTISONE should not be applied to the breasts to avoid accidental ingestion by the infant.

Pediatrics (<18 years of age): The safety of Hydrocortisone 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 Hydrocortisone in pediatric patients. 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).

Geriatrics (>65 years of age): The safety of Hydrocortisone 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 Hydrocortisone in geriatric patients. 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 Hydrocortisone 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 Hydrocortisone 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 (ACTH ₁₋₂₄) 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 Hydrocortisone. 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 Hydrocortisone.

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 EURO-HYDROCORTISONE 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 the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.
- EURO-HYDROCORTISONE 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.
- 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

A thin layer should be applied to affected areas once or twice a day for a maximum of 4 weeks. If the condition worsens or does not improve within 2-4 weeks, treatment and diagnosis should be re-evaluated.

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 (<18 years of age): Care should be taken when using EURO-HYDROCORTISONE 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)).

Geriatrics (>65 years of age): EURO-HYDROCORTISONE 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, EURO-HYDROCORTISONE 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, EURO-HYDROCORTISONE should be withdrawn gradually by reducing the frequency of application. Further management should be as clinically indicated. If toxic effects occur, EURO-HYDROCORTISONE treatment should be discontinued and symptomatic therapy should be administered.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

EURO-HYDROCORTISONE 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 Hydrocortisone have not been specifically investigated in any clinical studies. Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

Pharmacokinetics

The pharmacokinetics of Hydrocortisone (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 metabolized 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

45 g tube: Store between 15°C and 30°C. Do not freeze.

225 g jar: Store between 15°C and 30°C. Store in an upright position. Do not freeze.

Keep this product out of the reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

EURO-HYDROCORTISONE is a white, odorless washable cream.

EURO-HYDROCORTISONE contains Hydrocortisone USP 2.5 % w/w in a water-miscible emollient base.

Non-medicinal Ingredients: Cetareth-20, Cetostearyl Alcohol, Germaben II (Diazolidinyl Urea, Methylparaben, Propylene Glycol, Propylparaben), Light Mineral Oil, Purified Water, White Petrolatum.

EURO-HYDROCORTISONE is available in 45 g plastic tube and 225 g plastic jar.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

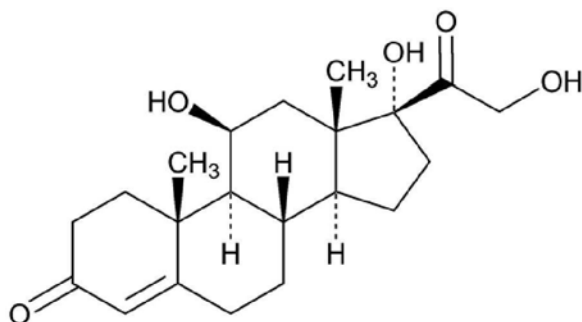
Common name: Hydrocortisone

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

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

Molecular weight: 362.46

Structural formula:



Physical properties: Hydrocortisone is a white to practically white, odorless, 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.

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. ^{Pr}Emo-Cort[®] (Cream 2.5%w/w - Lotion 2.5%w/v) Prescribing Information. GlaxoSmithKline Inc., Control No. 183835, revised September 8, 2015: 19 pages.
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. Schmahl 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

PrEURO-HYDROCORTISONE

Hydrocortisone Cream USP

2.5% (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 EURO-HYDROCORTISONE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

EURO-HYDROCORTISONE is used to help relieve the redness and itchiness of certain skin problems for up to 4 weeks.

What it does:

EURO-HYDROCORTISONE 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 EURO-HYDROCORTISONE if you:

- are allergic to hydrocortisone, other corticosteroids, any component of the container, or to any of the other ingredients in EURO-HYDROCORTISONE (see **What the non-medicinal 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 EURO-HYDROCORTISONE until you have checked with your doctor or pharmacist.

What the medicinal ingredient is:

Hydrocortisone

What the nonmedicinal ingredients are:

The non-medicinal ingredients in EURO-HYDROCORTISONE are: Cetareth-20, Cetostearyl Alcohol, Germaben II (Diazolidinyl Urea, Methylparaben, Propylene Glycol, Propylparaben), Light Mineral Oil, Purified Water, White Petrolatum.

What dosage forms it comes in:

EURO-HYDROCORTISONE is available in a 45 g plastic tube and 225 g plastic jar.

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. Apply only enough to cover the affected areas. EURO-HYDROCORTISONE should not be applied over large areas unless advised by a physician.

Only use EURO-HYDROCORTISONE for as long as your doctor recommends.

Inform your doctor if you have previously used corticosteroids.

Before using EURO-HYDROCORTISONE, talk to your doctor or pharmacist if:

- you are pregnant or planning to become pregnant.
- you are breastfeeding. If you do use EURO-HYDROCORTISONE 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 EURO-HYDROCORTISONE or use it less often.

IMPORTANT: PLEASE READ

While using EURO-HYDROCORTISONE, 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 EURO-HYDROCORTISONE:

- EURO-HYDROCORTISONE should be used with caution on the face, or in skin fold areas, such as the groin or the armpit.
- Avoid EURO-HYDROCORTISONE 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 EURO-HYDROCORTISONE with caution. You may need to use a smaller amount of EURO-HYDROCORTISONE 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 EURO-HYDROCORTISONE 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.

Usual dose:

Apply a thin film to the affected areas once or twice a day for a maximum of 4 weeks.

It is important to not stop using EURO- HYDROCORTISONE suddenly or your skin condition could flare up again. If your condition does not improve within 2-4 weeks of treatment, speak to your doctor or pharmacist.

If you use EURO-HYDROCORTISONE regularly make sure you talk to your doctor before you stop using it.

How to Apply EURO-HYDROCORTISONE:

- 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.

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

Overdose:

If you think you have taken too much EURO-HYDROCORTISONE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use EURO-HYDROCORTISONE, 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 EURO-HYDROCORTISONE to make up for missed doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines EURO-HYDROCORTISONE 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 EURO-HYDROCORTISONE and tell your doctor as soon as possible.

IMPORTANT: PLEASE READ

The following side effects have been reported in patients using Hydrocortisone 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 EURO-HYDROCORTISONE contact your doctor or pharmacist.

HOW TO STORE IT

45 g tube: Store between 15°C and 30°C. Do not freeze.
225 g jar: Store between 15°C and 30°C. Store in an upright position. Do not freeze.

Keep this product out of the reach and sight of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor,

Euro-Pharm International Canada Inc.
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