CORTY[®] CREAM

Hydrocortisone 1% w/w Cream

ACTIONS:

When applied topically, hydrocortisone (CORTY Cream) diffuses across cell membranes to form complexes with specific cytoplasmic receptors. These complexes enter the cell nucleus, bind to DNA, and stimulate transcription of messenger RNA and subsequent protein synthesis of enzymes responsible for anti-inflammatory effects, including inhibition of oedema, fibrin deposition, capillary dilation, and movements of phagocytes. Later stages of inflammation such as capillary production, collagen deposition, and keloid formation are also inhibited.

At a concentration of 1%, topically applied hydrocortisone has been found to bring about both subjective (reported by the patient i.e. "I feel better") and objective (measured by healthcare provider i.e. when a tumor shrinks or there are fewer cancer cells in the blood) improvements, usually within one week and often as soon as 24 to 48 hours after initiation of therapy. Systemic effects from prolonged external application of large amounts of hydrocortisone to wide areas of damaged skin have been minimal. Adrenal axis suppression has not been observed.

PHARMACOKINETICS:

Following topical application, hydrocortisone (**CORTY Cream**) diffuses through the skin by both transfollicular and transepiderm routes. Absorption varies according to anatomic site of application and ranges from 1% (forearm skin) to 26-29% (mucous membranes). Factors influencing penetration include concentration, vehicle, anatomic site, age, condition of the skin, and occlusion. The plasma level of hydrocortisone falls to 50% of its initial concentration in 90 minutes; the biological half life of hydrocortisone is to 12 hours. Biotransformation takes place primarily in the skin, and for any amount absorbed systematically, in the liver. 0.2% to 1.0% of hydrocortisone appeared in the urine over 10 days after topy cal application of C-14 radiolabelled hydrocortisone to normal skin.

INDICATIONS:

Hydrocortisone (CORTY Cream) is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

- Minor skin irritations, itching, and rashes caused by eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics & jewellery.
- Itchy anal/rectal areas (external); Discomfort caused by Hemorrhoids (external)
- Itching, redness, dryness, crusting, scaling, inflammation and discomfort of various skin conditions

DOSAGE & ADMINISTRATION:

- A thin film should be applied to the affected area three to four times daily.
- To use hydrocortisone cream (CORTY Cream) on the skin, wash or soak the affected area thoroughly before applying the medication, unless it irritates your skin. Then apply sparingly in a thin film and rub it in gently.
- Avoid prolonged use on the face, in the genital and rectal areas, and in skin creases and armpits unless directed to do so by your doctor.
- If you are using hydrocortisone (CORTY Cream) on a child's diaper area, do not use tight-fitting diapers or plastic pants. Such use may increase side effects.

CONTRAINDICATIONS:

Hydrocortisone (CORTY Cream) is contraindicated in patients with a history of hypersensitivity to the product or any of its constituent ingredients, patients with tuberculosis or fungal infection and/or herpes infections of the eyes, lips, or genitals.

WARNINGS & PRECAUTIONS:

- Although extensive use of hydrocortisone has not revealed evidence that enough hydrocortisone is absorbed to have systemic effects, greater absorption because of misuse or individual variability or unusual sensitivity could lead, at least theoretically, to a systemic effect.
- Patients are advised to contact their physician if the condition under treatment worsens or if symptoms persist for more than seven days or if symptoms clear and occur again within a few days.
- Hydrocortisone (CORTY Cream) is not recommended for use in children under two years of age.



- Hydrocortisone (CORTY Cream) should not be used for external feminine itching if a vaginal discharge is present.
- It (CORTY Cream) is not to be used for external anal itching if bleeding is present.
- · Contact with the eyes should be avoided.
- Hydrocortisone (CORTY Cream) should not be used under waterproof dressings unless advised to do so by a physician.
- Hydrocortisone (CORTY Cream) should not be used to treat acne.
- If the product (CORTY Cream) is applied with the fingertips, hands should be washed afterwards.

USE DURING PREGNANCY & LACTATION:

The safety of this medicinal product for use during human pregnancy or during lactation has not been established. Hydrocortisone (CORTY Cream) should only be used during pregnancy or lactation if recommended by a physician.

ADVERSE EFFECTS:

The safety profile of topically applied hydrocortisone preparations has been established through over 40 years of marketing experience. Topically applied hydrocortisone generally does not produce systemic effects due to minimal absorption. Absorption increases in the presence of skin inflammation or with the use of occlusive agents. Certain local effects such as skin atrophy may arise with prolonged use because of the antimitotic/ antisynthetic effect of hydrocortisone on cells. Clinically detectable atrophy rarely occurs with hydrocortisone in concentrations 0.5% or 1.0%.



Manufactured by: Deurali-Janta Pharmaceuticals Pvt. Ltd.

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