

# CORAZ™

Hydrocortisone Lotion USP, 2%

**A Two-step Convenience Kit for the Treatment of Seborrheic Dermatitis**



# Seborrheic Dermatitis and its Impact on Quality of Life

Seborrheic dermatitis is a common skin disorder affecting between 1% to 3%<sup>1</sup> of the population. The condition can be uncomfortable and unsightly with common manifestations including:

- ▶ Severe dandruff and itching
- ▶ Burning sensation
- ▶ Development of scales and plaques on the skin surface

1. Journal of Drugs in Dermatology, March-April, 2004 by Aditya K. Gupta, Karyn A. Nicol



## Puleré™ Medicated Wash

Puleré™ Medicated Wash is specially formulated with two key ingredients to help treat Seborrheic Dermatitis and can be conveniently used in the shower.

- ▶ 2% colloidal sulfur – anti-microbial
- ▶ 2% salicylic acid – keratolytic
- ▶ Available in a 6 fl. oz. bottle

### Important Safety Information

CORAZ™ Lotion is contraindicated in patients with a history of hypersensitivity to any of the components of the lotion. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more



# CORAZ™

Hydrocortisone Lotion USP, 2%

Coraz™ Kit is a two-step convenience kit combining a shampoo body wash and a mild leave-on topical steroid that is easy to apply to the scalp and other areas of the body.

*Please see back page for full prescribing information*

## Coraz™ Lotion (hydrocortisone lotion, USP 2%)

Coraz™ Lotion (hydrocortisone lotion, USP 2%) is a low-potency topical steroid to help treat the itching, redness and inflammation associated with Seborrheic Dermatitis.

- ▶ Non-greasy
- ▶ Dropper tip for easy scalp application



frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

# CORAZ™

Hydrocortisone Lotion USP, 2%

## DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Hydrocortisone is a member of this class. Chemically hydrocortisone is pregn-4-ene-3,20-dione, 11, 17, 21-trihydroxy, (11 $\beta$ ). Its structural formula is:



Each mL of CORAZ™ (Hydrocortisone Cream USP) 2% contains 20 mg hydrocortisone USP in a lotion base consisting of water, isopropyl alcohol, polysorbate 20, propylene glycol, and benzalkonium chloride.

## CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

## Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses (see **DOSE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

## INDICATIONS AND USAGE

Hydrocortisone Lotion is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

## CONTRAINDICATIONS

Hydrocortisone Lotion is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

## PRECAUTIONS

### General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid or use a sequential approach when utilizing the occlusive technique.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Occasionally, a patient may develop a sensitivity reaction to a particular occlusive dressing material or adhesive and a substitute material may be necessary.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS, Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

CORAZ™ is not for ophthalmic use.

## Information for the Patient

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.

4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

## Laboratory Tests

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating the HPA axis suppression.

## Carcinogenesis, Mutagenesis, and Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednicolone and hydrocortisone have revealed negative results.

## Pregnancy; Teratogenic Effects

Category C. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

## Nursing Mothers

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk but not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

## Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

## ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

- |                 |                                 |                            |
|-----------------|---------------------------------|----------------------------|
| 1. Burning      | 6. Hypertrichosis               | 11. Maceration of the skin |
| 2. Itching      | 7. Acneliform eruptions         | 12. Secondary infection    |
| 3. Irritation   | 8. Hypopigmentation             | 13. Skin Atrophy           |
| 4. Dryness      | 9. Perioral dermatitis          | 14. Striae                 |
| 5. Folliculitis | 10. Allergic contact dermatitis | 15. Milaria                |

## OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS, General**).

## DOSE AND ADMINISTRATION

Apply CORAZ™ to the affected area two to four times daily. Rub in gently.

## Occlusive Dressing Technique

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. Gently rub a small amount of cream into the lesion until it disappears. Reapply the preparation leaving a thin coating on the lesion, cover with plastic nonporous film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the medication. The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply CORAZ™ under an occlusive dressing in the evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusive regimen, additional lotion should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

## HOW SUPPLIED

CORAZ™ (Hydrocortisone Lotion USP) 2% is packaged in 1 fluid ounce (29.6 mL) dispenser bottles (NDC 14629-515-01).

## STORAGE

Store at controlled room temperature 68-77°F (20-25°C).

**CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.**

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Bi-Coastal Pharmaceutical Corp.®

Sales, Marketing, Consulting

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