Hydrocortisone valerate cream USP, 0.2% is a medium potency corticosteroid indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in adult patients. Hydrocortisone valerate cream USP, 0.2% has produced mild, reversible adrenal suppression in adult patients when used for extended periods of time. Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression. Increased numbers of fetal malformations (e.g., cleft palate) and striae, and miliaria.

**DESCRIPTION**

Hydrocortisone valerate cream USP, 0.2% contains hydrocortisone valerate, 11β,17,21-trihydroxy-9α-chloro-21-(2-propynyl)steroid, [15C]-21-(2-propynyl)hydrocortisone valerate, a synthetic corticosteroid for topical dermatologic use. The corticosteroids are a class of chemically related nonsteroidal anti-inflammatory agents. Corticosteroids act primarily by reducing the production of those mediators of inflammation responsible for the local tissue response.

Hydrocortisone valerate has a molecular weight of 446.58. It is a white, crystalline solid, soluble in ethanol and methanol, sparingly soluble in propylene glycol and sparingly soluble in water. Each gram of hydrocortisone valerate cream contains 2 mg of hydrocortisone valerate in a hydrophilic vehicle composed of carbomer 940, dibasic sodium phosphate, methylparaben, polyoxyl 2 stearyl ether, propylene glycol, purified water, sorbic acid, sulfates of sodium, sulfuric acid, and white petrolatum.

**PHARMACOKINETICS**

Hydrocortisone valerate cream USP, 0.2% is a corticosteroid in these patients with a history of hypersensitivity to any of the components of the preparation.

**INDICATIONS AND USAGE**

The treated skin area should not be bandaged, otherwise covered or wrapped, so as to be occlusive unless directed by a physician. Hydrocortisone valerate cream USP, 0.2% should not be applied in the diaper area if the patient requires diapers or plastic pants as these garments may constitute occlusive dressings. (See PRECAUTIONS)

**CONTRAINDICATIONS**

Patients using topical corticosteroids should be advised not to use these products in the ear, nose, or mouth. In addition, the use of topical corticosteroids on the skin barrier should be limited to acute, rather than chronic, conditions.

**PRECAUTIONS**

**Geriatric Use**

**Pediatric Use**

**Pregnancy**

**Breastfeeding**

**Information on Systemic Suppression**

**Radioisotopic Incorporation Studies**

**Inhalation**

**Interactions**

**Adverse Reactions**

The following local adverse reactions have been reported with topical corticosteroids, and they may occur more frequently with the more potent drugs. These reactions are listed in an approximate decreasing order of frequency: irritation, eczema, pruritus, application site reaction, rash, rash maculopapular, and dry skin were all reported at least twice as frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of frequency: irritation, eczema, pruritus, application site reaction, rash, rash maculopapular, and dry skin were all reported at least twice as frequently with the use of occlusive dressings. (See PRECAUTIONS)
Like other topical corticosteroids, hydrocortisone valerate has anti-inflammatory, antipruritic and vasoconstrictive properties.

Each gram of hydrocortisone valerate cream USP, 0.2% contains 2 mg hydrocortisone valerate in a hydrophilic vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have been shown to result in significant systemic absorption to produce demonstrable quantities in human plasma. In most cases, however, much less drug is recovered from plasma than is locally available in the skin. Therefore, systemic absorption of topical corticosteroids is generally considered low and probably of little clinical significance.

Hydrocortisone valerate has a molecular weight of 446.58. It is a white, crystalline solid, soluble in ethanol and water.

Hydrocortisone valerate has not been shown to affect fertility or reproductive performance. There are no studies which assess the effects of hydrocortisone valerate on fertility and general reproductive performance.

Hydrocortisone valerate cream USP, 0.2% was shown to be non-mutagenic in the Ames-Salmonella/Microsome Plate Test. There are no studies which assess the effects of hydrocortisone valerate on fertility and general reproductive performance.

Urinary free cortisol test

7. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

5. Hydrocortisone valerate cream USP, 0.2% should not be applied in the diaper areas as diapers or plastic pants may occlude the area.

4. Patients should report to their physician any signs of local adverse reactions.

3. The treated skin area should not be bandaged, otherwise covered or wrapped, so as to be occlusive unless directed by a physician.

2. This medication should not be used for any disorder other than that for which it was prescribed.

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

Information for Patients

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

- This medication should not be used in the diaper areas as diapers or plastic pants may occlude the area.
- If irritation develops, hydrocortisone valerate cream USP, 0.2% should be discontinued and appropriate therapy should be used. If a favorable response does not occur promptly, use of hydrocortisone valerate cream USP, 0.2% should be discontinued.

PRECAUTIONS: Pediatric Use.

Studies performed with hydrocortisone valerate cream USP, 0.2% indicate that it is in the medium range of topically administered corticosteroids that result in sufficient systemic absorption to produce demonstrable quantities in human plasma. In most cases, however, much less drug is recovered from plasma than is locally available in the skin. Therefore, systemic absorption of topical corticosteroids is generally considered low and probably of little clinical significance.

ADVERSE REACTIONS

The following local adverse reactions have been reported with topical corticosteroids, and may occur more frequently with higher potency corticosteroids. These reactions include: burning, itching, irritation, dryness, redness, and erosion of the skin. The possibility of systemic absorption and adverse reactions cannot be ruled out, therefore, patients should be warned of this possibility.

In controlled clinical studies involving pediatric patients 2 to 12 years of age (n=153), the incidence of adverse experiences, regardless of relationship to the use of hydrocortisone valerate cream, 0.2%, was approximately 29%.

Upon discontinuation of hydrocortisone valerate cream, 0.2%, the adverse experiences reported in controlled studies involving pediatric patients 2 to 12 years of age (n=153) were: burning (13%), itching (9%), dryness (9%), rash (7%), and erosion (6%).

Allergic, contact dermatitis, and contact urticaria are possible (see PRECAUTIONS). The potential for such reactions with the use of topical corticosteroids is less than with systemically administered corticosteroids.

In rare instances, anaphylactic shock has been reported. If an allergic reaction occurs, the medication should be discontinued immediately and appropriate therapy initiated.

HWP SUPPLIES

Hydrocortisone Valerate Cream USP, 0.2% is supplied in the following tube sizes:

- 60 g NDC 0713-0668-60

Storage:

Store at 59-79°F (15-35°C).

For use on mild to moderate skin irritation.

It is highly effective in the following skin conditions: 

- Acne, rosacea, and photodermatoses
- Atopic dermatitis and other eczematous disorders
- Contact dermatitis
- Dyshidrotic eczema
- Pityriasis rosea
- Seborrheic dermatitis
- Ulcerative discoid eczema
- Varicose eczema
- Zoster rash

- Hydrocortisone valerate cream USP, 0.2% should not be used more than 2 times a day on any part of the body.
- Hydrocortisone valerate cream USP, 0.2% should not be applied to the diaper area.
- Hydrocortisone valerate cream USP, 0.2% should not be used for facial rashes.
- Hydrocortisone valerate cream USP, 0.2% should not be used for children's diaper rash.
- Hydrocortisone valerate cream USP, 0.2% should not be used for children with chickenpox or measles, as this may spread the disease through the child and others in the household.

For Use on Mild to Moderate Skin Irritation

- Acne, rosacea, and photodermatoses
- Atopic dermatitis and other eczematous disorders
- Contact dermatitis
- Dyshidrotic eczema
- Pityriasis rosea
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PK-7664-0     320

Distributed by:

Taro Pharmaceuticals Inc.

60 g NDC 0713-0668-60

To report SUSPECTED ADVERSE REACTIONS, contact G&W Laboratories, Inc. at 1-800-922-1038 or www.fda.gov/medwatch.

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