Empirical formula is C₂₁H₃₀O₅ and the structural formula is: 

![Structural formula of hydrocortisone]

Each milliliter contains 25 mg of hydrocortisone (2.5% w/v) in a specially formulated vehicle containing alcohol (48.8% w/w), purified water, polysorbate 20 and benzethonium chloride.

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

The mechanisms 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. However, if the skin barrier is disrupted, percutaneous absorption can occur in large amounts. The degree of percutaneous absorption of topical corticosteroids is influenced by vehicle properties, including potency and occlusive dressings.

The mechanisms of anti-inflammatory activity of the topical corticosteroids are believed to involve their ability to suppress the hydrocortisone have revealed negative results.

Dosage and Administration: Topical corticosteroids are available in various strengths and preparations. The selection of the appropriate strength and route of administration depends on the condition being treated. The thickness of the skin and the site of application are factors that may influence the choice of strength and vehicle.

Contraindications: Topical corticosteroids are contraindicated in patients with a history of hypersensitivity to any of the components of the preparation.

Precautions: General: Systemic absorption of topical corticosteroids has resulted in rare cases of glucocorticoid withdrawal symptoms ( cushingoid state). These reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are more likely to occur when the potency of the topical corticosteroids and their metabolites are also excreted from the body.

Topical corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. The liver and kidney metabolic pathways of the corticosteroids and their metabolites are also excreted from the body.

Precautions and Usage: Topical corticosteroids are usually applied to the skin in a thin film three or four times daily depending on the severity of the condition. The treated skin area should not be bandaged or otherwise covered, except as directed by the physician. If an infection develops, the use of occlusive dressings should be discontinued and appropriate therapy instituted.

Indications and Usage: Texacort® Topical Solution contains hydrocortisone as the active corticosteroid, having the chemical formula C₂₁H₃₀O₅ and the structural formula is: 

![Structural formula of hydrocortisone]

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

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: The following tests may be helpful in evaluating the HPA axis suppression:

- Urinary free cortisol test
- ACTH stimulation test

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 prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dose 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 in quantities 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 intraocular 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 bitemporal papilledema.

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 frequency: burning, itching, irritation, dryness, folliculitis, hemorrhagic, occlusion irritation, hypertrichosis, acneiform eruptions, hypopigmentation, and hyperpigmentation of the skin, secondary infection, skin atrophy, striae, miliaria.

Oversorption: Topically applied corticosteroids can be absorbed in sufficient amount to produce systemic effects (See Precautions).

Dosage and Administration: Topical corticosteroids are generally applied to the affected area as a thin film for three or four times daily depending on the severity of the condition. Occlusive dressings may be used for the management of pruritic or resistant conditions.

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

How Supplied: Texacort® Topical Solution 2.5% is available in a 1 fl. oz. plastic bottle with an applicator tip. NDC 0178-0450-01.

Storage at controlled room temperature 15° to 30°C (59° to 86°F).

Rx Only