**Texacort™**  
**Topical Solution 2.5%**  

**HYDROCORTISONE TOPICAL SOLUTION**  
Pabanol and Lipid-Free  

**FOR EXTERNAL USE ONLY**  

**DESCRIPTION:**  
Topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Texacort Topical Solution contains hydrocortisone as the active corticosteroid, having the chemical name 11β,17α,21-trihydroxy-9α-fluoro-16α-methyl-17β-estr-4-en-3,20-dione, USP  and the structural formula is:

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\begin{align*}
\text{C}_{21}\text{H}_{30}\text{O}_5
\end{align*}
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Each milliliter contains 25 mg of hydrocortisone (2.5% W/V) in a specially formulated vehicle containing (48.6% W/W) purified water, polysorbate 20, and isoceteth-20.  

**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 measurements in vitro, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a 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 to treatment of resistant dermatoses. (See DOSAGE 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 in the bile.  

**INDICATIONS AND USAGE:**  
Texacort Topical Solution 2.5% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.  

**INDICATIONS:**  
- psoriasis  
- recalcitrant conditions.  

**Occlusive dressings may be used for the management of**

**psoriasis or recalcitrant conditions.**  

**Dosage and Administration:**  
- generally applied to the affected area as a thin film for three or four times daily depending on the severity of the condition.  

**DOSAGE AND ADMINISTRATION:**  
Topical corticosteroids are often administered under occlusive dressings. Thus, occlusive dressings may be a valuable therapeutic adjunct to treatment of resistant dermatoses. (See DOSAGE AND ADMINISTRATION).  

**ADVERSE REACTIONS:**  
These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hemorrhaging, infection, perioral dermatitis, presence of a second infection, pruritus, redness, scaling, sensitivity, stinging, and symptom relief.  

**ADVERSE REACTIONS:**  
- burning, itching, irritation, dryness, folliculitis, hemorrhaging, infection, perioral dermatitis, presence of a second infection, pruritus, redness, scaling, sensitivity, stinging  

**Information for the Patient:**  
- Patients using topical corticosteroids should receive the following information and instructions:  
  - This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.  
  - Patients should be advised not to use this medication for any disorder other than for which it was prescribed.  
  - The treated skin area should not be bandaged or otherwise covered or wrapped to be occlusive unless directed by the physician.  
  - Patients should report any signs of local adverse reactions indicating systemic absorption or occlusive dressing.  
  - 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 cortisol test and 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.  

**Pharmocology:**  
- Corticosteroids are generally well tolerated by 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 topical corticosteroids.  

**REPRODUCTION:**  
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.  

**MILK AND BREAST-FEEDING:**  
- Administration of topical corticosteroids to children should be limited to the amount necessary for the management of inflammatory dermatoses.  

**RECOMMENDATIONS:**  
- The patient should be informed that topical corticosteroids should be administered with a thin film to the affected area only.  

**Definition of Usage:**  
- Texacort Topical Solution 2.5% is available in a 1 fl. oz. plastic bottle with an applicator tip, NDC 0178-0455-01, and in a 3 mL sample packet, NDC 0178-0455-03.  

**Prescriber Information:**  
- Store at controlled room temperature 15° to 30°C (59° to 86°F).