Triamcinolone Acetonide Ointment USP, 0.025%, 0.1%, 0.5%
For Dermatologic Use Only
Not For Ophthalmic Use

DESCRIPTION
The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents. Triamcinolone acetonide is designated chemically as 16α,17α,21-trihydroxy-16β-fluoro-11β,16α-dihydroxy-1,4-pregnadiene-3,20-dione. 

PRECAUTIONS
General - Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

CONTRAINDICATIONS
Topical corticosteroids are generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition. Treatment of resistant dermatoses (see INDICATIONS AND USAGE).

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: burning, itching, irritation, dryness, atrophy, sensitization, and ocular discomfort. Topical corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see OVERDOSAGE).

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 dermatuses (see DOSAGE AND ADMINISTRATION). Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systematically 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
Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS
Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS
General - Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifested by decreased adrenocorticotrophic hormone (ACTH) response to stimulation tests. Topical corticosteroids have been shown to produce suppression of the HPA axis and adrenocortical atrophy when used, by themselves or concurrently with other types of corticosteroids, in high concentrations, and when administered to large surface areas or under occlusive dressing. The potential for a significant increase in percutaneous absorption of topical corticosteroids can be reduced by limited use, the use of a single agent, the use of lower potency formulations, and the use of an occlusive dressing for the management of psoriasis or recalcitrant conditions. Patients receiving treatment with topical corticosteroids should be evaluated periodically for signs of HPA axis suppression. 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. Conditions which may suppress the immune system may be exacerbated by topical corticosteroids (see OVERDOSAGE).

Carcinogenesis, Mutagenesis, 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: Teratogenic Effects: Pregnancy 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 the 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.

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: burning, itching, irritation, dryness, atrophy, sensitization, and ocular discomfort. Topical corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see OVERDOSAGE).

DOSAGE AND ADMINISTRATION
Topical corticosteroids are generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.

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

STORAGE
Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].