CLINICAL UPDATE

Brand Name	Tritocin™
Generic Name	triamcinolone acetonide
Drug Manufacturer	Eckson Labs, LLC

Clinical Update

TYPE OF CLINICAL UPDATE

First time Brand

FDA APPROVAL DATE

May 03, 2021 – FDB addition

LAUNCH DATE

April 29,2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA)- 213619

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

Tritocin™ (triamcinolone acetonide) Ointment, USP 0.05% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

MECHANISMS OF ACTION

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties. May depress the formation, release, and activity of endogenous chemical mediators of inflammation (kinins, histamine, liposomal enzymes, prostaglandins) through the induction of phospholipase A_2 inhibitory proteins (lipocortins) and sequential inhibition of the release of arachidonic acid. Triamcinolone has intermediate to high range potency (dosage-form dependent).

DOSAGE FORM(S) AND STRENGTH(S)

Tritocin™ (triamcinolone acetonide) Ointment, USP 0.05%.

DOSE & ADMINISTRATION

Apply a thin film to the affected area two to four times daily.

Occlusive Dressing Technique

Occlusive dressings may be used for the management of psoriasis or other recalcitrant conditions. Apply a thin film of ointment to the lesion, cover with a pliable 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 Tritocin™ (triamcinolone acetonide) Ointment, USP 0.05% 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 occlusion regimen, additional ointment 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.

EFFICACY

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.