Pramosone® Lotion (hydrocortisone acetate and pramoxine hydrochloride)

DESCRIPTION: Pramosone® Lotion is a topical preparation containing hydrocortisone acetate 1% w/w and pramoxine hydrochloride 1% w/w in a hydrophilic lotion base containing stearyl alcohol, cetyl alcohol, FORLAN, Contains: petrolatum, lanolin, hydrogenated coconut oil, white vaselinum, white petrosel, alcohol and cold water, glycerin, triethanolamine, propylene glycol, deionized water, dimethicone, dimethyldistearylammonium chloride, sorbic acid, and purified water.

Topical corticosteroids are anti-inflammatory and anti-pruritic agents. The structural formula, the chemical name, molecular formula and molecular weight for active ingredients are presented below.

[Chemical structure image]

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

The mechanism of anti-inflammatory activity of topical corticosteroids is unclear. Various laboratory methods, including vancomycin assays, are used to compare potency and clinical efficacy of the topical corticosteroids. There is some evidence to support that a recognizable correlation exists between vasoconstrictor action and therapeutic efficacy in man.

Pramoxine hydrochloride is a topical anesthetic agent which provides temporary relief from itching and pain. It acts by stabilizing the neuronal membranes of nerve endings with which it comes into contact.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicule, the integrity of the epidermal barrier, and the site of application of irritants.

Topical corticosteroids can be absorbed from normal intact skin. Information and adverse reactions in the skin (in vivo) or other processes in the skin (in vivo) may vary percutaneous absorption. Discontinue dressings substrates increases the percutaneous absorption of topical corticosteroids. These absorption pathways remain of critical importance for treatment of resistant dermatoses. (See DOSAGE AND ADMINISTRATION.)

Once absorbed into the skin, topical corticosteroids are distributed throughout 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 topically applied corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE: Topical corticosteroids are indicated for the relief of 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 preparation.

PRECAUTIONS: General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucocorticosteroids in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large areas, prolonged use, and the addition of occlusive dressings. Therefore, patients using a large dose of a potent topical steroid applied to a large surface area and under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, attempts should be made to withdraw the drug. To reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug, though signs and symptoms of adrenal insufficiency may occur requiring supplemental systemic corticosteroids. If this occurs, systemic corticosteroids may be necessary. Adrenal insufficiency may be more pronounced in patients treated with any form of monoamine oxidase inhibitor or a tricyclic antidepressant. The patient should be advised of the signs and symptoms of adrenal insufficiency which include nausea, vomiting, anorexia, mood changes, hypotension, or hypoglycemia.

Labetalol, a mixed α- and β-adrenergic receptor antagonist, has been reported to potentiate the effects of topical corticosteroids. Therefore, patients using topical corticosteroids and labetalol should be monitored closely for hypothalamic-pituitary-adrenal (HPA) axis suppression.

Hypothyroidism: Hypothyroidism is a known condition that may be exacerbated by topical corticosteroids. Therefore, patients using topical corticosteroids and hypothyroidism should be monitored closely for hypothyroidism.

Spironolactone: The use of spironolactone in patients using topical corticosteroids may result in a decrease in effectiveness of spironolactone.

Thiazide diuretics: The use of thiazide diuretics in patients using topical corticosteroids may result in a decrease in effectiveness of thiazide diuretics.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of the drug in foods or to study the effect on reproduction or fertility. Long-term administration of corticosteroids has resulted in growth suppression and adrenal suppression. Adrenal suppression may cause a decrease in long-term effectiveness of corticosteroids.

Teratogenic Effects: Pregnancy Category C: Pramoxine is generally considered to be a non-specific irritant when administered systemically or topically. However, since topical corticosteroids are not always avoided during pregnancy, if the potential benefits outweigh the potential risk, the use of this drug should be avoided in the first trimester of pregnancy.

Pregnancy: All corticosteroids suppress hypothalamic-pituitary-adrenal (HPA) axis suppression, progestational effects, and pituitary-adrenal (HPA) axis suppression. Adrenal suppression may cause a decrease in long-term effectiveness of corticosteroids. Therefore, patients using topical corticosteroids and pregnancy should be monitored closely for adrenal suppression.

Lactation: The effects of pramoxine on milk production and infant development are unknown. Therefore, patients using topical corticosteroids and lactation should be monitored closely for milk production and infant development.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroids-induced HPA axis suppression and Cushing's syndrome than adult patients because of a larger skin surface area to body weight ratio.

ADVERSE REACTIONS: The following adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently than with the use of occlusive dressings.

Burning, Hypersensitivity, Itching, Irritation, Prolonged use, Periorbital dermatitis, Ramsay Hunt Syndrome, Allergic contact dermatitis, Milia, Ocular effects, Vascular effects, Systemic effects, Local effects, Acneiform eruptions, Supersensitivity reactions, Local irritation, pramoxine hydrochloride, pramoxine, pramoxine HCl, HCl, hydrochloride, acetate, hydrocortisone acetate, occlusive dressings, occlusive, elastomer, elastomeric, soft, alcohol, propylene glycol, glycerin, triethanolamine, succinate, sorbic acid, purified water, FORLAN, petrolatum, lanolin, hydrogenated coconut oil, vaselinum, deionized water, dimethicone, dimethyldistearylammonium chloride, sorbic acid, purified water,_socket, Alum, Zinc Oxide, Pramoxine Hydrochloride, Hydrocortisone Acetate, St. Mary's Cornflower, Yew, milk, leucine, tryptophan, histidine, arginine, ornithine, and cytokines.

Inflammation develops, topical corticosteroids should be discontinued and appropriate treatment instituted.

In the presence of dermatological infections, the use of an appropriate antibiotic or antifungal agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.