

DermAssure® Cream

Background:

DermAssure® Cream is a compound consisting of a combination of clinically safe and extremely effective active ingredients. Accordingly, some of the medications contained in the compound are by Rx (prescription), and some are OTC (over the counter). DermAssure® Cream originated as a response to an extremely urgent need to develop an effective and reliably curative therapy to address the most complex types of Dermatitis, those which generally do not respond to the conventional barrier creams routinely available in our Neonatal Intensive Care Units. As it happens, our population of patients, specifically the group comprised of extreme premature and of extremely low birth weights, very often suffer from the comorbid effects of the antibiotic therapy which they readily require as life saving measures. To be specific, the very same group of antibiotics they require to protect them from potentially lethal infections, will cause them to secondarily develop the symptoms which predispose the formation of their rash: loose stools and yeast overgrowth.

General facts:

The pharmacologic properties of the ingredients in DermAssure® Cream are curative for a broad spectrum of other clinical dermatologic conditions, many of which are also currently encountered in other groups of patients. At the forefront of the problem list challenging the medical community, are rashes commonly affecting the expanding elderly population; rashes which may result from Opiate addiction; rashes which affect patients suffering from Morbid Obesity, Diabetes Mellitus, Cancer patients that undergo Chemotherapy, and rashes affecting Extreme Athletes. Typically, these rashes result from the effects of a milieu where persistent moist skin conditions are prevalent. Generally, where there is a loss of skin integrity, there is a relative incapacitation of the protective capacity of the skin, a progression of the injury which may consequently result in a secondary skin infection by a number of skin opportunistic pathogens such as: Candida Albicans, Dermatophytes, or bacteria which frequently colonize the skin of humans like Staphylococcus Aureus, or Streptococcus Pyogenes. Once these organisms gain a portal of entry, an infection typically results. The infections that result from pathologic overgrowth, generally prove extremely challenging for clinicians to treat successfully. The group of the conditions just listed, and other less common but nonetheless important rashes can be effectively treated with the topical application of DermAssure® Cream. Our compound has been granted a patent from the United States Patent and Trademark Office and has been used without complications in our fragile patient population for several years.

There is abundant clinical evidence to support the use of barrier creams for the management of conditions like the Dermatitis associated with infants suffering from Neonatal Abstinence Syndrome (NAS), as well as patients with Short Bowel Syndromes, conditions which result in the placement of an Ostomy, or patients that suffer from incontinence. In these patients, the repeated exposure of the skin to their gastric contents results in the erosion and denudement of the site. Of note, infants being born to Opiate addicted mothers many whom will subsequently develop "Neonatal Abstinence Syndrome" typically develop a diaper rash which can be extremely painful to the patient, particularly during the time when the infant voids or stools. This rash typically results as a sequelae (complication) of the exposure of the groin or perianal skin which while covered by the patient's diaper is repeatedly exposed to the mixture of the infant's stool and urine which is subsequently chemically altered by the fecal bacteria. This region of skin then loses its natural ability to act as a protective barrier. The most superficial layers of skin over the perineum will erode 2ry to the caustic effect, and these patients typically develop a contact dermatitis akin to scalded skin. The mechanism responsible for this symptom is GI tract hyper-motility; typically, this condition is present in patients with opiate withdrawal. Moreover, conventional creams used like the OTC products available to patients and their clinicians are ineffective. Importantly, the inability to resolve this condition rapidly and effectively, results in the prolongation of the patient's hospital stay. A key element in the successful clinical management of these patients, is the ability of the clinician to wean the patient off his or her medications in order to discharge from them from the hospital. A patient treated for abstinence and who remains irritable, inconsolable, febrile, unable to feed or sleep well will not be discharged from the hospital facility. Therefore, having a truly effective barrier cream is of paramount importance since it promotes faster healing and shorter hospital stays.

Other patients that have derived great benefit from the excellent barrier properties of DermAssure®, are the elderly with pendulous breasts, and or those whom may also have significant amount of pannus and thus have a propensity to develop Candidiasis within the skin folds. Additionally, the patients confined to a bed or with decreased ability to ambulate and in whom it is necessary to prevent or treat for the sores which can result, have also benefited from DermAssure® therapy. Barrier creams are an important adjunct to the relief of pressure and the debridement which form a part of the mainstay therapy in these types of lesions.

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