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(54) Title: HEALING, MOISTURIZING, HUMECTANT AND EMOLIENT COMPOSITION FOR TOPICAL ADMINISTRATION IN INTERTRIGO SKIN LESIONS, SKIN LESIONS DUE TO URINARY AND FAECAL INCONTINENCE AND OTHER RELATED INJURIES.

(57) Abstract: HEALING, MOISTURIZING, HUMECTANT AND EMOLIENT COMPOSITION FOR TOPICAL ADMINISTRATION IN INTERTRIGO SKIN LESIONS, SKIN LESIONS DUE TO URINARY AND FAECAL INCONTINENCE AND OTHER RELATED INJURIES. The present invention relates to a medicament resulting from a combination of substances for treatment of intertrigo skin lesions, skin lesions from urinary and faecal incontinence and other related injuries. These substances act synergistically contributing to tissue restoration and wound healing. The present invention relates to a solution whose composition contains vitamin A, D and E; clotrimazole, zinc oxide and linoleic acid associated with capric and caprylic acids.



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Descriptive report of patent of invention for "HEALING, MOISTURIZING, HUMECTANT AND EMOLIENT COMPOSITION FOR TOPICAL ADMINISTRATION IN INTERTRIGO SKIN LESIONS, SKIN LESIONS DUE TO URINARY AND FAECAL INCONTINENCE AND OTHER RELATED INJURIES".

[001] Field of the Invention: This invention relates to a composition resulting from a combination of substances that act synergistically in the treatment of skin lesions intertrigo, skin lesions by urinary and faecal incontinence and other related injuries.

BACKGROUND OF THE INVENTION

[002] The man's skin is the mantle of the covering of organism, indispensable to life and which isolates the organic components from the external environment, corresponding to 15% of their body weight. It presents constant changes, having great capacity for renewal, repair and a certain degree of impermeability.

[003] The skin can be easily damaged mechanically, chemically, biologically and by radiation. The major functions of the skin are: protect the body against chemical and physical damage and prevent the loss of water and other substances by the body.

[004] The skin is a complex tissue, composed of multilayers that can be divided into three main layers, the epidermis, the dermis and the hypodermis. The epidermis is formed by keratinized stratified epithelial tissue, with significant structural and functional variations depending on its anatomical site.

[005] The skin consists of: keratinocytic system, composed of epithelial cells called keratinocytes, responsible for the body of the epidermis and its attachments (hairs, nails and glands); melanocytic system, formed by melanocytes; Langerhans cells, with immune function; Merkel cells, integrated into the nervous system, and indeterminate dendritic cells.

[006] DMDM Hydantoin and Iodopropynil Butylcarbamate (IPBC) are both bactericidal and fungicidal. It inhibits the growth of gram-positive and gram-negative bacteria, yeasts and mold.

[007] Clotrimazole is a topical antimycotic acting on the site where it is applied to dermatophytes, yeasts, fungi, etc. Its main function is fungistatic or fungicidal depending on the concentration in the infection. It is effective against *Trichomonas vaginalis*, gram-positive microorganisms (streptococci / staphylococci) and gram-negative microorganisms (*Bacteroides* / *Gardnerella vaginalis*).

[008] Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity belonging to the group of azoic derivatives. It acts on fungi by inhibiting the synthesis of ergosterol, causing structural and functional damage of the cytoplasmic membrane. The broad spectrum of activity of clotrimazole in vitro and in vivo includes dermatophytes, yeasts, fungi and and so on.

[009] Primary resistance variants of sensitive fungal species are very rare, and only very isolated cases of secondary resistance to sensitive fungi have been observed under therapeutic conditions.

[010] Studies have shown that, after dermatological and vaginal application, only small amounts of clotrimazole (<2% and 3 - 10% of the dose, respectively) were absorbed. The peak plasma concentration of clotrimazole was <10 ng / mL, below the limit of detection and did not cause measurable systemic effects or adverse effects.

[011] Vitamin A is related to the protective action on the skin and mucosa, participates in the strengthening of the immunological system, participates in the development and maintenance of the epithelial tissue, synthesizing mucus, keeping the skin intact and humidified.

[012] Hypovitaminosis A, that is, the lack of this vitamin, causes skin xerosis and increased keratinization, dry and flaky skin.

[013] Vitamin A is also known as retinol, belonging to the class of retinoids, due to the fact that it generates pigments necessary for the functioning of the retina.

[014] Vitamin A has antioxidant power helping in skin regeneration.

[015] Retinol helps the skin retain water and recover, getting with a look better.

[016] Vitamin A penetrates the skin and normalizes the keratinization process, leaving the skin smooth and soft, reduces the thickening of the epidermis and normalizes the dry skin.

[017] The mechanism of action of retinol may be linked to a product of its metabolism, the transretinoic acid. This acid binds to receptors in the cell nucleus and interacts with certain DNA sequences, regulating the production of certain proteins and enzymes, reducing the signs of skin damage. It also undergoes oxidation before the structures essential for homeostasis, hence its antioxidant action.

[018] Vitamin A is found in food in two ways:

[019] Preformed vitamin A, which can be obtained from products of animal origin in the form of retinoids such as fish, meat, poultry and dairy products.

[020] Pro-vitamin A, present in foods of plant origin in the form of carotenoid, like some fruits and vegetables. The most common type of this is the beta-carotene, it is a precursor of Vitamin A.

[021] In the human body, vitamin A can be found in three forms, retinol, retinal and retinoic acid, the latter being the main and most abundant intracellular metabolite in mammals.

[022] There are five forms of vitamin A, the most important is the retinol in the form of TRANS and CIS.

[023] Retinol esters are vitamin A linked to a fatty acid, being the form in which vitamin A is ingested through food of animal origin. The oxidized form of this vitamin is called retinal or retinaldehyde. And Retinoic Acid, is the acid of vitamin A, when it oxidizes.

[024] Vitamin A accumulates in the liver.

[025] Cod liver oil, in the case of external application, is important because it is rich in vitamins A and D, being beneficial for the metabolism of the tissues, controls the inflammatory reactions and acting in synergy with the zinc oxide,

helps in the protection of the skin.

[026] Topical retinoids inhibit the accumulation of polymorphonuclear leukocytes (PMN), a key feature of inflammatory dermatoses, in addition to reducing several other inflammatory and noninflammatory lesions.

[027] Vitamin A (Retinol Palmitate) is used for cellular nutrition and collagen replacement.

[028] Vitamin D is a group of liposoluble prohormones, being the two main forms, vitamin D2 ergo-calciferol (ergocalciferol) and vitamin D3.

[029] Vitamin D3 is produced by the human organism through exposure to the sun, specifically to ultraviolet B radiation acting on an element (7-dehydrocholesterol) present in the epidermis, being the best natural source of vitamin D. It is soluble in fat and can be stored in cells adipose.

[030] Vitamin D influences the production of hormones in the body, improving certain skin conditions such as psoriasis, vitiligo and scleroderma, in addition to controlling mood.

[031] Topical application of vitamin D has been linked to increased expression of antimicrobial LL-37 peptide in human skin. LL-37 is an antimicrobial peptide predominantly expressed by keratinocytes that performs various skin health functions, including the control of microbial flora on intact and damaged skin, attracting cells from the immune system, promoting epithelial repair, and increasing the angiogenesis necessary for the healing of the skin.

[032] Decrease of expression of various antimicrobial peptides has been reported in certain skin conditions, such as atopic dermatitis and chronic leg ulcers.

[033] Zinc oxide is a chemical compound whose chemical formula is ZnO. Zinc oxide is insoluble in water but very soluble in acidic solutions.

[034] It is used as a key component in creams for newborns and young children because of its powerful action against all types of itching and skin irritation.

[035] It is also a component of cosmetics for adults and, especially,

sunscreens because, due to their presence in the cream, a very effective protection layer is formed. Its action is decisive in blocking ultraviolet rays.

[036] This powder, transformed into cream when mixed with some moisturizing or oily base, has anti-inflammatory, antipruritic, antiseptic and healing action. It is suitable in case of burns or as a preventive of these, in cases of rashes, bed sores and all kinds of skin irritation.

[037] The healing action of the preparations with zinc oxide results from the total coverage that this powder gives to the skin, creating a propitious environment that encourages the cellular recovery.

[038] Together with the antiseptic action of zinc oxide - which prevents the proliferation of microorganisms in the injured skin - this substance also has astringent action and its use is very appropriate due to the antiseptics allied to the drying of the lesions.

[039] Another benefit of the dermatological use of zinc oxide is the reduction of skin redness as a secondary symptom of inflammatory processes.

[040] Zinc oxide is widely used to inhibit fungal growth.

[041] In medicine, zinc oxide enters in the treatments for dermatological problems like eczema, various dermatitis, psoriasis, redness of the skin, acne and burns.

[042] It is used in creams and ointments in concentrations ranging from 10 to 15% (in some specific cases, this concentration may reach 50%).

[043] Not only it act as a physical filter, preventing the sun's rays of directly reaching the skin to be protected as it has an effective action also in blocking UVA and UVB radiation because its particles reflect this radiation preventing it of reaching the body.

[044] In treatments for skin blemishes it is one of the most efficient products to allow the skin, little by little, regain its texture and coloration.

[045] Among the symptoms of zinc deficiency in our body, we have a deficiency in the healing of the skin.

[046] Zinc oxide acts as a cutaneous protector, antiseptic and astringent

exerting a healing and protective action of the skin on the affections that present superficial eruptions.

[047] Several studies indicate the application of ointment or paste containing zinc oxide in its composition.

[048] A study conducted to evaluate subclinical changes in the functions of the corneal layer of skin with dermatitis during treatment with the zinc oxide paste and vaseline showed that zinc oxide preparation reduced the risk of fungal infection.

[049] There are no reports of drug interaction between Retinol Palmitate, Colecalciferol and Zinc Oxide.

[050] Vitamin E is a fat-soluble (soluble in fat) vitamin.

[051] Vitamin E consists, in fact, of eight different molecules, between four tocopherols and four tocotrienols, and the structures α , β , γ or δ are determined according to the position of the methyl group (CH₃). The alpha-tocopherol form is considered to be "vitamin E".

[052] It acts as a lubricant, moisturizing and regenerating skin that suffered the action of time, sun, pollution and oxidative stress, mainly to protect membranes against lipoperoxidation. As it is collagen stimulant, it also increases the firmness and elasticity of the skin.

[053] Therefore, vitamin E is widely used in topical products for disease prevention or photoaging. After topical application, it is easily absorbed by the skin. Vitamin E is a highly desirable ingredient in formulations to rejuvenate and protect cutaneous tissues because it has antioxidant capacity in vivo offering protection against free radicals, reducing cellular oxidative damage, which can affect the integrity of the tissues that make up our body .

[054] Vitamin E is widely used in post-sun products because it reduces UV-induced damage, decreases erythema and skin sensitivity after exposure to UV light.

[055] It prevents cell damage by inhibiting the formation of free radicals, improving blood circulation and aiding in tissue regeneration.

[056] It is present in baby rash creams, after-shave and hands and feet moisturizer because of its anti-inflammatory, soothing and healing properties.

[057] Very high doses of vitamin E (active substance) reduce the absorption of vitamins A.

[058] Vitamin E participates in the formation of all tissues of mesodermal origin (fundamental substance, collagen and elastic fibers of the connective tissue, smooth and striated muscles, vessels) and in the maintenance of its functions. In the cell participates in the metabolism of nucleic acids as well as in the respiratory chain.

[059] Vitamin E is a biological antioxidant that prevents the spontaneous oxidation of polyunsaturated compounds, responsible for the formation of harmful free radicals, thus preventing the formation of carcinogenic nitrosamines, protecting the skin from UV rays and the early appearance of wrinkles. It is not by chance that many creams and beauty products are fortified with this vitamin. Sometimes a deficiency can be evidenced with skin problems that can appear with various imperfections like dryness, peeling, etc.

[060] Due to its lipophilic properties vitamin E accumulates in cell membranes protecting them under the functional aspect, mainly as to the inhibition that exerts in the peroxidation of the lipids. Vitamin E contributes, in particular, to the stabilization of the lysosomal, mitochondrial and capillary membranes and, consequently, to the maintenance of the normal erythrocyte resistance. Still based on this action, vitamin E promotes an increase in phagocytic activity.

[061] The deficiency of this vitamin leads, through the peroxidation of the lipids, to the accumulation of lipofuscin or pigment of wear of the tissues.

[062] Vitamin E intervenes at different stages of arachidonic acid synthesis and therefore acts on the metabolism of prostaglandins. Studies have shown that platelet incorporation of vitamin E, obtained through oral supplementation, is associated with an inhibition of platelet aggregation. In premature infants placed in an incubator, vitamin E prevents the formation of

retrolental fibroplasia and bronchopulmonary dysplasia.

[063] Vitamin E (Tocopherol Acetate) is used for anti-inflammatory and antioxidant action.

[064] Fatty acids are monocarboxylic acids obtained from oils and fats. They have important functions in the human body.

[065] Fatty acids are organic substances found at room temperature in the solid and liquid and semi-solid phases. They belong to the group of carboxylic acids, compounds that have the carboxyl, carbon attached to an oxygen and a hydroxyl.

[066] In general, fatty acids have saturated (only single bonds) or unsaturated (one or more bonds between carbon carbons) open carbon chains, in which the carbon number (R) may range from 4 to 22 atoms.

[067] Fatty acids are monocarboxylic acids, that is, they have only one carboxyl group.

[068] Stearic acid is a saturated fatty acid also called octadecanoic acid because it has eighteen carbon atoms in its structure. It belongs to a class of compounds called carboxylic acids, which are characterized by having the carboxyl functional group COOH. At room temperature it is solid, looking like a microgranulated wax. It is used in the production of various cosmetics and pharmaceuticals.

[069] Obtained from the fractionation of fatty acid through the hydrolysis of sebum of animal origin. In powder or granules white to slightly yellowish, it has a slight characteristic odor and is well used as an agent of consistency (due to its unique properties). Biodegradable, non-flammable, toxic or polluting.

[070] Stearic Acid consists on the mixture of the solid fatty acids of fatty matters and constituted mainly of stearic acid and palmitic acid.

[071] Because it is a fatty acid, stearic acid can be saponified and is widely used in cosmetic formulations of shaving creams, soaps, evanescent creams and creamy lotions. Due to its high solidification point, it is mainly used as a viscosity and consistency donor in formulations of deodorant creams and

creams.

[072] Linoleic acid is a polyunsaturated fatty acid also called octadec-9,13-dienoic acid, as it has eighteen carbon atoms and two double bonds (at carbons 9 and 13) in its structure.

[073] The essential fatty acids (those that the body can not synthesize) are mainly in the composition of plant cells, and their presence is essential in the diet, especially in the case of linoleic and linolenic acids.

[074] The omega-6 and omega-3 acids are two families of polyunsaturated fatty acids, each represented by an essential acid: linoleic acid (omega-6) and α -linolenic acid (omega-3), which in turn, originating other essential acids of longer chains, called long chain polyunsaturated fatty acids.

[075] The omega-3 acid is anti-inflammatory, antithrombotic, antiarrhythmic and lowers blood lipids, having vasodilator property. These beneficial effects have been demonstrated in the prevention of heart disease, hypertension, type 2 diabetes, rheumatoid arthritis among others.

[076] The sources of saturated fatty acids are obtained by the consumption of various chocolates, red meat (bovine, pork, etc.), eggs, whole milk and milk derivatives, animal fat etc.

[077] The sources of polyunsaturated fatty acids are obtained by the consumption of oils extracted from vegetables (corn, sunflower, soybeans, nuts, almonds etc.), fish etc.

[078] In general, fatty acids are called essential because they are not produced by the body.

[079] Fatty acids play several roles for the organism, among them:

[080] Helps, in general, in the control of inflammations, infections and lesion;

[081] They favor the proper blood coagulation;

[082] They favor the production of hormones and

[083] They favor the production of antibodies.

[084] Some fats are part of a group of lipids, also called glycerides, which

are compounds formed by the union of a molecule of glycerol, which is a molecule of trialcohol glycerin (propanetriol) and three fatty acids (long chain carboxylic acids, usually with 4 to 22 carbon atoms in even numbers, with only one carboxyl group), so glycerides are also called triglycerides.

[085] Linoleic acid stimulates the inflammatory process, angiogenesis, migration and cell proliferation and increases the resistance of the skin.

[086] Triacylglycerol, also known as triglycerides, is the generic name for any tri-ester derived from the combination of glycerol (a trialcohol) with acids, especially fatty acids (long chain alkyl carboxylic acids), in which the three hydroxyls (from glycerol) underwent condensation with the acids, which need not necessarily be the same. Triacylglycerols are readily recognized as oils or fats.

[087] In a simplified way, a triacylglycerol is formed by the union of three fatty acids to a molecule of glycerol, whose three hydroxyl groups (-OH groups) bind to the carboxylic radicals of the fatty acids.

[088] Capric and caprylic acid triglycerides are medium chain triglycerides (MCTs) consisting mainly of esters of caprylic (C8) and capric (C10) acids.

[089] Due to chain size, caprylic and capric acid triglycerides have excellent alcohol solubility and hence their importance in the applicability of pharmaceuticals. These compounds are considered toxicologically and dermatologically innocuous and are classified as GRAS (Generally Recognized As Safe) by the FDA.

[090] Fully saturated emollient ester, recommended as an alternative to mineral or vegetable oil in various personal care and pharmaceutical products, due to its structural composition, because it is a lubricant and emollient, to confer fine and soft emollience leaving a non occlusive film on the surface of the skin, be a good spreader, be an excellent vehicle or diluent for active principles in topical preparations, be a good solvent for chemical sunscreens, have excellent dermatological behavior, be nontoxic, have low turbidity, be inert and stable to oxidation.

[091] Capric triglyceride is a combined triester, a mixture of capric and

caprylic acids. It is also known as fractionated coconut oil. Its most popular use is as a emollient (to soften the skin) because of its ability of rapid penetration. This compound is a very popular ingredient in various products to the skin and soaps.

[092] Some benefits of capric triglyceride include the fact that it is not oily in addition to having a very light texture. It is also quickly absorbed, being highly compatible with the skin.

[093] Capric triglyceride is derived from coconut. Before the oil is even processed, it has high levels of saturated fat, with a content of plus or minus 90%. In its purest form, it has a milky color, although after refinement, the oil becomes transparent (and liquid at room temperature).

[094] The essential fatty acids increase the resistance of the skin.

[095] Long chain polyunsaturated fatty acids play important cellular functions such as maintenance of membrane integrity and fluidity, membrane enzyme activities and eicosanoid synthesis, such as prostaglandins, leukotrienes and thromboxanes. These, in turn, have the capacity to modify inflammatory and immunological reactions, altering leukocyte functions and accelerating the process of tissue granulation.

[096] The application of these products protect the integrity of the skin and increase its hydration. Essential fatty acid creams such as linoleic acid, caprylic acid, capric acid, vitamin A, vitamin E and soy lecithin are used for this purpose.

[097] Among the essential fatty acids we have linoleic and linolenic acids.

[098] Chemotaxis promotes the migration of neutrophils into the wound through a chemical stimulus. Neutrophils are the first cells to reach the wound.

[099] Essential fatty acids are needed to maintain the integrity of the skin due to its ability to function as a water barrier. These acids act by promoting chemotaxis and angiogenesis, keeping the medium moist and, thus, accelerate the process of tissue granulation.

[100] In addition to the prevention and treatment of pressure ulcers, they can also prevent and treat dermatitis, venous and neutrophic ulcers, open ulcers

with or without infection.

[101] Linoleic acid is a mediator that accumulates macrophages and leukocytes and speeds up the healing process.

[102] Medium Chain Triglycerides (MCTs) - capric acid, caprylic acid, caproic acid and lauric acid are used as vehicle and emollient.

[103] Lanolin present in moisturizing creams, soaps and shampoos is a material made up of various types of substances, obtained from sheep's wool.

[104] Lanolin consists of various compounds, including esters and polyesters of long chain alcohols and fatty acids, predominantly unsaturated fatty acids, represented by a high proportion of eicosapentaenoic (EPA), linoleic and docosahexaenoic acids.

[105] It is obtained as a byproduct of sheep wool cleaning. Lanolin is a yellowish grease and is excreted by the sebaceous glands of these animals.

[106] Lanolin as a skin moisturizer can prevent water loss through the skin, keeping it moisturized, as its long chains have polar ends that attach to the water molecules in the skin.

[107] This moisturizing action makes it a moisturizing or emollient (softener), also increasing the hydration and elasticity of the skin. Because of this, many breastfeeding mothers use this moisturizer on their breasts to prevent cracking and pain.

[108] For the healing process, some medications to wound treatment and wound healing contain lanolin as an ingredient.

DETAILING OF THE INVENTION

[109] Wound can be defined as any alteration of the anatomical integrity of the skin, generating an lesion in the same, resulting from any type of trauma.

[110] The classification of wounds is an important form of systematization, necessary for the evaluation and registration process. Thus, the wounds can be classified, according to the time of tissue repair, in acute and chronic. Acute wounds come from surgeries or trauma and repair occurs at an appropriate time without complications. Chronic wounds are those that are not repaired in the

expected time and present complications. Risk factors associated with chronic wounds include: high blood pressure, diabetes mellitus, poor circulation, immunodeficiency, and infection. Among the most common chronic wounds are venous ulcers, arterial ulcers, neuropathic ulcers, and pressure ulcers.

[111] Chronic wounds are related to the increased cost of hospital care and with various infectious complications, local infection, cellulitis of neighboring tissues, contiguous osteomyelitis and bacteremia / sepsis.

[112] The treatment of these skin lesions, wounds, involves systemic and local aspects. The local treatment is called dressing, and it is the procedure of cleaning and covering a skin lesion, with the purpose of helping to restore tissue integrity or prevent colonization of the insertion sites of invasive, diagnostic or therapeutic devices (eg catheters and drains).

[113] The term "pharmaceutical composition" refers to a mixture of two or more active ingredients with its carrier in order to enable its application to an organism.

[114] The financial costs of treating wounds are high, especially because of the lack of an effective drug.

[115] Topical treatment in intertrigo skin lesions, skin lesions due to urinary and fecal incontinence and other related injuries is difficult to treat and is therefore a long, expensive treatment and causes great suffering to those with this lesion.

[116] The compound object of this patent application solves these problems, as it has all the necessary properties to optimize the cure of these skin lesions:

[117] - Acts contributing to the healing of the lesions. It is presented as a cream having in its composition vitamin A, D and E; clotrimazole, zinc oxide and linoleic acid associated with capric and caprylic acids.

[118] - It has bacterial, antifungal and therapeutic action. Promotes faster wound cure through more effective lesion healing.

[119] - It treats the lesions contributing to a better cicatrization,

reduction of the time of treatment and reduction of the possibility of infection, because it creates a barrier and a more efficient physiological response against infectious microorganisms.

[120] - It is a topical dermatological compound with therapeutic functions in the skin and mucosa that, due to its effectiveness in healing, accelerates this process with consequent reduction of costs, treatment schedule and medical attention generating a therapeutic overall gain.

[121] - It has effective curative effect in the treatment of wounds without similar in the market. Those available in the market are cosmetic, not being efficient in wound healing, because of their compositions, leaving, as a consequence: poor healing, longer treatment time and higher cost.

[122] - It is a therapeutic dermatological medicine, nontoxic, restorative and cicatrizant of the skin or mucosas, preventing, even, the hypertrophic cicatrization, for which a composition of active principles is used that together they have a synergic action such that they bring better results, having no similar in the market with the same effect, being therefore a novelty with non-toxic action and unmatched dermatological therapeutic effect. In its composition the product proposed by the applicant has several active principles and coadjuvant.

[123] - It presents excellent scatterability and effects, among them, the contribution to the wound healing process from the cleansing due to autolytic and enzymatic debridement, reepithelization and maturation of the new epidermal tissues until, finally, healing of the lesion.

[124] - Linoleic acid, the main fatty acid in the omega-6 family associated with caprylic and capric acids, has potent antiedematogenic topical action. It exerts an important chemotactic role for macrophages, being fundamental in the expression of components of the fibrinolytic system (regulation of collagenase production); favors the autolytic debridement in the bed of the wound by contributing with the production of metalloproteins, inducing the granulation and being able to accelerate the cicatrization process.

[125] It has been observed that linoleic acid is able to inhibit the growth of *Staphylococcus aureus* by altering the synthesis of proteins, cell wall, nucleic acids and cell membranes during division.

[126] Essential fatty acids and vitamins A and E present excellent results in healing and restoration of the skin, having a fast and efficient response with the development of granulation tissue, intense angiogenesis and acceleration of the healing process in a few days, combined with low cost and no effect collateral.

[127] The Ministry of Health of Brazil recognizes the importance of essential fatty acids (AGEs), indicating them for prevention and treatment of pressure, venous and neurotrophic ulcers, as well as dermatitis and treatment of open wounds with or without infection. (Manual de Condutas para Úlceras Neurotróficas e Traumáticas - MS; pg 42; 2002).

[128] The Brazilian Society of Dermatology also recognizes the importance of "Essential Fatty Acids (AGEs) and indicates that they can be used in all types of lesions, in the various stages of the cicatricial process and as a preventive of injuries."

[129] Associação Brasileira de Farmacêuticos affirms: The topical application of fatty acids in the treatment of wounds as an important therapeutic tool should be considered.

[130] Medium Chain Triglycerides may have uses in the treatment and prevention of ammoniacal dermatitis and pressure ulcers, forming a protective barrier for the skin, preventing maceration, besides being of importance in the processes of cellular inflammation, providing relief after the first application and nutrition local cell, in addition to having a great capacity for tissue regeneration.

[131] Clotrimazole is widely used in various medicines for the treatment of eczema (skin lesion) and inflammatory processes of the skin (dermatitis), especially those caused by fungi. These infections can occur in many parts of the body and often manifest themselves through redness, peeling or inflammation of the skin, often accompanied by burning, pruritus (itching) or wet

wounds.

CONCLUSIONS:

[132] Based on the foregoing in this patent application, it is concluded that the product which the patent is sought has superior effect in the treatment of the wounds, promoting its more effective cure, with less cost and in less time.

[133] The compound presented in this document for patent registration incorporates synergistically the benefits of several active principles and coadjuvant that by themselves alone do not have the same effectiveness.

[134] There is no patent notice of the joint use of the active and coadjuvant principles of this formula and its synergistic effects. With this, this product presents itself with a novelty and for this reason it is requested its patent with the INPI.

[135] The better results in tissue regeneration, the shorter cure time provided by the product presented in this patent application result in reduction of patient suffering as well as cost savings and operating time gain.

[136] The drugs found in the pharmaceutical market today do not present the same efficiency of the proposed patent for several reasons ranging from the undue amount of active components to the individualized use of components that in themselves do not contribute as effectively in healing as the product proposed here for be patent.

[137] It is concluded that the product whose patent is requested is a novelty meeting the requirements of patentability, since it confers an inventive activity, as provided in article 8 of Law 9,279 (Law on Patents, Trademarks and Related Rights) of May 14, 1996, Brazil.

FORMULATION

[138] In this stage of the document will be exposed the technical information of the preparation of the proposed product for treatment of wounds and the benefits arising from the use in the treatment of the regeneration of skin lesions.

[139] The cream is a complex of active and coadjuvant principles that

synergistically produce a more effective effect on epithelial restoration in the case of chronic or acute lesions.

Table 1. Composition and solution concentrations.

Retinol	0,165 a 0,263
Cholecalciferol	0,0003 a 0,0008
vitamin E	0,158 a 1,03
Zinc oxide	3,06 a 6,02
Clotrimazole	0,02 a 0,463
triglyceride of caprylic and capric acids	15 a 33
linoleic acid (unsaturated fatty acid)	8,75 a 16,89
Lanolin	1,83 a 7,66
Disodium EDTA	0,002 a 0,0333
Butylene glycol	1,9 a 3,03
DMDM Hydantoin and Iodopropynil Butylcarbamate (IPBC)	0,07 a 0,13
Vanilin	0,005 a 0,0067
cod liver oil	1,87 a 3,53
butylated hydroxyanisole	0,002 a 0,01
Talc	0,54 a 4,16
mineral oil	0,050 a 1,66
petrolatum	3,017 a 10,86
polyethylene	2,8 a 5,7
Lavender	0,001 a 0,003
benzyl alcohol	0,31 a 1,13
cetostearyl alcohol	1,6 a 4,9
sorbitan stearate	3,55 a 8,03
cetyl palmitate	0,867 a 2,2
Polysorbate 60	0,43 a 3,1
purified water (deionized)	21 a 36

[140] Clotrimazole is used as topical antimycotic having its therapeutic effect in the region where it has been applied by acting on dermatophytes, yeasts, fungi, etc. Its main function is fungistatic or fungicidal.

[141] Clotrimazole inhibits the synthesis of ergosterol, causing structural

and functional damage of the fungal cytoplasmic membrane.

[142] There are rare cases of variants of primary and secondary resistance of species of sensitive fungi. In therapeutic cases, there are only very few secondary resistance evolutions by sensitive fungi.

[143] Studies have shown that few amounts of clotrimazole are absorbed, causing no measurable systemic effects or adverse effects.

[144] Clotrimazole is widely used in various medicines for the treatment of eczema (skin lesion) and inflammatory processes of the skin (dermatitis), especially those caused by fungi.

[145] Vitamin D is beneficial for the skin.

[146] Studies report the topical application of vitamin D and its binding to the increased expression of antimicrobial LL-37 peptide in human skin. LL-37 is an antimicrobial peptide prevalently expressed by keratinocytes that play a variety of roles in skin health, including the control of microbial flora on intact and damaged skin, attracting cells from the immune system, promoting epithelial repair, and increasing the angiogenesis necessary for the healing of the skin.

[147] Vitamin A has protective action on the skin and mucosa, helps strengthen the immune system, promotes the development and maintenance of epithelial tissue, synthesizing mucus, keeping the skin intact and humidified.

[148] Skin xerosis and increased keratinization, dry skin and scaly are evidence of hypovitaminosis A.

[149] The antioxidant power of vitamin A helps in regenerating the skin.

[150] Retinol contributes to the retention of water by the skin and on the its recovery, leaving it with a better appearance.

[151] The process of keratinization is solved because vitamin A enters the skin leaving it smooth and soft, reducing the thickening of the epidermis and renewing the dry skin.

[152] The mechanism of action of retinol is linked to its oxidation before structures essential for homeostasis.

[153] Vitamin A is found in food in two ways:

[154] Overnight administered cod liver oil is beneficial for tissue metabolism because of its rich content of vitamins A and D, controls inflammatory reactions and acting synergistically with zinc oxide, helps to protect the skin.

[155] The accumulation of polymorphonuclear leukocytes (PMN) is inhibited by topical retinoids. This accumulation is characteristic of inflammatory dermatoses. Retinoids reduce numerous inflammatory lesions.

[156] Vitamin A (Retinol Palmitate) is used for cellular nutrition and collagen replacement.

[157] Zinc oxide is fundamental in creams for newborns and young children due to their powerful action against itching and skin irritations.

[158] It is used in cosmetics for adults, especially in sunscreens because it has a fundamental action in blocking ultraviolet rays.

[159] Zinc oxide creams made of moisturizing or oily base, are excellent anti-inflammatory, antipruritic, antiseptic and healing. It is indicated for burns and all kinds of skin irritation.

[160] The healing action of the preparations with zinc oxide results from the total coverage that this powder gives to the skin, creating a propitious environment that encourages the cellular recovery.

[161] Zinc oxide has a drying action on the lesions. Its antiseptic action prevents the proliferation of microorganisms in the injured skin.

[162] Zinc oxide reduces skin redness, a secondary symptom of inflammatory processes.

[163] Zinc oxide inhibits the growth of fungi.

[164] The deficiency in skin healing is one of the symptoms of zinc deficiency.

[165] Zinc oxide acts as a skin protector, antiseptic and astringent exerting a soothing, healing and protective action of the skin in affections that have superficial eruptions.

[166] Studies have concluded that zinc oxide preparations reduce the risk

of fungal infection.

[167] There are no reports of drug interaction between Retinol Palmitate, Colecalciferol and Zinc Oxide.

[168] Vitamin E has lubricating, moisturizing and regenerating effects of skin damaged by time, sun, pollution and oxidative stress, mainly by protection against the lipoperoxidation given by it the membranes. It increases the firmness and elasticity of the skin as it is stimulating the collagen.

[169] In view of this, vitamin E is widely used in topical products to prevent disease or photoaging, and is easily absorbed by the skin.

[170] Vitamin E is important in formulations to rejuvenate and protect skin tissue due to its antioxidant capacity, giving protection against free radicals and reducing cellular oxidative damage, which can affect the integrity of the skin tissues.

[171] Vitamin E optimizes blood circulation and contributes to tissue regeneration.

[172] Because of its anti-inflammatory, soothing and healing properties, it is used in baby rash, after-shave and moisturizer creams for hands and feet.

[173] Vitamin E participates in the formation of all tissues of mesodermal origin (fundamental substance, collagen and elastic fibers of the connective tissue, smooth and striated muscles, vessels) and in the maintenance of its functions.

[174] Vitamin E deficiency can manifest itself through problems in the skin, presenting in the form of various imperfections such as dryness, peeling, etc.

[175] Vitamin E has lipophilic properties, accumulating in the cell membranes, this protects them as to the functional aspect, mainly in the inhibition of lipid peroxidation. Vitamin E is essential in the stabilization of lysosomal, mitochondrial and capillary membranes and, therefore, in maintaining the normal resistance of erythrocytes. Vitamin E stimulates increased phagocytic activity.

[176] Its deficiency leads to accumulation of lipofuscin or tissue wear

pigment due to lipid peroxidation.

[177] it stimulates increased Vitamin E acts on the metabolism of prostaglandins, since it has action in the synthesis of arachidonic acid. Vitamin E prevents the formation of retrolenticular fibroplasia and bronchopulmonary dysplasia in preterm infants at infant incubator.

[178] Vitamin E (Tocopherol Acetate) is used as an anti-inflammatory and antioxidant agent.

[179] Stearic acid is used in the production of various cosmetics and pharmaceuticals.

[180] Due to its high solidification point, it is mainly used as a viscosity donor and consistency in formulations of deodorant creams and creams.

[181] Linoleic acid (omega-6) and α -linolenic acid (omega-3), which in turn give rise to other long chain essential acids, called long chain polyunsaturated fatty acids.

[182] The omega-3 acid is anti-inflammatory, antithrombotic, antiarrhythmic and lowers blood lipids, having vasodilator property.

[183] Linoleic acid contributes to the synthesis of collagen by promoting the accumulation of fibroblasts due to its ability to attract macrophages, which stimulate PDGF (platelet-derived growth factor).

[184] In general, fatty acids are called essential because they are not produced by the body.

[185] Fatty acids play several roles for the body, including:

[186] Helps, in general, in the control of inflammations, infections and lesions;

[187] They favor the proper blood clotting;

[188] They favor the production of hormones and

[189] They favor the production of antibodies.

[190] Linoleic acid stimulates the anti-inflammatory process, angiogenesis, migration and cell proliferation and increases skin resistance.

[191] Hypertrophic scarring and the appearance of keloids in scarring

cease to exist because the production of collagenase stimulated by macrophages balances the production of collagen.

[192] Growth factors promote the development of an organ, and the skin is the largest organ in our body. This growth of the skin occurs through mitogen or mitogenic agents which stimulate cell division, triggering mitosis, mainly by relieving the intracellular negative controls that block the progression of the cell cycle.

[193] Cell growth means increasing cell mass through the synthesis of proteins and other macromolecules.

[194] Before the cell divides, it has to grow until it reaches an adequate and constant size, which depends, among other factors, on the availability of growth factors.

[195] Substances of a polypeptide nature are polypeptides and proteins. In general, polypeptides with 100 or more amino acids are called proteins, and those with more than 10 and less than 100 amino acids are called polypeptides.

[196] EGF (epidermal growth factor) is one of the main growth factors acting on the epidermal, endothelial and fibroblast cells; stimulating angiogenesis (formation of new vessels), cell proliferation and collagen synthesis.

[197] Epidermal growth factor (EGF) is mitogenic for epithelial cells and fibroblasts. In the healing of skin wounds, EGF is produced by keratinocytes, macrophages and other inflammatory cells that migrate into the wound area stimulating cell division. EGF is considered a polypeptide with potent mitogenic activity in different cell types.

[198] The product proposed in this patent application influences the growth factor favoring it.

[199] Macrophages are the major cells involved in the control of the tissue repair process, degrading and removing components of damaged connective tissue, such as collagen, elastin and proteoglycans.

[200] Macrophages provide chemotactic factors which attract inflammatory

cells to the wound region and produce prostaglandins, a dilator vessel that influences microvessel permeability. Macrophages produce several growth factors.

[201] The proposed product positively influences bringing the macrophages to the site of the wound.

[202] The healing process involves primarily three phases: inflammation, formation of granulation tissue and deposition of extracellular matrix and remodeling.

[203] Hypergranulation tissue is very important in the treatment of wounds, which may delay the healing process and develop a complex wound.

[204] Hypergranulation tissue presents as an excess of granulation tissue, forming beyond the level of the wound bed, generating tension at the edges, preventing the migration of basal epithelial cells and consequently healing.

[205] Linoleic acid together with vitamin E, present in the product proposed in this patent application, avoids hypergranulation.

[206] In order for healing to take place, cleaning and debridement of the wound is necessary. Cleansing consists of the use of fluids to remove bacteria, fragments, exudates, foreign bodies, residues of topical agents, since debridement refers to the removal of adhered necrotic tissues or foreign bodies and particles in the wound using mechanical, surgical or chemical techniques.

[207] Linoleic acid contributes to the production of MMP-1 (collagenase) and MMP-3 (stromelysin).

[208] Linoleic acid participates in the production of MMPs and, as a result, macrophages produce autolytic debridement and collagenases enzymatic debridement aiding in the formation of granulation tissue.

[209] Linoleic acid, through the action of the enzymes elongase and desaturases, becomes prostaglandins and leukotrienes, which are immunomodulatory.

[210] Triacylglycerol, also known as triglycerides, is the generic name for any tri-ester from the combination of glycerol (a trialcohol) with acids, especially

fatty acids (long chain alkyl carboxylic acids), in which the three hydroxyls (of glycerol) underwent carboxylic condensation with the acids, which need not necessarily be equals. Triacylglycerols are readily recognized as oils or fats.

[211] In a simplified way, a triacylglycerol is formed by the union of three fatty acids to a molecule of glycerol, whose three hydroxyl (-OH groups) bind to the carboxylic radicals of the fatty acids.

[212] Caprylic and capric acids triglycerides are medium chain triglycerides (MCTs) consisting mainly of esters of caprylic (C8) and capric (C10) acids.

[213] Due to chain size, caprylic and capric acid triglycerides have excellent alcohol solubility and hence their importance in the applicability of pharmaceuticals. These compounds are considered to be toxicologically and dermatologically innocuous and are classified as GRAS (Generally Recognized As Safe) by the FDA.

[214] Totally saturated emollient triester, recommended as an alternative for mineral or vegetable oil in various personal care and pharmaceutical products, due to its structural composition. In addition, it is lubricating and emollient, giving fine and soft emollience leaving a non-occlusive film on the surface of the skin. It is a good spreader, an excellent vehicle or diluent for active principles in topical preparations, good solvent for chemical sunscreens, has excellent dermatological behavior, is nontoxic, has low turbidity, is inert and stable to oxidation.

[215] Capric triglyceride is a combined triester, a mixture of capric and caprylic acids. It is also known as fractionated coconut oil. Its most popular use is as a emollient (to soften the skin) because of its ability to rapidly penetrate. This compound is a very popular ingredient in various skin care products and soaps.

[216] Some benefits of capric triglyceride include the fact that it is not oily and has a very light texture. It is also quickly absorbed, being highly compatible with the skin.

[217] Capric triglyceride is derived from coconut. Before the oil is even processed, it has high levels of saturated fat, with a content of plus or minus 90%. In its purest form, it has a milky color, although after refinement, the oil becomes transparent (and liquid at an approximate ambient temperature of 25 degrees celcius).

[218] The essential fatty acids increase the resistance of the skin.

[219] Long-chain polyunsaturated fatty acids, including linolenic acid, play important cellular roles, such as maintenance of membrane integrity and fluidity, membrane enzyme activities and eicosanoid synthesis, such as prostaglandins, leukotrienes and thromboxanes. These, in turn, have the capacity to modify inflammatory reactions, stimulate platelet aggregation, promote the action of leukocytes in the lesion and immunological, altering leukocyte functions and accelerating the process of tissue granulation. All this contributes to the process of epithelialization and epidermal maturation.

[220] The application of these products protects the integrity of the skin and increases its hydration. Essential fatty acid-based creams such as linoleic acid, caprylic acid, capric acid, vitamin A, vitamin E and soy lecithin are used for this purpose.

[221] Essential fatty acids are necessary to maintain the integrity of the skin, due to its ability to function as a water barrier. These acids act by promoting chemotaxis and angiogenesis, keeping the medium moist and, thus, accelerate the process of tissue granulation.

[222] In addition to the prevention and treatment of pressure ulcers, they can also prevent and treat dermatitis, venous and neutrophic ulcers, open ulcers with or without infection.

[223] Medium Chain Triglycerides (MCTs) - capric acid, caprylic acid, caproic acid and lauric acid are used as vehicle and emollient.

[224] Lanolin in moisturizing creams, soaps and shampoos is a material made up of several types of substances, obtained from sheep's wool.

[225] Lanolin consists of various compounds, including esters and

polyesters of long chain alcohols and fatty acids, predominantly unsaturated fatty acids, represented by a high proportion of eicosapentaenoic (EPA), linoleic and docosa-hexaenoic-acid (DHA).

[226] It is obtained as a byproduct of sheep wool cleansing. Lanolin is a yellowish grease and is excreted by the sebaceous glands of these animals.

[227] Lanolin as a skin moisturizer can prevent the loss of water by the skin, keeping it hydrated, because its long chains have polar ends that attach to the water molecules in the skin.

[228] This moisturizing action makes it a moisturizing or emollient (softening) substance, also increasing the hydration and elasticity of the skin. Because of this, many breastfeeding mothers use this moisturizer on their breasts to prevent cracking and pain.

[229] For the healing process, some wound treatment and cicatrization medications contain lanolin as an ingredient.

INFERENCES

[230] Linoleic acid, the main fatty acid in the omega-6 family associated with caprylic and capric acids, has potent anti-oedematogenic topical action. It exerts an important chemotactic role for macrophages, being fundamental in the expression of components of the fibrinolytic system (regulation of collagenase production); favors the autolytic debridement in the bed of the wound by contributing with the production of metalloproteins, inducing the granulation and being able to accelerate the cicatrization process.

[231] It has been observed that, in vitro, linoleic acids inhibit the growth of *S. aureus* by acting as antimicrobial agents and can be used in the treatment of wounds.

[232] Inhibition of growth of *Staphylococcus aureus* by linoleic acid, as it alters the synthesis of proteins, cell walls, nucleic acids and cell membranes during division.

[233] Essential fatty acids and vitamins A and E present excellent results in healing and restoration of the skin, having a rapid and efficient response with

the development of granulation tissue, intense angiogenesis and acceleration of the healing process in a few days, together with the low cost and free from side effects.

[234] Studies have evaluated the influence of topical administration of linoleic acid (n-6) on the wound healing process in rats. It was observed that animals treated topically with linoleic acid showed a significant reduction in the area of the wound from the 5th day.

[235] The Ministry of Health of Brazil recognizes the importance of Essential Fatty Acids (AGEs), indicating it for prevention and treatment of dermatitis, pressure ulcers, venous and neurotrophic; treatment of open sores with or without infection. (Manual de Conduas para Úlceras Neurotróficas e Traumáticas - MS; pg 42; 2002)

[236] The Brazilian Society of Dermatology also recognizes the importance of "Essential Fatty Acids (AGEs) and indicates that they can be used in all types of injuries, in the various stages of the cicatricial process and as a preventive of injuries."

[237] Brazilian Association of Pharmacists affirms: The topical application of fatty acids in the treatment of wounds should be considered as an important therapeutic tool.

[238] Medium Chain Triglycerides may have uses in the treatment and prevention of ammoniacal dermatitis and pressure ulcers, forming a protective barrier to the skin, preventing maceration, and being of importance in the processes of cellular inflammation, providing relief after the first application and local cellular nutrition, in addition to having a great capacity for tissue regeneration.

[239] The proposed product is a safe, effective and inexpensive drug and is excellent for the treatment of skin wounds as it effectively collaborates in healing and analgesia.

[240] In view of the foregoing, there is the patent right to the proposed product, topical cream for healing of chronic or acute skin and mucosal lesions,

as it meets the novelty requirement of the rules of patents for inventions of the Law of Intellectual and Industrial Property of Brazil in its new Article 8.

PREPARATION

[241] 1. Heat the polyethylene, petrolatum, butylated hydroxyanisole, benzyl alcohol, cetostearyl alcohol, mineral oil, sorbitan stearate, cetyl palmitate, polysorbate 60 and lanolin to 75 ° C in a water bath.

[242] 2. Heat the water to 70 ° C and dissolve the disodium EDTA and butylene glycol;

[243] 3. Pour the components of item 4 into the container containing the components of item 3, stirring moderately and maintaining the temperature for eight to ten minutes, until emulsion formation, preventing the development of foam;

[244] 4. In a suitable container, it triturate the zinc oxide and talc;

[245] 5. Decrease the stirring rate and cool to 35 ° C and add under stirring zinc oxide, talc, cod liver oil, DMDM Hydantoin and Iodopropynil Butylcarbamate (IPBC), lavender, vanillin solubilized in alcohol q.s., unsaturated fatty acid and triglyceride of capric and caprylic acids;

[246] 6. Stir until the mixture is homogeneous;

[247] 7. Add powdered clotrimazole;

[248] 8. Wait 24 hours to add retinol, cholecalciferol, vitamin E, and clotrimazole to this ointment base.

HOW TO USE

[249] Wash affected area with warm water and mild soap, rinse and dry the skin with soft fiber tissue without rubbing.

[250] After cleaning apply the proposed product in this patent application as a thin layer, spreading it lightly over the affected area.

[251] Perform this process four times a day until complete healing of the lesion.

CLAIMING

1. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions characterized by synergic action of active ingredients clotrimazole, vitamin A, vitamin E, vitamin D, oxide of zinc and linoleic acid associated with capric and caprylic acids and of excipients, being that the healing composition is applied directly onto the wound and affected adjacent areas.

2. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that the composition comprises from about 0,02% to about 0,463% by weight of clotrimazole, from about 0,205% to about 0,263% by weight of retinol, from about 0,0003% to about 0,0008% by weight of cholecalciferol, from about 0,158% to about 1,03% by weight of vitamin E, from about 3,06% to about 6,02% by weight of zinc oxide, from about 15% to about 33% by weight of triglyceride of caprylic and capric acids and from about 8,75% to about 16,89% by weight of linoleic acid.

3. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that clotrimazole, linoleic acid, retino and vitamin E act synergistically promoting healing.

4. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that autolytic debridement is optimized by linoleic acid accelerating the regeneration of tissues.

5. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and

faecal incontinence, and other related lesions according to claim 1, characterized by the fact that linoleic acid and vitamins A, D and E contribute to the development of granulation tissue and promote angiogenesis in order to accelerate the healing and restoration process of the skin.

6. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that clotrimazole is a high efficiency antifungal.

7. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that oily components of the cream have bactericidal action due to the presence of linoleic acid, which stimulates the inflammatory process, angiogenesis, migration and cell proliferation and increases the resistance of the skin.

8. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that healing composition optimizes tissue reepithelization.

9. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that healing composition has essential fatty acids, especially linoleic acid, vitamin A, D and E, capric acid and caprylic acid, which together possess potent antiedematogenic activity, favor the autolytic debridement in the wound and induce granulation accelerating the process of healing.

10. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and

faecal incontinence, and other related lesions according to claim 1, characterized by the fact that zinc oxide has astringent and antiseptic properties, acting as a healing agent and protector of the skin in conditions that present superficial eruptions.

11. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that zinc oxide forms a protective layer on the injured skin surface, preventing the irritation by the air and fixing the clothes on the skin, thus reducing the burning and pruritus, creating an environment conducive to the cellular recovery, besides what, given its dry effect, makes the medium unfavorable for bacterial growth.

12. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that Zinc oxide reduces skin redness, a secondary symptom of inflammatory processes, and is effective in cases of rashes, bedsores and all kinds of skin irritation.

13. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that topical application of vitamin D exerts control of the microbial flora on the damaged skin, attracting cells of the immune system, promoting the epithelial repair and increasing the angiogenesis necessary for the healing of the skin.

14. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that vitamin E has anti-inflammatory, soothing and healing properties, promoting an increase in phagocytic activity allowing healing.

15. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that wound healing composition and disinfection and tissue restoration, has as its coadjuvant ingredients the DMDM Hydantoin, cod liver oil and lanolin that contribute synergistically with the other substances of the composition to the healing of the lesions.

16. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that Vitamin A has antioxidant power helping in skin regeneration, participates in cell nutrition and replenishes collagen, penetrates the skin and normalizes the keratinization process and its interaction with certain DNA sequences, regulates the production of certain proteins and enzymes, reducing the signs of damage to the skin.

17. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 15, characterized by the fact that Cod liver oil is rich in vitamins A and D, being beneficial for tissue metabolism, controlling inflammatory reactions and acting synergistically with zinc oxide, helps in protecting the skin.

18. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 15, characterized by the fact that DMDM Hydantoin and Iodopropinyl Butylcarbamate (IPBC) inhibits the growth of grass-positive and gram-negative bacteria, yeasts and mold.

19. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 15,

characterized by the fact that lanolin has a moisturizing action making it a moisturizing or emollient substance, increasing the hydration and elasticity of the skin, thus contributing to the healing process.

20. A healing, moisturizing, humectant and emollient composition for topical administration in intertrigo skin lesions, skin lesions due to urinary and faecal incontinence, and other related lesions according to claim 1, characterized by the fact that is a restorative and healing composition of the skin.