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Report on “Losterin” cream clinical approbation in complex and mono therapy of chronic dermatosis accompanied by hyperkeratosis

Clinical base: Dermatovenerologic dispensary # 9 of Public Health authority of Moscow Central administrative region, Dermatovenerologic dispensary # 30, Zelinograd administrative region of Moscow

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Moscow 2011

Introduction

Majority of skin diseases may be listed as chronic dermatosis, accompanied by hyperkeratosis and exfoliation. Among these are such common diseases as: psoriasis, atopic dermatitis with lichenification, squamosal hyperkeratotic form of mycosis, as well as such rare nosological entities as ichthyosis, keratoderma, etc.

Due to that, medical practitioners face such patients daily, most of the time they are the majority of adult consultation group. Pharmacology achievements, in particular combination of steroids with exfoliating medications, allowed to improve the life quality of patients significantly, and medications availability at pharmaceutical network has reduced doctors activity in prescribing medications according to old fashioned reliable prescriptions, since it drastically reduced treatment compliance.

On top of that, traditional prescription medications stand down to effectiveness of official ointment medications and its organoleptic and cosmetic properties. With the course of time, doctors and patients start using ready-to-use external medications more seldom.

However, the time has gone by, and new issues arose in the matter of dermatosis treatment accompanied by hyperkeratosis. Such issues are: usage duration of combined medications and monosteroids, anti-relapsing and preventive therapy, treatment for hyperkeratotic processes and exfoliation, correction of which was initially troubled due to genetic nature of disease.

At present, there takes place re-evaluation of cosmeceutics in a therapy of skin treatment for patients with such chronic dermatosis. There is a line of modern (mainly foreign) medical cosmetics for hyperkeratosis skin treatment, which are highly recommended, but may hardly likely be available for a daily use and are often limited by such actions as smoothening, exfoliation and moisturizing. Antiproliferative, resolving, antipruritic, anti-inflammatory,

antibacterial and wound-healing actions are usually left to basic medications, in most cases based on steroids.

However, such properties, with preservation of such properties as smoothening, moisturizing and exfoliation effects are common for classic dermatropic ingredients: naphthalan, urea, salicylic acid, D-panthenol, a complex of natural oils, alkaloids and flavonoids. Such medications are present on the market in one form or another, however cosmetic organoleptic properties of pastes produced on a base of these components are far from being ideal and are not used by patients very often.

That is why, there appeared a necessity to develop and apply a cosmetic product, which would not contain glucocorticosteroid hormones, coloring agents and fragrances, made in accordance with traditional dermatological prescriptions with all described above qualities, produced on acceptable organoleptic and cosmetic base, with a reasonable price and increased compliance. That very job has been performed by an interstate company LLC "Greenwood", which created "Losterin" cream, containing naphthalan (3%), urea (10%), salicylic acid, D-panthenol, Japanese pagoda tree extract.

Main active ingredients of Losterin cream (according to manufacturer):

Resin free naphthalan (3%) is a purified from resinous substances, with a significant anti-inflammatory, anesthetic, vasodilating, desensitising and antibacterial action, improves microcirculation, increases metabolic process intensity and stimulates skin trophic functions.

Carbamide/Urea (10%) is an effective moisturizing agent, easily penetrates into deep layers of epidermis, and serves as a conductor for other active ingredients of medication. Possesses keratolytic (exfoliating), wound healing and bacteriostatic properties.

Salicylic acid (0,1%) is an active component of willow bark. Possesses anti-inflammatory, antiseptic, wound healing and keratolytic actions.

D-panthenol (provitamin B5) stimulates skin and mucous coat regeneration, normalizes cellular metabolism, accelerates mitosis and increases durability of collagen fibers. It possesses regenerative and anti-inflammatory action.

Japanese pagoda tree extract contains a complex of alkaloids and flavonoids, including rutin, which possesses anti-inflammatory action, able to thicken vascular walls and decreases its fragility. Japanese pagoda tree alkaloids are able to suppress proliferation of keratinocytes, reducing skin exfoliation. Japanese pagoda medications are used for purulent inflammation processes (wounds, burns, trophic plaques), seborrhea, psoriasis, inflammation and dermatomycosis of skin, eczema, lupus, furunculus.

Thus, "Losterin" cream components possess significant anti-inflammatory, antipruritic, exfoliating and anti-microbial action, promotes skin regeneration, increases skin barrier, prevent the feeling of dryness and irritation.

Clinical approbation goals:

1. To evaluate effectiveness and safety of Losterin cream in a therapy of patients with chronic dermatosis accompanied by hyperkeratosis
2. To identify subjective evaluation of Losterin cream application effectiveness as a monotherapy and combined therapy in comparison with previous treatment, received by the patient.

3. To evaluate patients' subjective tolerance and adherence to treatment.
4. To evaluate possibility of Losterin cream long-term prophylactic use.

Clinical bases: Approbation took place on a base of Dermatovenerologic dispensary # 9 and 30 of Public Health authority of Moscow

Inclusion criteria:

- Presence of chronic dermatosis accompanied by hyperkeratosis.
- Disease length period – no less than 5 years.
- Previous therapy with other medications and cosmetic products.
- Process exacerbation within at least a month before consultation, treatment absence for at least 2 months before the beginning of “Losterin” cream usage.
- Standard consent of a patient.

Exclusion criteria:

History of allergy to medication components

Study materials and methods:

Number of patients taking part in a study is equal to 20. Patients' age- from 19 to 66 years old (no age requirement). Size of the effected skin area was not a selection criterion, however most patients had local effected area of 1-5% of body (calculations performed based on a “palm size” rule).

Safety and clinical effectiveness control in the group took place weekly, with a further preventive regime of application – once every 2-4 weeks in accordance with standard maps (see enclosures) with a further algebraic calculation.

Organoleptic and cosmetic properties of medication were evaluated subjectively, during the last consultation after the end of the treatment course.

Patients classification according to disease:

Disease/patients number (localization)	Previous therapy		Therapy during study period	
	Local	System	Local	System
Psoriasis vulgaris/2 (elbows, knees, singular plaque on body)	Topic steroids, mainly combined with salicylic acid	Hepatoprotectors, B group vitamins, vascular and desensitizing medications	Losterin monotherapy	Hepatoprotectors, B group vitamins, vascular and desensitizing medications
Eczema (mainly tilotic forms) / 12 / (hands and/or feet)	Topic steroids, mainly combined with salicylic acid	Antihistamines, calcium medications, vitamins A and E	Losterin monotherapy – 8 patients, combined with topic steroid – 4 patients, in 4 weeks – preventive application – 9 patients	Antihistamines, calcium medications, vitamins A and E

Atopic dermatitis with severe lichenification / 2 (bend of elbows, poples)	Topic steroids, mainly with no salicylic acid, cosmetic products	Antihistamine, calcium medications, vitamins A and E	Combination with topic steroid, in 4 weeks – preventive application	Antihistamines, calcium medications, vitamins A and E
Feet mycosis, squamosalhyperkeratotic form / 2 (feet)	External antifungal medications	-	Combination with antimycotic medication, in 4 weeks – preventive application	-
Professional eczema / 1 (hands)	Softening creams, rarely – topic steroids	Rarely - antihistamines	Losterin monotherapy	-
Plantaris keratoderma / 1 (feet)	Salicylic acid, Radevit	Vitamins A and E	Losterin monotherapy, in 4 weeks – preventive application	Vitamins A and E

“Losterin” cream application method:

Medication is used on effected areas 2 – 3 times a day (no limitations on area size). Treatment course – 28 days.

Study results:

While evaluating received results, we have to note that the selection does not allow any general conclusions. Thus one patient with psoriasis and one patient with a professional eczema noted disease exacerbation after 2 weeks of Losterin cream therapy, therefore they stop the treatment. The occurrence of positive changes timeframe for the second patient with psoriasis stood down to that, while using traditional therapy, therefore we made a decision not to include patients with such dermatosis into the study.

In other cases, for the patients with atopic dermatitis, feet mycosis and plantaris keratoderma, we have noted progredient reduction (at a weekly evaluation) of such symptoms as hyperkeratosis, exfoliation, cracks, erythema, oozing exfoliation during mycosis, itching. By the end of the 4th week of Losterin cream usage, it was possible to achieve full clinical remission (for mycosis, atopic dermatitis, most of eczemas), which was positively evaluated not only by the researches, but also by patients. Subjective evaluations (compared to the previously used external medications) were also on the side of Losterin cream application.

14 patients of the group expressed a desire to use cream for the preventive measures, however such usage regime had not been developed or offered by the manufacturing company, therefore we did not recommend the reduction of application to once a day.

The first patients’ feedback results, received by us were hopeful.

All patients gave positive evaluation to organoleptic and cosmetic properties of the cream, packaging quality and convenience of use, there were positive comments on LLC “Greenwood” price policy. There were no side effects noted on application area during cream approbation.

Conclusion:

1. Clinical effectiveness among the patients with chronic dermatosis accompanied by hyperkeratosis varies depending on a particular disease, however in general, cream may be evaluated as an effective and safe cosmetic product for this diseases group. Prescription list should be further confirmed and specified depending on the forms and the stages of pathological skin processes.
2. The majority of patients considers it rational to use Losterin as a monotherapy or in a combination with other medications, compared to their previous treatments.
3. Losterin cream (according to subjective evaluations) is well tolerated; there has been noted a high compliance rate of patients towards the therapy.
4. Due to the safety of Losterin cream components and its multi-sided actions, there is a possibility to use it long-term as a preventive measure of chronic dermatosis accompanied by hyperkeratosis. Such opportunity evaluation is a subject for further investigations.

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