

## State Health Institution “Tulskiy dermatovenerologic dispensary”

Approved by  
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### Clinical study report on effectiveness and application safety of “Losterin” cream in chronic dermatosis therapy among children

**Clinical base:** State Health Institution “Tulskiy dermatovenerologic dispensary”

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The most popular skin disease among children is atopic dermatitis (AtD) and different eczemas (E). Lately there has been noted a stable growth of such dermatosis, and it is highly spread. Disease data lead to lowering of child’s socioenvironmental adaptation.

Atd is a chronic allergic dermatosis among persons with a genetic predisposition to atopy, characterized by exudative and/or lichenous eruption, increased serumal Ig E and hyperresponsiveness to specific and non-specific stimulants (Batkaev E. A., 2011). Some authors assume, that the main releasing mechanism in AtD development is inflammation, arising due to penetration of allergens and irritants into skin. Others believe that the main chain in AtD development is a damage of epidermal skin barrier, which leads to inflammation development due to allergen penetration. Thus, AtD is a disease of multifactorial nature. Eczema is a chronic reoccurring disease with severe inflammatory symptoms, caused by serous inflammation of epidermis and derma (N. G. Korotkiy). It is characterized by evolutionary polymorphism of eruption elements, oozing and itching. The process begins mainly with face, hands, and has a tendency to spread on body and limbs. One of the eczematous forms is dyshydrosis, which, in its turn, differs by localization on palms and feet where (due to a horny layer of epidermis) erythematous stage is demonstrated slightly, with prevailing of well-formed vesicle – so called “sago pearls” (N. G. Korotkiy). There is clinically proven fact, that external therapy is pathogenically reasoned and required for every patient with AtD and E. During held studies, it has been also proven, that positive results in disease treatment may be achieved by using not only topic glucocorticosteroids, but also by using non-hormonal medications based on natural components, traditionally used in dermatology (naphtalan, urea, salicylic acid, oil tar, etc.). It significantly reduces the risk of side effects, removes a need for long term use of corticosteroids, helps to support remission.

Together with dermatologists, “Bestwood Pharma” company has developed “Losterin” cream medication (75 ml), for application in complex treatment of skin for patients with different dermatosis.

Losterin cream contains a complex of active components, traditionally used for skin diseases treatment:

- **Resin free naphtalan** (3%) is a purified from resinous substances, with a significant anti-inflammatory, anesthetic, vasodilating, desensitise 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 exfoliating properties.
- **D-panthenol** (provitamin B5) stimulates skin and mucous coat regeneration, normalizes cellular metabolism, accelerates mitosis and increases durability of collagen fibers. It increases reparative and barrier skin functions, provides 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.
- **Almond oil** contains vitamins E and F, complex of fatty acids, the main of which is oleinic acid. It regulates lipid and water skin balance, activates cell regeneration process, possesses anti-inflammatory, cleansing, soothing, nurturing properties, has anesthetic and antipruritic actions.

**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.**

#### **Losterin cream is recommended for:**

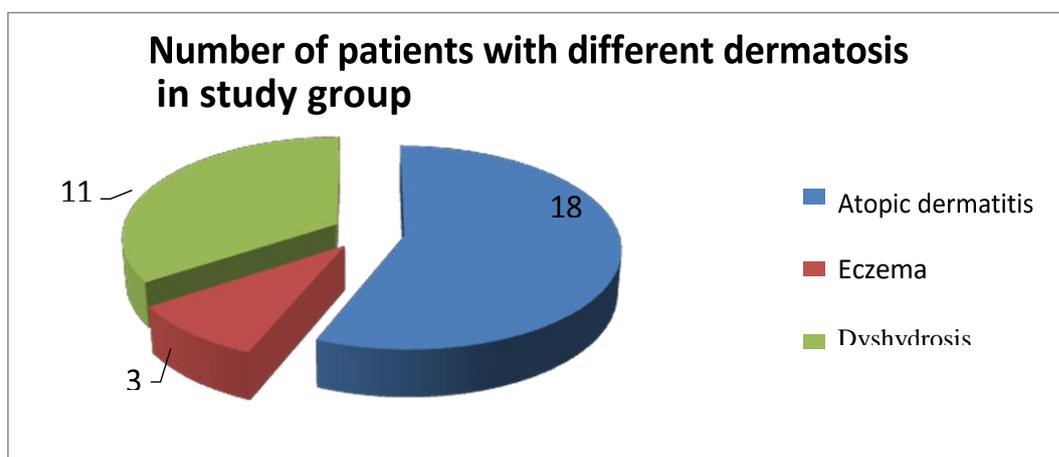
- Complex therapy for different forms of dermatitis/dermatosis with severe skin dryness: Psoriasis, eczema, atopic dermatitis, seborrhea dermatitis, ichthyosis, xerosis;
- For chronic dermatosis exacerbation prevention, remission prolongation;
- For damaged skin barrier, skin dryness and irritation.

**Clinical approbation goal** – is to evaluate effectiveness and safety of Lorestin cream in a therapy of chronic dermatosis among children.

**Clinical base:** Study took place at State Health Institution “Tulskiy dermatovenerologic dispensary” (Tula city).

#### **Study materials and methods.**

There were 32 children (15 boys, 17 girls) under surveillance in State Health Institution “Tulskiy dermatovenerologic dispensary”, who were suffering from atopic dermatitis, eczema and dyshydrosis. Patients age – from 9 months to 18 years.



Patients were under surveillance for 21 day. All patients used Losterin cream in a period of disease exacerbation as a monotherapy. The medication was used on affected areas twice a day (with no limitations regarding the area size).

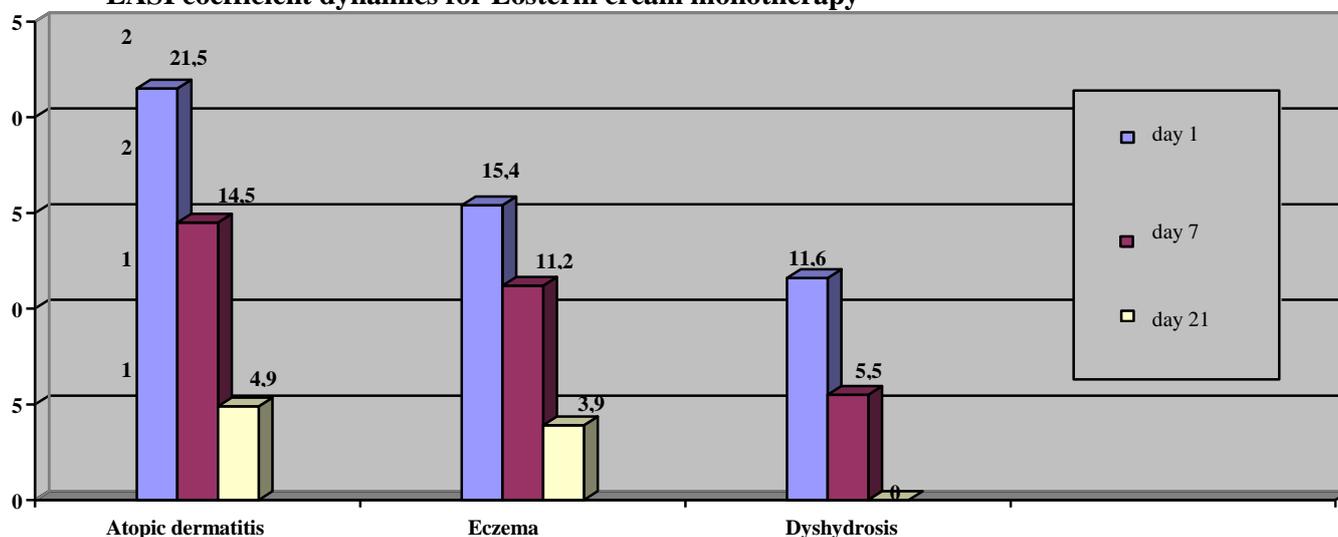
Index EASI was used to objectively evaluate clinical demonstration severity level and therapy effectiveness. EASI index below 20 points corresponded to light severity, from 20 to 60 – medium severity.

Criterion for therapeutic effectiveness of conducted treatment was a regress of disease clinical demonstrations and reduction of EASI index points.

**Study results:**

An average group EASI index among the patients with atopic dermatitis was 21,5 prior treatment. Significant improvement after beginning of Losterin cream therapy was noted on day 7, as an erythema reduction or resolution, swelling, papulose reduction, itching reduction (an average EASI index in a study group was 14,5 points). By the end of 21 day of treatment, EASI index in a study group came to 4,9 points (complete of partial resolution of inflammation area, significant reduction of dryness and itching).

**EASI coefficient dynamics for Losterin cream monotherapy**



EASI index among the patients with eczema in the study group prior to treatment was equal to 15,4 points. By the end of day 7 of treatment, we noted partial resolution of inflammation area, erosion epithelialization (average EASI index in the study group equaled to 11,2 points). By the end of 21<sup>st</sup> day of treatment, EASI index among the patients of this group equaled to 3,9 points.

An average EASI index among the patients with dyshydrosis was 11,6 points. All patients noted positive dynamics within the first week of treatment – dryness and hyperkeratosis have significantly reduces, there was noted cracks epithelialization (average EASI index among the patients equaled to 5,5). By the end of 21<sup>st</sup> day of treatment, dermatic process had regressed fully, with an average EASI index equaling to 0 among the patients.

Conducted clinical study proved Losterin cream high clinical effectiveness.

Diagnosis	Remission (%)	Improvement (%)	No changes (%)
Atopic dermatitis	67%	32,5%	0,5%
Eczema	72%	28%	–
Dyshydrosis	100%	–	–

67% of the patients of group with atopic dermatitis have reached full remission, 32,5% of them had improvements, and only 0,5 % of the patients had no effect from the conducted therapy.

72% of the patients of group with eczema have reached full remission, 28% of them had improvements. Full clinical cure was achieved among all patients with dyshydrosis (100%).

### **Conclusion**

Thus, conducted clinical study proved effectiveness and safety of Losterin cream application for children starting from the age of 9 months. Natural ingredients of Losterin cream possess significant anti-inflammatory, antipruritic, exfoliating action, promotes regeneration of effected skin, prevent the feeling of dryness and irritation. In order to achieve stable results, it is necessary to apply Losterin cream twice a day during 14 – 21 days.

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