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Lukoskin: A pragmatic approach of Ayurveda, scientifically validated by modern clinical studies

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ABSTRACT

Leucoderma is wide spread on the world map in its prevalence. India is on top having high incidence of this disease. A newer poly component herbal formulation for promising treatment of Leucoderma, both for topical and oral use has been formulated and evaluated for efficacy, safety and non-toxicity by Defence Research and Development Organization (DRDO). The clinical study carried out at Govt. District Hospital, Pithoragarh, showed that 65% of patients completely recovered while the rest 35% were in the phase of recovery during the clinical study period of 90-750 days. The studies have been further supported by other clinical experiences as well.

INTRODUCTION

Nearly 100 million people worldwide are affected by vitiligo. Gujarat, India is considered to have the highest prevalence in the world with 8.8% of the local people affected by Vitiligo. It remains unclear what causes damage to melanocytes and their subsequent total inactivation and/or disappearance in Vitiligo skin. There are several theories; the most prominent are autoimmune, neurohumoral, related to abnormal detachment of melanocytes from the epidermal layers and auto cytotoxic. None are mutually exclusive, and it is likely that each of them partially contributes to the disease development.

SCIENTIFIC STUDIES

A) Clinical evaluation of lukoskin for efficacy

The product was evaluated clinically on patients of different ailment age and extent of disease spread, under the active guidance and supervision of the Allopathic and Ayurvedic Doctors from Govt. District Hospital, Pithoragarh.

The product was distributed to more than 600 patients out of whom 100 patients were placed under the regular observation.¹

Result: The observations revealed that out of 100 patients, 65 were completely recovered and the rest 35 were in the phase of recovery during the study period of 90-750 days in both groups. Patients tolerated the medicine very well and no untoward effects were observed.¹

B) Experimental Studies for Efficacy

Experimental studies for about 60 days with Polyherbal formulation in the form of oral liquid and Ointment in black hair mice was carried out. Animals were divided in four groups. Group 1 served as control group, received neither ointment nor oral liquid. Group 2 received both oral liquid and ointment either on one side or on both sides. Group 3 received only ointment and no oral liquid, where as group 4 received only oral liquid and no ointment. *Among these, group 2 showed most promising & efficacious results of skin pigmentation and intense anagenic recurrence as manifested by bluish skin with pigmentation and jet black hair growth against the control mice with pinkish skin and grey hair.*²

C 1) Safety studies for non-cytotoxicity

Studies revealed that no change in food and water intake, skin fold thickness or body weight in the treated groups

Table 1 Study findings according to body part affected

Recovery according to body part affected					
Body part	No. of patients under treatment	Recovery		Efficacy (%) complete recovery	Time taken (days)
		Above 60 (%)	100 (%)		
Arms	13	4	9	69.23	250-700
Feet	23	8	15	65.21	250-750
Head	28	10	18	64.28	220-280
Neck	19	6	13	68.42	220-250
Thorax-hips	17	7	10	58.82	90-180
Total	100	35	65	65.00	90-750
Maximum efficacy 69.23% was recorded in Arms affected patients					

Table 2 Study findings according to age and sex wise ratio

Category	No. of patients under treatment	Recovery		Efficacy (%) complete recovery	Time taken (days)
		Above 60 (%)	100 (%)		
FEMALE					
Below 40 yrs.	32	06	26	81.25	90-250
Above-40 yrs.	10	04	06	60.00	250-550
MALE					
Below-40 yrs.	35	10	25	71.42	250-600
Above-40 yrs.	23	15	08	34.78	350-750
TOTAL	100	35	65	65.00	90-750
Maximum recovery was found in females below 40 years of age					

were seen. Non-cytotoxicity evaluation studies on mouse melanoma cells (B₁₆ F₁₀) showed non-cytotoxicity upto **400 mg/ml** with **Lukoskin ointment** constituents and **200 mg/ml** with **Lukoskin oral liquid** constituents.²

C 2) For ointment - Skin irritation test

The acute dermal toxicity/ skin sensitization studies were carried at ITRC, Lucknow with Polyherbal anti-leucoderma formulation, on mucous membrane for irritation test on rabbit vagina and observed for any visible sign of erythema or oedema. *The product was found to be non irritant to mucous membrane and did not produce any signs of erythema or odema in vaginal mucous membrane of rabbit.* In acute dermal toxicity, LD₅₀ was found to be more than 2000mg/kg body weight. In sub acute dermal toxicity, animal tolerated the total dose and did not show any adverse effects on their health. In skin sensitization test, it was found to be non-sensitizer in Guinea pigs. Further primary skin irritation tests showed that extracts induced mild erythema on the day of application and there was no effect 24 hours later.³

C 3) Safety studies for oral liquid

The acute oral toxicity of liquid oral dose was evaluated at ITRC, Lucknow, using male and female healthy rats. Five rats of each sex were dosed, acclimatized, fed with standard animal diet and water ad libitum along with anti-leucoderma product. LD₅₀ was found to be above 5000 mg/kg body weight, with no significant difference in feed and water intake and general behavior being normal, with no sign of any toxicity in treated group as compared to control group.³

DOSAGE0: Ointment was applied gently from pigmented to non-pigmented area, once or twice a day and oral liquid was taken simultaneously. After half an hour the area was exposed to sun either before 11 am or after 3 pm for 5-20 mins. Mild irritation/blister was considered to be a positive sign for erythema/ pigmentation. In some hypersensitive patients if severe irritation persisted, the medicine was diluted with Chameli (Jasmine) oil before application. **Oral liquid** in Adults 1 to 2 ml. (20 to 40 drops) and in children ½ ml. to 1 ml. (10 to 20 drops) diluted in a cup of water twice or thrice a day.⁴

Table 3 Beneficial Advice for Leucoderma Patients for better and speedy recovery⁴

Particulars	Encouraged to be followed	May be followed	Discouraged to be followed
Food intake	Nutritious, Easy to Digest	Nutritious, Easy to Digest	Acidic, Sour, Difficult to Digest, Mutton, Chicken, Fish/ Sea Food, Eggs, Junk Food, Samosa, Chole Batture etc.
Vegetables	Lauki juice, Carrot, Petha, Sitaphal, Beetroot, Mushroom	Green Vegetables -Spinach, Broccoli, Beans; Onion Cooked, Tomato Cooked, Red Chillies, Green Chillies Cooked, Garlic, Potatoes, Cucumber/Kakri	Tomato Raw, Lemon, Raw Onion, Green Chillies,
Fruits	-	Banana, Chickoo, Watermelon, Coconut,	Citrus Fruit, Apple, Pear, Mango, Orange, Sweet Lemon, Pomegranate, Pineapple, Plum, Litchi, Peach, Papaya, Guava, Amla, Grapes
Dry Fruits	Almond, Peanut, Walnut, Flax seed	Cashew nut, Pistachio	Resins
Cereals/Pulses	Bengal Gram sprouted, Chapati	Mong, Arhar, Masoor, Corn, Upma, Rice, Soyabean, Wheat, Oats,	Urad dal, Maggi/Pasta, Bread, Fine Flour, Jelly, Cakes and Cookies
Fats	MUFA (Mustard) Oils, PUFA (Soya, Surajmukhi) Oils	Cow's Ghee (in moderation)	Avoid Excessive Intake of Fats/ Vanaspati Ghee
Sweets	-	Sugar, Jaggery, Honey, Chocklate	-
Milk/Milk Products	Take Milk with a gap of 2 Hrs. Form Any Food Article	Paneer and Butter (in moderate qty.)	Curd, Butter Milk, Fermented Milk Products
Drinks/Beverages	Copper Vessel Water	Non-Carbonated drink	Alcohol, Cold Drink (Carbonated/Sour)
Chemical Exposure	-	Harsh Detergent/Soap with gloves	Harsh Detergent/Soap/ Chemicals, Deodorants, Perfumes, Hair-colour, Scented Sticks, Mosquito Coils, Pesticides/Insecticides,
Scratching/Rubbing/ Prolonged Skin Contact	In case of irritation , application of Jasmine oil	-	Rubbing/Scratching in case of irritation. Use of Rubber Slippers/Footwares
Essential Nutrient Supplements	Vitamin and Minerals (VitB12, Folic Acid, Vit E, Alpha Lipoic Acid, Calcium, Potassium in recommended dosage.	Recommended Daily Advisable Dose	Excessive Intake Of Vit C

CONCLUSION

Leucoderma treatment still has been considered to be a challenge before the medical practitioners as it is very difficult to treat Leucoderma. The extensive clinical and experimental studies reveal that LUKOSKIN is highly effective, safe and non toxic in the recommended dosage. The product brings a ray of hope for Leucoderma patients who have been continuously under the darkness of the social stigma.

REFERENCE

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