

GREAT BREAKTHROUGH TREATMENT *for Leucoderma*

by

D.R.D.O.



**DEFENCE RESEARCH & DEVELOPMENT ORGANISATION
MINISTRY OF DEFENCE**

Research Technology Transferred to

AIMIL
PHARMACEUTICALS (INDIA) LIMITED



Giving back smiles

**Over 25000
patients benefited
with...**

LUKOSKINTM 

A Comprehensive & Safe treatment for Leucoderma

- ✓ **Scientifically Proven**
- ✓ **Clinically Evaluated**
- ✓ **Toxicologically Tested**

LUKOSKIN



Ointment/Oral Liquid

Enriched With Rare Selected Herbs
From Himalayas

Research Product of
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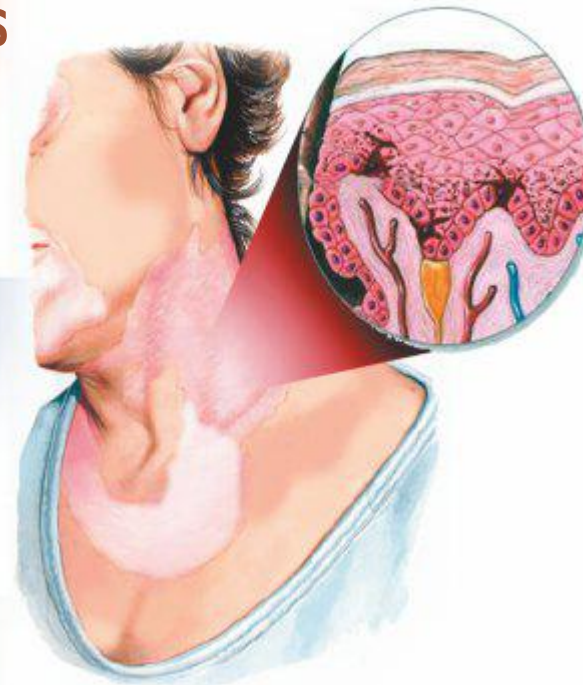


A REVOLUTION IN SKIN HEALTH CARE

A COMPREHENSIVE, SAFE AND LONG LASTING APPROACH IN THE MANAGEMENT OF LEUCODERMA

ACTIVATES MELANIN SYNTHESIS

Helps in the release of SH-group bound copper as free copper, which activates tyrosinase activity.



EXERTS PHOTOSENSITISATION

Helps to initiate erythema on the spots of vitiligo, due to its furanocoumarin contents on exposure to UV light or sunlight.

ENHANCES BLISTER HEALING

Reduces irritation and the formation of blisters, simultaneously checks hyperpigmentation in the skin.

VITILIGO or Leucoderma is an idiopathic, acquired disorder of skin, which causes pigmentary disfigurement mostly in dark skinned individuals. Patients with Vitiligo develop white spots in the skin with varying size and location. These spots occur when pigment cells or melanocytes are destroyed and/or pigment melanin can no longer be produced.



MODULATES IMMUNITY

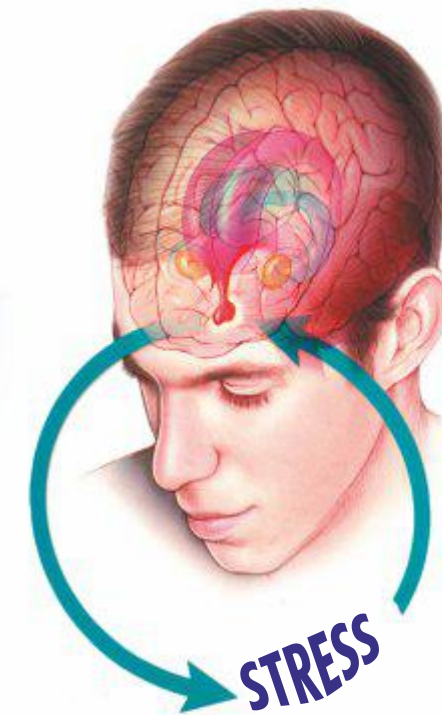
Modulates immunity with regard to both non-specific cellular and humoral immune response.

REDUCES STRESS

Exerts relaxing effect on CNS, thus helps improve psychological and emotional trauma in such patients.

REGULATES METABOLISM

Improves the hepatocytes functioning which gradually, helps improve the immune system.



Lukoskin is a result of extensive Research & Development, which has been processed meticulously, standardized for required parameters and studied clinically. DARL (Defence Agricultural Research Laboratory) has its core competence in development of herbal products, utilizing medicinal plants of high altitude areas of the Himalayan region for relieving the sufferings of mankind.



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STIMULATES PHOTSENSITIZATION & MELANIN FORMATION

ACTIVATES THE TYROSINASE ACTIVITY & FACILITATES AMINO ACID TRANSPORT



Ammi majus (Vishnag)

An important herb for the treatment of Leucoderma, has been introduced into India from Egypt and naturalized in Jammu region. It is found in Himalayas at a height of 4000-6000 ft. It is a rich source of furanocoumarins like methoxsalen & bergaptes.

Ammi majus (Vishnag) is rich in furanocoumarins well known as photo-sensitizer for initiation of erythema on the spots of Vitiligo by the exposure to UVA radiations or sunlight. Furanocoumarins accelerate the destruction of sulphhydryl groups by photo-oxidation and this may increase the formation of melanin in skin.

Ammi majus (Vishnag) helps in the release of SH-group bound copper as free copper, which activates the tyrosinase activity for melanin synthesis.

(Standardization of Botanicals, Vol 2, 2005)

FORMATION OF WHITE PATCHES ON SKIN



(a micronutrient needed for melanin synthesis.) (Free sulphhydryl groups in epidermal tissues)

Formation of $-SH - Cu$ complex

Availability of free Cu^{++} Decreases

Tyrosinase activity Decreases

(An Enzyme needed for conversion of tyrosine into melanin)

Melanin Synthesis Decreases

Depigmentation (Leucoderma)

ACTION OF LUKOSKIN

$-SH - Cu$ complex

(Inactivated / bound copper form)

LUKOSKIN

Source of Natural Furanocoumarins

in presence of UV Light (Sunlight)

Photo-oxidation

Breaks $-SH - Cu$ complex

Releases free Cu^{++}

Activates Tyrosinase

Tyrosine

Tyrosinase Enzyme

Melanin



Psoralea corylifolia (Bakuchi)

Psoralea corylifolia (Bakuchi) helps in the release of SH-group bound copper as free copper, which activates the tyrosinase activity for melanin synthesis.

Psoralea corylifolia (Bakuchi) contains furanocoumarins like psoralen, which stimulate skin to produce melanin pigment when exposed to sunlight & its seeds are believed to facilitate amino acid transport across the intestinal mucosa. Seeds are also a rich source of furanocoumarins, thus working as photo-sensitizer for the initiation of erythema on the spots of Vitiligo.

Furanocoumarins initiate the transformation of DOPA to melanin under the influence of UV Light or sunlight. Oxidation of the sulphhydryl groups may be responsible for the pigmentation as proved by the fact that epidermal tissues contain free sulphhydryl groups, which bind the copper required for the function of tyrosinase.

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ACTING SYSTEMICALLY - CORRECTING INTERNALLY

• SUPPLEMENTS COPPER AND L-DOPA

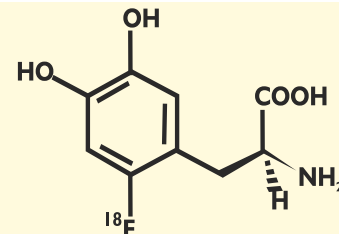


Mucuna pruriens (Kaunch)

Mucuna pruriens (Kaunch) is rich in L-DOPA (L-3,4- dihydroxyphenylalanine) and copper. Since L-DOPA is a precursor of melanin, it is easily converted to melanin.

(Biol sci space, 2004 Nov; 18(3):165-6)

L-dopa



Ash of *Psoralea corylifolia* (Bakuchi) & *Ammi majus* (Vishnag) is rich in copper therefore, it has been incorporated to supplement copper needed for the tyrosinase activity for melanin synthesis.

• EXERTS ANTI-INFLAMMATORY ACTION

Skin photosensitization is a free radical mechanism, which creates heat sensation & blister formation.

Calotropis sps. (Arka) & *Aloe vera* (Kumari)

.They exert anti-inflammatory effects mainly by inhibiting histamine and partly by inhibiting PGE₂, which further reduces irritation & hence blister formation.

(Mediators inflamm. 2005 Aug 31, (4): 228-232)

HASTENS BLISTER WOUND HEALING

Calotropis sps. (Arka) significantly augment the healing process by markedly increasing collagen, DNA & protein synthesis and epithelization leading to reduction in wound area.



Calotropis sps. (Arka) & *Aloe vera* (Kumari)

• IMPROVES AUTO-IMMUNE SYSTEM



Centella asiatica (Mandookparni)

Scientific studies revealed immuno-modulating activity of *Centella asiatica* (Mandookparni) with regards to both non-specific cellular and humoral immune responses.








Centella asiatica (Mandookparni) has liver restoring properties which gradually improves the auto-immune system and simultaneously exerts soothing effect on CNS, thus helps improve Psychological and emotional trauma in the patients. The scientific study revealed immuno-modulating activity of *Centella asiatica* (Mandookparni) with regards to both non-specific cellular and humoral immune responses.

(Askim Pac J cancer Prev. 2005 Jul-Sep; 6(3):396-400)

• RESTORES ANTI-OXIDANT DEFENCE

Ocimum americana (Krishn Tulsi) has been found to check possible oxidative damage of body tissues caused by free radical. *Ocimum americana* (Krishn Tulsi) has protective effect or anti-cataract effect supported by restoration of the anti-oxidant defence system i.e superoxide dismutase (SOD), glutathione peroxidase (GSTPx), Catalase (CAT) and glutathione-s-transferase (GST) and inhibition of protein insolubilization of lenses as well.

(Curr Eye Res. 2005 Jul; 30(7): 583-91)


NO UNDESIRABLE EFFECTS LIKE

NAUSEA

VOMITTING

HEADACHE

GASTRIC IRRITATION

PURGING


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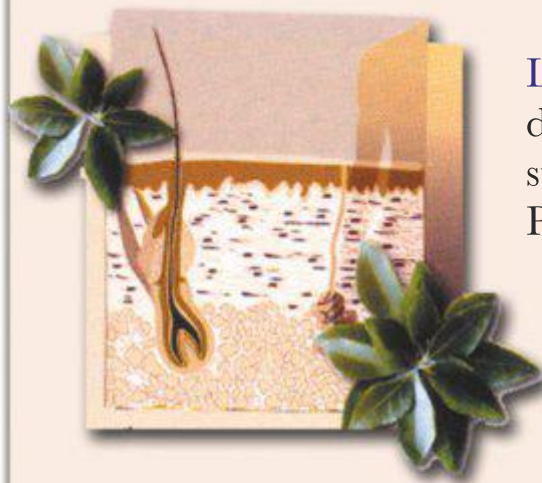


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EVALUTATION OF EFFICACY & POTENCY

CLINICAL STUDY CONDUCTED BY DRDO



Lukoskin is being evaluated on the volunteers of various age group of 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 OBSERVATION HAS PROVED THAT :

- OUT OF 100 PATIENTS 65 HAVE COMPLETELY RECOVERED
- REST 35 ARE IN THE PHASE OF RECOVERY
- MAXIMUM EFFICACY OF 69.23% WAS RECORDED IN ARMS AFFECTED PATIENTS
- DURATION OF TREATMENT WAS 90 TO 750 DAYS.
- NO SIDE EFFECTS OBSERVED.



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

Sex wise Recovery

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.

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EVALUATION OF SAFETY AND NON-TOXICITY

CLINICAL STUDY PROVING EFFICACY

Introduction

A clinical study was conducted with lukoskin to evaluate the efficacy and safety profile in Leucoderma patients. In the study, 60 patients with Leucoderma were selected, out of which 50 continued with lukoskin therapy for complete duration of 2 years. All the patients were advised to take combo therapy of Lukoskin oral liquid and ointment simultaneously.

(Oral Liquid: 10 drops once or twice daily with a cup of water.)

Ointment : Applied on white patches followed by sun exposure for 5 to 30 min.)

Results

Benefit	No. of patients	Percentage
Most significant results	17	34
Significant results	19	38
Average results	10	20
Not relieved	4	8
Total	50	100%

Conclusions

MANY FACTS CAME FORWARD AS A RESULT OF EFFICACY OF THE DRUGS GIVEN:

- PROGRESS OF WHITE PATCHES STOPPED.
- NORMAL COLOR OF SKIN STARTED TO DEVELOP IN WHITE PATCHES.
- ERUPTION OF NEW WHITE PATCHES PREVENTED.
- LFT PARAMETER IMPROVES.
- LESS RESPONSE WAS FOUND IN PATCHES OVER BONY PROMINENCES AND MUCOUS MEMBRANE AREAS.

(Mgt. Skin Dis. Through Ay., National Aca. Ay. 2011, Pg: 228-234)

Toxicity

No toxic symptoms arose, except blisters in 12 patients which were healed by applying the jasmine oil for some time and the treatment re-started.

STUDY PROVING NON-TOXICITY BY ITRC*

Medicinal plants for Lukoskin were received from Defence Agricultural Research Laboratory (DARL), Pithoragarh and toxicity was evaluated at ITRC, Lucknow.

Introduction

Toxicity tests in animal models are required for safety evaluation and also for planning further studies. In this study, acute toxicity studies of alcoholic extracts of the medicinal plants were carried out for the determination of oral LD₅₀ and primary skin irritation.

Results

There was no mortality with the alcoholic extracts upto 3200 mg/kg dose. The oral LD₅₀ is above 5.0 g/kg for the alcoholic extracts.

The general behavior of the rats was normal.

There was no significant difference in feed and water intake of the treated groups as compared to the control group. Primary skin irritation test showed that the extracts induced mild erythema on the day of application and there was no effect 24 hr later.

There was no significant change in the percent weight gain compared to the control group except at a dose of 6400 mg/kg of alcoholic extracts of medicinal plants for Leucoderma.



* Indian Toxicological & Research Centre

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EFFICACY STUDIES ON SKIN PIGMENTATION

SHOWING INTENSE PHASE OF RECOVERY WITH DUAL THERAPY

Experimental studies for about 60 days with Lukoskin oral liquid and Ointment in black hair mice, nurtured to age onset graying of hair, revealed signs 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.

Studies on black hair mice, nurtured to age onset graying of hair, for signs of skin pigmentation and anagenic recurrence -

S. No.	Group of animals treated with	Colour appearance on observation region (stratum corneum)		Sign of anagenic recurrence phase
		On skin	On hair growth	
1.	Sham control (no ointment, no oral liquid)	Pinkish skin	Grey hair	No sign
2.	a. Oral liquid and ointment (on one side)	Bluish skin with pigmentation	Jet black hair	Intense phase
	b. Oral liquid and petroleum jelly (on other side)	Slight bluish skin with pigmentation	Blackish hair	Present
3.	a. Ointment (on one side)	Slight bluish skin with pigmentation	Blackish hair	Present
	b. Petroleum jelly (on other side)	Pinkish skin	Grey hair	No sign
4.	Only oral liquid (no ointment)	Slight bluish skin with pigmentation on both sides	Blackish hair	Present

Safety Studies

There was no change in food and water intake, skin fold thickness or body weight in the treated group.

Non-cytotoxicity studies

Non-cytotoxicity 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 respectively.

Study conducted at : Indian Institute of Chemical Biology (IICB) Kolkata

Before Treatment



After 300 Days

BETTER RESULTS
EFFECTIVE APPROACH

Before Treatment



After 450 Days

NON-TOXIC
NO ADVERSE EFFECTS

Before Treatment



After 300 Days

COMPREHENSIVE
EFFECTIVE
& COMPLETELY SAFE

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LUKOSKIN COMBINATION THERAPY AND DIETARY ADVICE, TREATS LEUCODERMA BY COMBATING THE CAUSATIVE FACTORS

YES !

DIETARY ADVICE

NO !

- Take Copper rich water after storing it in a copper vessel for at least 8 hrs. 
- Increase green vegetables, Carrot, Bottle Gourd & also Beans, Pulses 
- Consume soaked Bengal grams 30-50 gms. and 3-4 almonds per day as an Immunomodulator. 
- Deworming is necessary in case of worms infestation. 
- For proper liver functioning and regularising metabolic process, Amlycure DS can be taken with the advice of Physician. 
- Fresh and Clean Giloe extract or Alovera juice should be taken regularly as an immunomodulator. 

- Avoid acidic (sour) foods, Citrus fruits (viz. Lemon, Orange), Apple, Mango, Grapes, Tomato, Amla, Pickles, Curd, Lassi (Butter milk) & Chilli, Whey, Fine flour (Maida), Urad dal. 
- Cut Non-Vegetarian diet & fast foods. 
- Avoid beverages like Cold drinks. 
- Avoid contact with chemical based detergents/soaps. 
- Milk should be avoided along with the followings : Salt, Salty foods, Radish and non-veg. 
- Avoid direct skin contact with the followings: Perfumes, Deodorants, Hair Dye, Pesticides and other strong chemicals. 

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A COMPREHENSIVE & EFFECTIVE APPROACH IN THE MANAGEMENT OF LEUCODERMA

KEY FEATURES

■ SKIN PHOTO-SENSITIZER

■ STIMULATES MELANIN SYNTHESIS

■ IMMUNOMODULATOR

■ ANTI-STRESS

INDICATION :

LEUCODERMA/VITILIGO (WHITE SKIN PATCHES) OR AS DIRECTED BY THE PHYSICIAN.

DOSAGE :

OINTMENT :

APPLY GENTLY FROM PIGMENTED TO NON-PIGMENTED AREA, ONCE OR TWICE A DAY AND TAKE ORAL LIQUID. AFTER HALF AN HOUR, EXPOSE THE AREA TO SUN EITHER BEFORE 11 AM OR AFTER 3 PM FOR 10-20 MINS.

Mild irritation/blister is a positive sign for erythema/ pigmentation. In some hypersensitive patients if severe irritation persists, apply or dilute the medicine with Chameli (Jasmine) oil or seek Physician's advice.

ORAL LIQUID :

Adults : 1 to 2 ml. (20 to 40 drops) diluted in a cup of water BD or TDS.

Children : ½ml. to 1 ml. (10 to 20 drops diluted in a cup of water BD or TDS. or as directed by the Physician.

VISIBLE RESULTS : 1-3 months

RECOVERY PERIOD : 1-2 years (Depending upon onset of disease, age of patient & progression of diseases & diet and life modification.

MAINTENANCE : 1 year after complete recovery.

SAFETY: Safe in children above 1 year.



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