cyspera®

PIGMENT CORRECTION

PIGMENT CORRECTION

scientis
THE PIGMENTATION AUTHORITY

Dr Behrooz Kasraee, MD
Dermatologist
Chief Scientific Officer, Scientis SA

 Courtesy of Dr Chau Yee Ng (Taiwan)

Cyspera® – Effective on Acne and Acne PIH

Baseline	3 days	2 Weeks

Post-Acne PIH
Protocol: 1) Intensive (15min); 2) Boost (day & night)

Data on file

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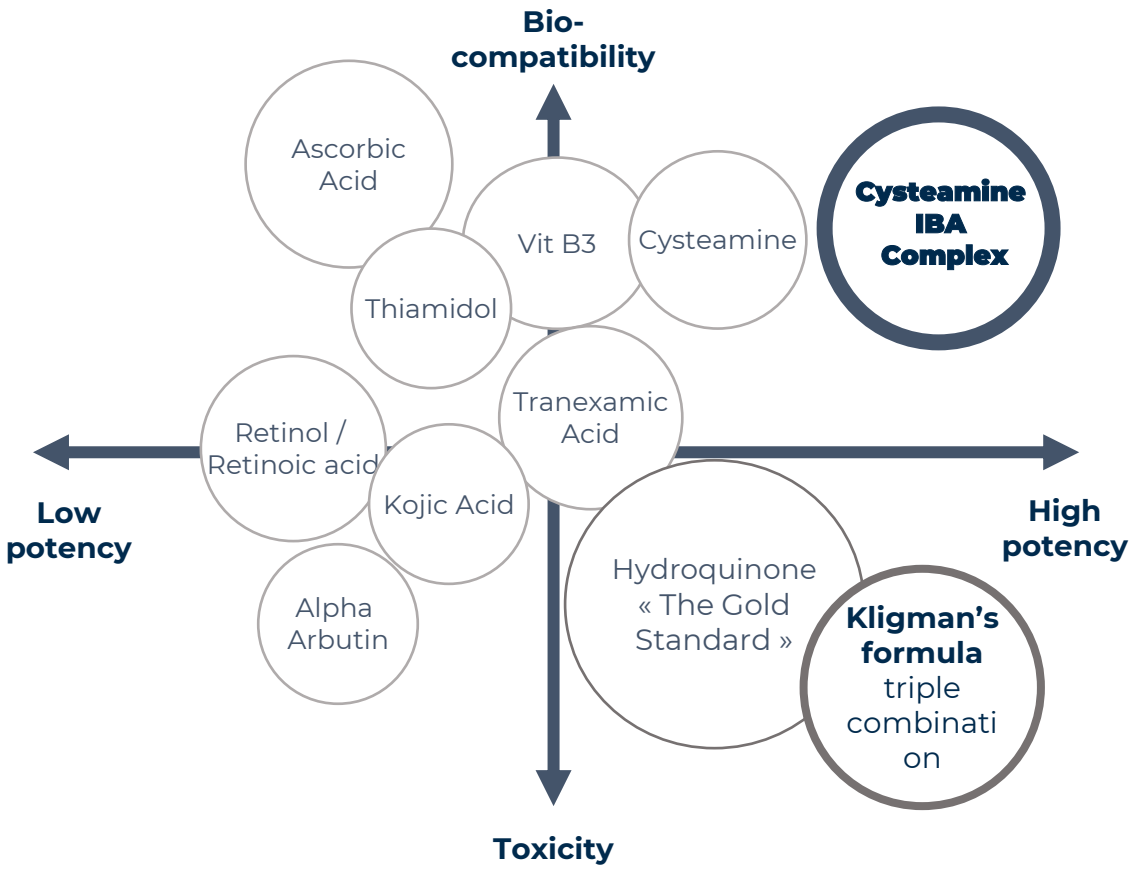
WHY THE NEED: Powerful and well-tolerated



Cysteamine Isobionic-Amide Depigmenting Complex provides **superior benefits in pigmentation:**

- ✓ **"Pigmentation disorders are psychologically devastating"** (1). Patients seek non-visible (no downtime) treatments which are safe for long-term use
- ✓ Clinicians seek effective **non-mutagenic, non-carcinogenic** agents which do not carry risk of chemical vitiligo
- ✓ **The Safety of hydroquinone** is an area of significant debate despite status as the gold standard to reduce hyperpigmentation[2]
  - ✓ Reputation as a *potentially mutagenic and carcinogenic compound known to induce ochronosis[3]
  - ✓ HQ combinations can lead to irritation and phototoxic reactions
- ✓ Non-hydroquinone topical agents such as tranexamic acid, kojic acid, arbutin, azelaic acid, retinoids, hydroxy acids have shown lower efficacy. All are generics.

Note: size represent notoriety of Active ingredient

(1) Pearl Grimes, MD FAAD
(2) Westerhof et al. Hydroquinone and its analogues in dermatology - a potential health risk. J Cosm. Derm. 2005:4(2):55-9.
(3) Miles and Wilkerson, The dark side of hydroquinone for skin lightening: 3-fold increased risk of skin cancer. J Investigative Derm. 2022:5.936.
DOI:10.1016/j.jid.2022.05.936

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What is Cysteamine?

More than 50 years ago, cysteamine was shown to be significantly more effective than hydroquinone *in vivo*

CYSTEAMINE

In 1966, Prof. Chavin discovered the physiologic activity of cysteamine in skin pigmentation, while studying black goldfish models.

In 1968, Professor Fitzpatrick's studies showed that Cysteamine is significantly stronger than hydroquinone in vivo, but its intense odor prohibited its use in topical products.

In 2010, Dr Behrooz Kasraee developed a new technology that significantly increases cysteamine stability and reduces its intense odor

In 2013, Dr Christophe Hsu presented at the AAD Annual Meeting the significant efficacy and safety of Cysteamine 5% on a first cohort of 30 melasma patients[1]

Chavin W. et al, 1966, Die Naturwissenschaften 53(16):413-414
E Frenk et al. Arch Dermatol 97 (4), 465-477. 4 1968
SS Bleehen et al. J Invest Dermatol 50 (2), 103-117. 2 1968

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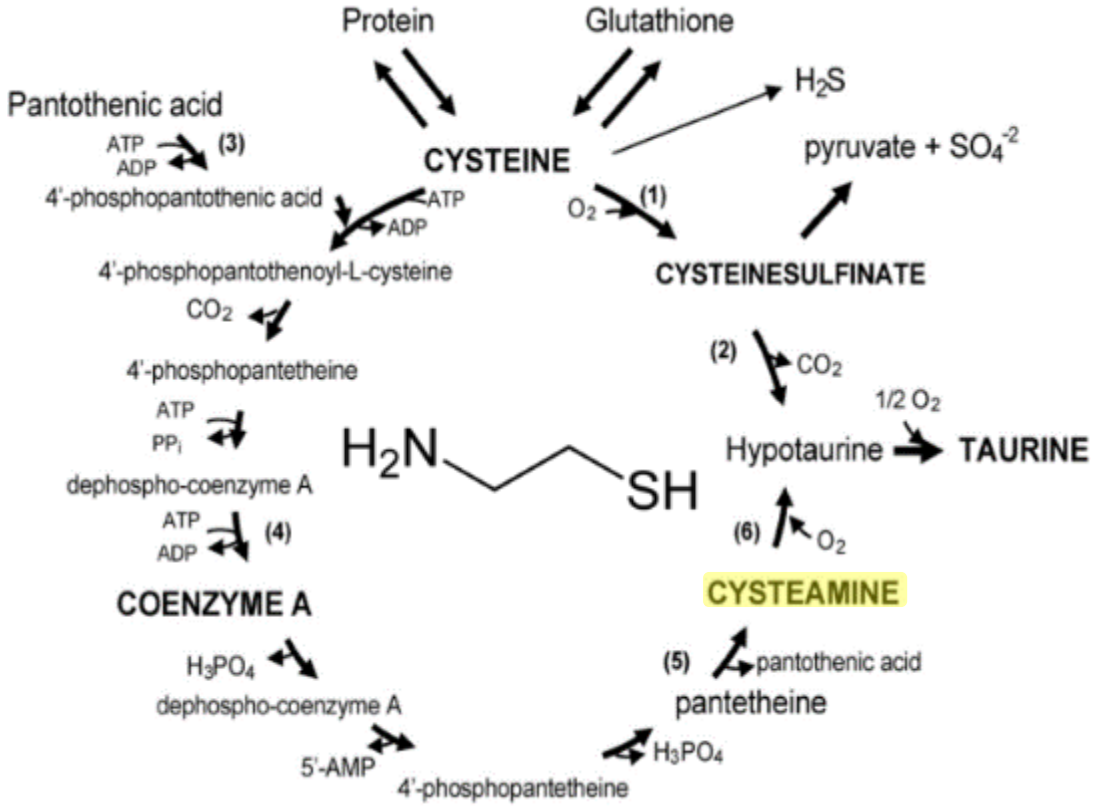
Cysteamine is a physiological molecule

CYSTEAMINE

Cysteamine is **the simplest aminothiol** physiologically produced in humans from the essential amino-acid **cysteine**



Concentrated in human milk, cysteamine acts as an intrinsic antioxidant and is known for its protective role

Physiological Levels of Cysteamine		
Mouse*	Meat	79.6 nmol/g
	Kidney	106.7 nmol/g
	Milk	-
Cow**	Meat	350 µg/l
	Kidney	1330 µg/l
	Milk	124 µg/l
Human**	Milk	2345 µg/l

Sources: data on file

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Cysteamine – A naturally-occuring antioxidant, with multiple effects on the melanogenesis pathways

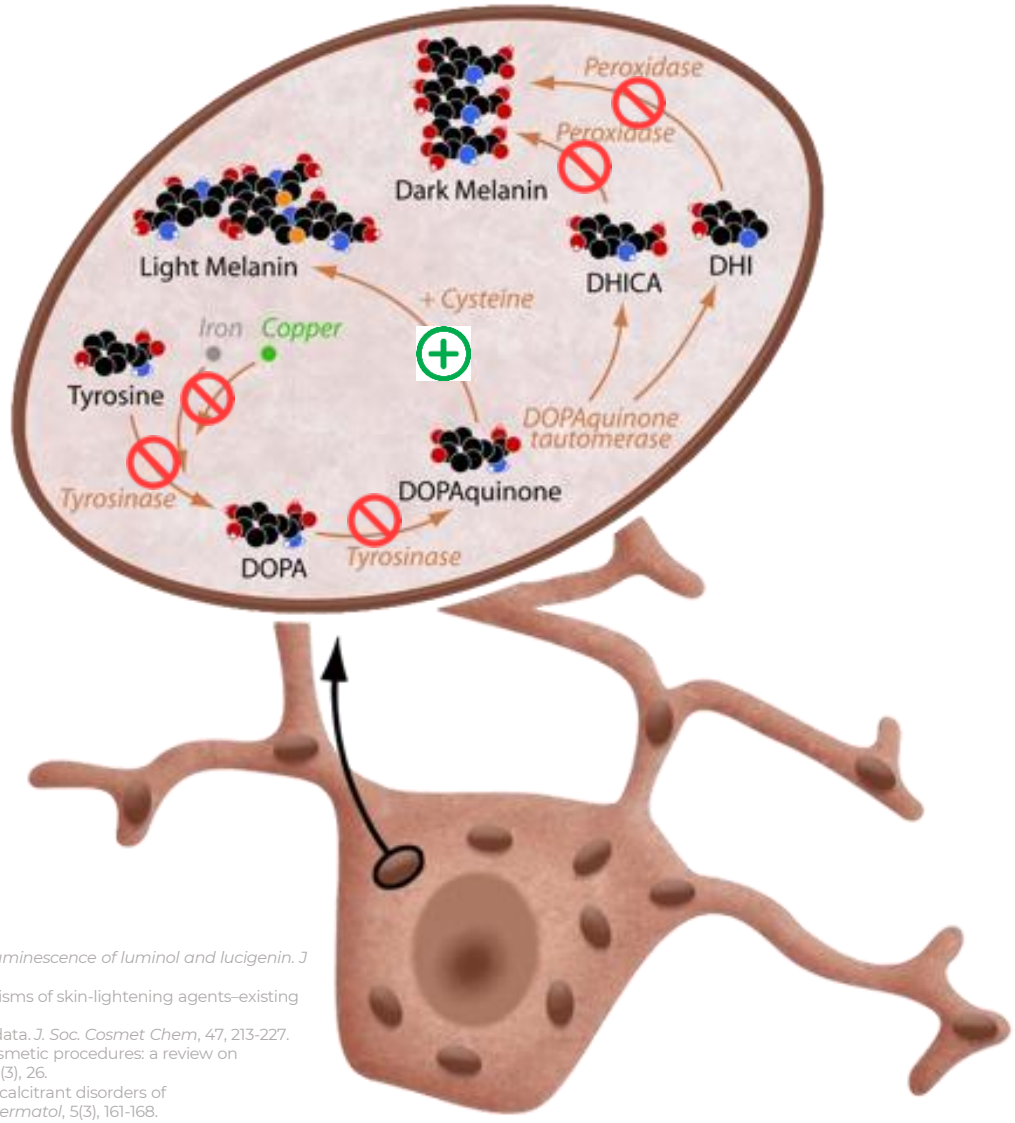
CYSTEAMINE

Enzymatic Pathway :
- **Inhibition** of tyrosine hydroxylation [1]
- **Inhibition** of DOPA oxidation [1]
- **Inhibition** of indole polymerisation through peroxidase inhibition [1]

Iron Chelation Pathway :
- **Inhibition** of Fenton-type reactions through iron and copper ion quenching [2,3]

Glutathione cascade impeding effect :
- Increase of intra-cellular glutathione bypassing Eu-melanin pathway by **activating Pheomelanin pathway** [3,4]

Other effects :
- Dopaquinone **quenching** (removing dopaquinone from the pathway) [5]
- Reduction of dark melanin in stratum corneum into a lighter form through **antioxidant effect** [6,7]
- Removal of superficial epidermal layers containing melanin and acceleration of epidermal turnover through **keratolytic effect** [7-10]



: Quenching

: Inhibition

: Activation

[1] Wood J M, et al (1991). Studies on the reactions between human tyrosinase, superoxide anion, hydrogen peroxide and thiols. *Biochim Biophys Acta*, 1074(3), 378-385.
[2] Sakurai H, et al. (1971). Studies on the sulfur-containing chelating agents [...]. *Chem Pharm Bull*, 19(7), 1416-1423.
[3] de Matos D G, et al. (1995). Effect of cysteamine on glutathione level [...]. *Mol Reprod Dev*, 42(4), 432-436.
[4] Parvez S, et al (2006). Survey and mechanism of skin depigmenting and lightening agents. *Phytother Res*, 20(11), 921-934.
[5] Alfieri, M. Let al. (2022). Disentangling the puzzling regiochemistry of thiol addition to o-quinones. *J Org Chem*, *87*(7), 4580-4589.
[6] Bottu G. (1989). The effect of quenchers *on the chemiluminescence of luminol and lucigenin. J Biolumin Chemilumi*, 3(2), 59-65.
[7] Gillbro JM et al.(2011). The melanogenesis and mechanisms of skin-lightening agents–existing and new approaches. *Int J Cosmet Sci*, 33(3), 210-221.
[8] Manuszak MA, et al.. (1996). single-fiber tensile kinetic data. *J. Soc. Cosmet Chem*, 47, 213-227.
[9] Cruz CF, et al. (2016). Human hair and the impact of cosmetic procedures: a review on cleansing and shape-modulating cosmetics. *Cosmetics*, 3(3), 26.
[10] Stratigos AJ, et al.. (2004). Optimal management of recalcitrant disorders of hyperpigmentation in dark-skinned patients. *Am J Clin Dermatol*, 5(3), 161-168.

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Part 2

What is Isobionic-Amide?

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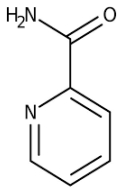
Isobionic-Amide : a new Anti-Inflammatory agent with anti-acne effects

ISOBIONIC-AMIDE

Pyridine family:

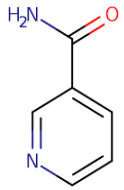
Isobionic-Amide

> potency

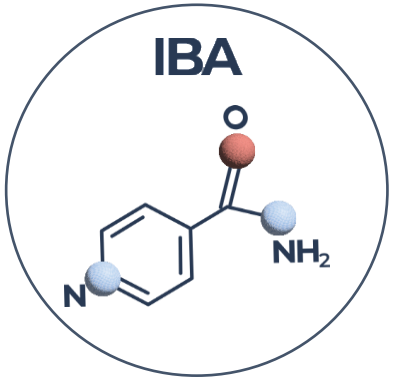


Picolinamide

> potency



Niacinamide



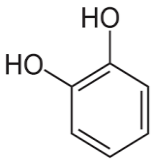
Chemical isomers configuration: Para ---------- Ortho ---------- Meta

Biphenol family:

Hydroquinone

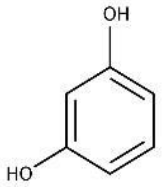
> potency

Catechol



> potency

Resorcinol



- ✓ **In 2011, Dr. Behrooz Kasraee discovered Isobionic-Amide while researching cysteamine's interactions with isomers from the pyridine family.**
- ✓ **Works synergistically with Cysteamine.**
- ✓ **Inflammation**: Soothes chronic, low-grade inflammation. and reduces flare-ups in rosacea, eczema, or acne
- ✓ **Photoaging**: UV-induced inflammation accelerates collagen loss and uneven pigmentation.
- ✓ **Dyschromia** (melasma, lentigines, PIH): Often driven by chronic inflammation and oxidative stress.

Sources: data on file

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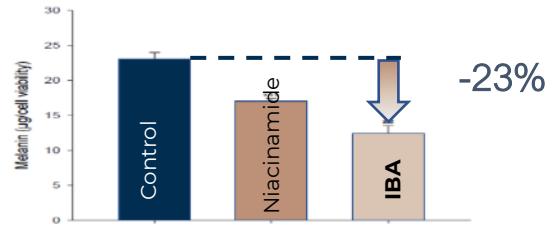
Depigmenting activity of Isobionic-Amide

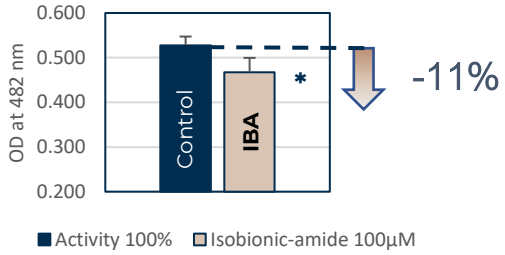
ISOBIONIC-AMIDE

Depigmenting activity of Isobionic-Amide[1]

- Discovered through analysis of pyridine isomer configuration
- Established in 2011 to act as Pigment control by:
  - Inhibition of melanosomal transfer

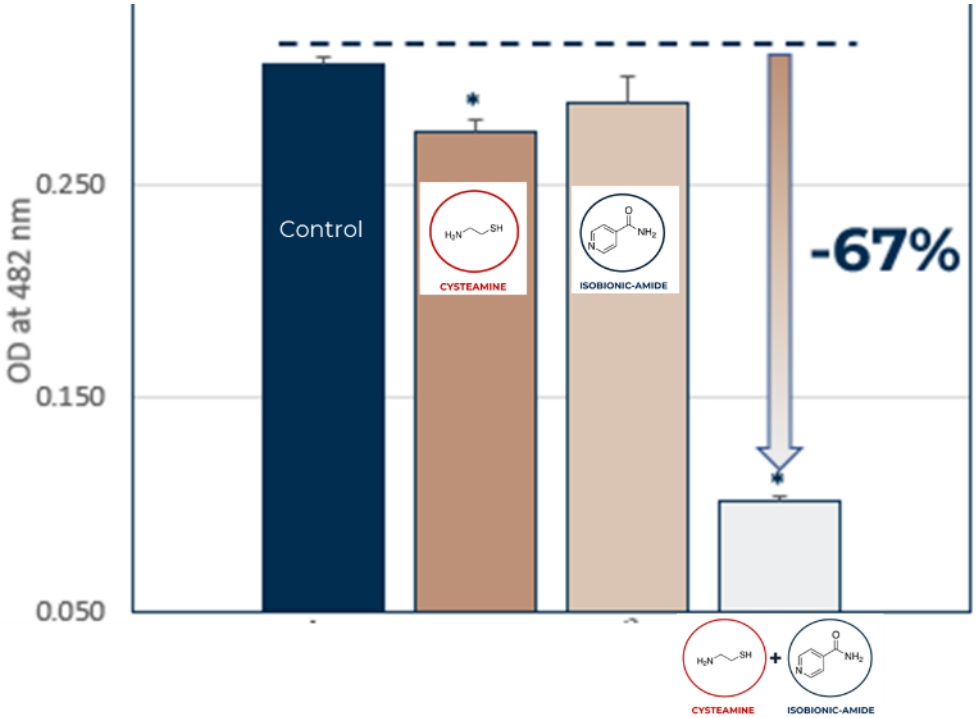


  - Inhibition of tyrosinase



Multiplying 6x the tyrosinase inhibition activity [2]

- Isobionic-Amide multiplies by 6x the tyrosinase inhibition effects when applied in combination with Cysteamine



(1) Kasraee et al. (2011) Experimental Dermatology
(2) Kasraee B. (2024). J Am Acad Dermatol.; 91 (3) : AB245

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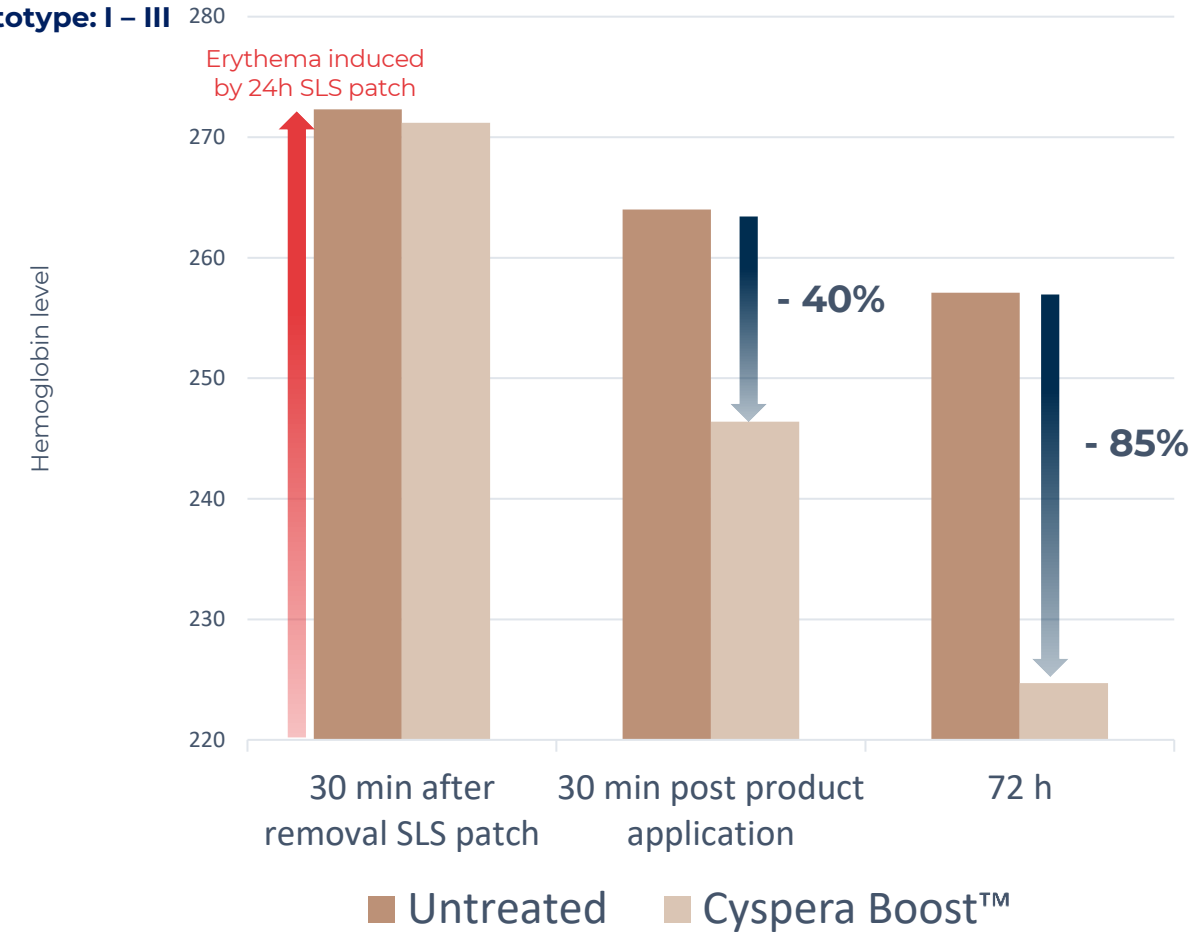
Anti-inflammatory effects of Isobionic-Amide

ISOBIONIC-AMIDE

22 female subjects

18 – 45 years old

Phototype: I – III



(Natural recovery process) (applied daily after SLS patch removal)

Cyspera Boost™ accelerates the skin's natural recovery process and reduces skin erythema:

- ✓ By **40%** in just 30 minutes with one single application
- ✓ By **85%** in 3 days with just 3 applications
- ✓ Transepidermal water loss (indicating skin barrier repair) was also improved by 31%

 Data on File (Scientis SA)

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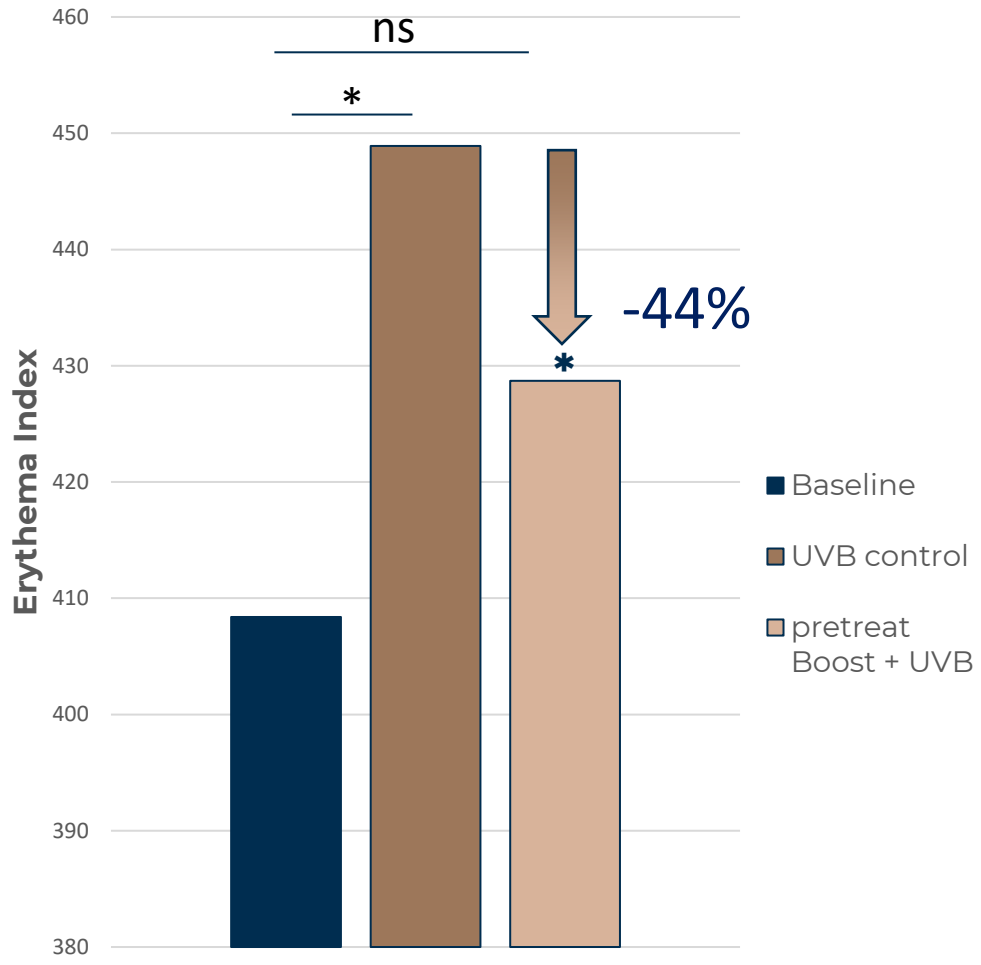
IBA protects the skin from UV-induced erythema

ISOBIONIC-AMIDE

5 hours post-UVB irradiation

the erythema index was measured using SkinColorCatch®

UVB | Boost™ pretreated | Baseline



*, p<0.05

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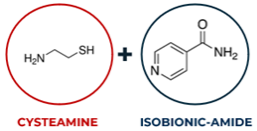
Part 3



Potentiating Effects

OF THE CYSTEAMINE – ISOBIONIC-AMIDE DEPIGMENTING COMPLEX

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Gold Standard Efficacy with Cysteamine Isobionic-Amide Depigmenting Complex

A double blind, randomized and placebo-controlled study to investigate the **safety and efficacy** of Cysteamine Isobionic-Amide Depigmenting Complex compared to modified Kligman's formula for the treatment of melasma.

- ✓ **Cyspera® Intensive System**= Isobionic-Amide Cysteamine depigmenting complex (N=30)
- ✓ **Placebo** (N=20)
- ✓ **Tri-luma® Kligman's Formula**= 4% Hydroquinone, 0.05% tretinoin and 0.01% Fluocinolone Acetonide (N=30)

FEBRUARY 2024 9 VOLUME 23 • ISSUE 2

ORIGINAL ARTICLE JOURNAL OF DRUGS IN DERMATOLOGY

Cysteamine Isobionic-Amide Complex Versus Kligman's Formula for the Treatment of Melasma: Equal Efficacy and Rapid Onset of Action

Mukta Sachdev MD,[a] Pearl E. Grimes MD,[b] Valerie Callender MD,[c] Corey L. Hartman MD,[d] Susan C. Taylor MD,[e] Nada Elbuluk MD MSc,[f] Ashraf Badawi MD,[g] Yoko Funasaka MD PhD,[h] Joyce Lim MD,[i] Chau Yee Ng MD,[j] Seemal R. Desai MD[k]

[a]Department of Dermatology, Manipal Hospital, Bangalore, India
[b]Dermatology University of California, Los Angeles, CA
[c]Howard University College of Medicine Medical Director, Callender Dermatology & Cosmetic Center, Founder & Principal Investigator, Callender Center for Clinical Research, Glen Dale, MD
[d]Skin Wellness Dermatology, Birmingham, AL
[e]Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA
[f]USC Department of Dermatology, Keck School of Medicine, CA
[g]Laser Institute, Cairo University, Egypt
[h]Department of Dermatology, Nippon Medical School, Tokyo, Japan
[i]Joyce Lim Skin and Laser Clinic, Singapore
[j]Department of Dermatology, Chang Gung Memorial Hospital, Taipei, Linkou, Taiwan Vitiligo Clinic, and Pigment Research Center, Chang Gung Memorial Hospital, Linkou, Taiwan Department of Dermatology and Aesthetic Medicine Center, Jen-Ai Hospital, Taichung, Taiwan
[k]Department of Dermatology, The University of Texas Southwestern Medical Center, and Innovative Dermatology, Dallas, TX

Inclusion Criteria

N=50

- Female subjects **aged 25-45 years**
- Subjects of skin phototype III-IV
- Subjects with **moderate-to-severe melasma**
- Subjects with **Mixed or Epidermal Melasma**

Exclusion Criteria

- Subjects with only dermal Melasma
- Subjects with on hormonal therapy
- Subjects who had a skin lightening procedure or who've been treated with Hydroquinone in the past 8 weeks

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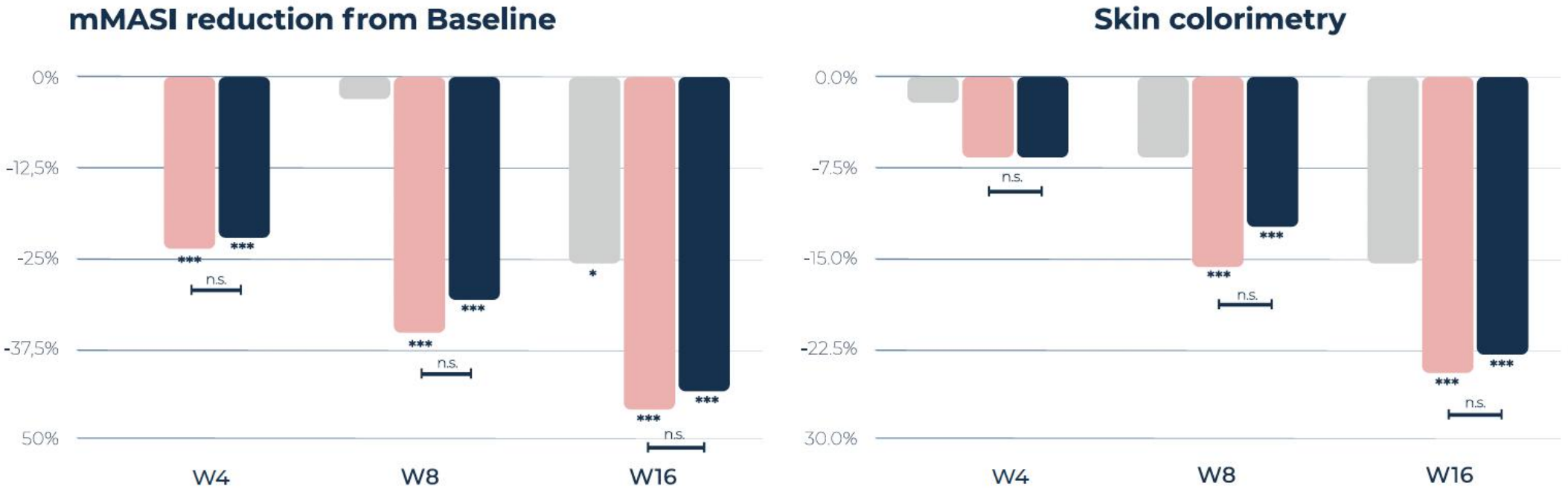
Cysteamine IBA complex as effective & fast onset of action as Triluma®



Placebo (N=20) Tri-luma® Kligman's Formula **Cyspera® Intensive System**

✓ Improved melasma appearance as effectively as Triluma®

✓ Melasma severity is significantly reduced as early as week 4

Sachdev M, et al. 2024. J Drugs Dermatology
*** : versus baseline, p<0.001; n-s: non significative between groups

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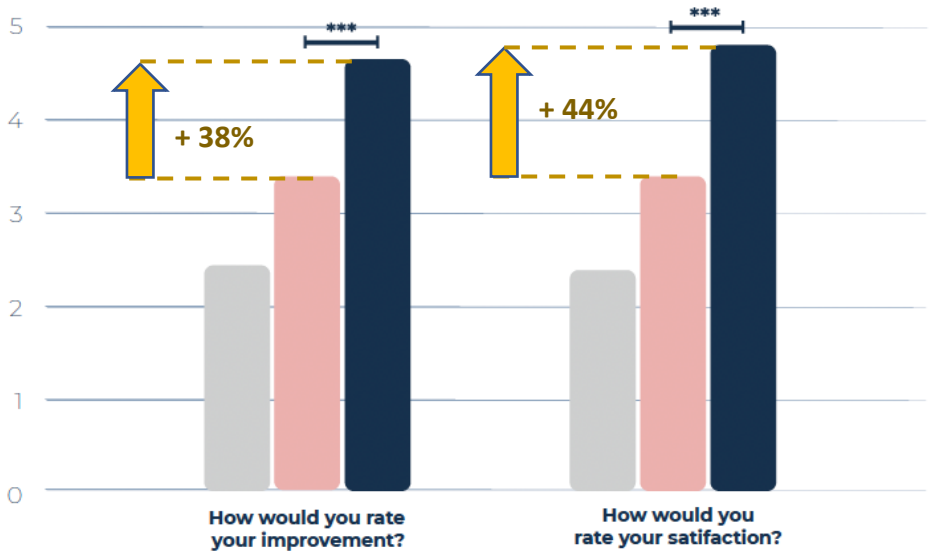
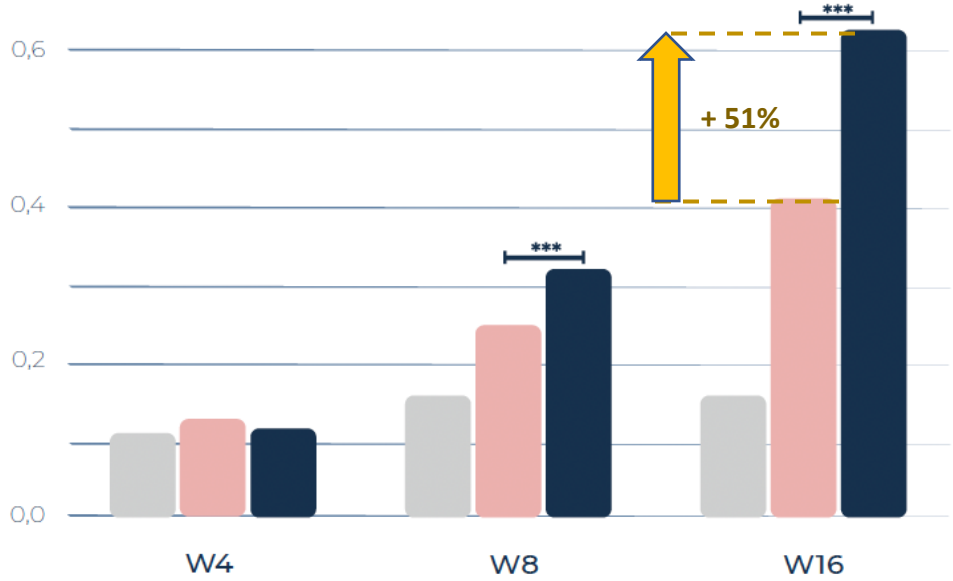
Higher Patient Satisfaction with Cysteamine Isobionic-Amide vs. Triluma®

Patients' Satisfaction



Improvement of Quality of life



Placebo (N=20)

Kligman's Formula
= 4% Hydroquinone, 0.05% tretinoin and 0.01% Fluocinolone Acetonide (N=30)

Cyspera® Intensive System
= Isobionic-Amide Cysteamine Pigment Correction Complex (N=30)

Sachdev M, et al. 2024. J Drugs Dermatology
*** : versus baseline, p<0.001; n-s: non significative between groups

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Significant therapeutic response to cysteamine in hyperpigmentation

Before | After 8 weeks | After 12 weeks

Case report by © Dr. Huang Yung-Hsueh (Taiwan)

cyspera® PIGMENT CORRECTION

Significant therapeutic response to cysteamine in a melasma patient resistant to Kligman's formula

Patient under Kligman's formula treatment (Pigmanorm cream) for the past 5 years

Discontinuation of Kligman's formula and treatment with Cysteamine for 4 months

continued Cysteamine use twice weekly as maintenance therapy for the past 3 years.

Case report by Kasraee et al, 2019, JDT

cyspera® PIGMENT CORRECTION

Cysteamine safety and efficacy for pigmented scars, original formulation

Baseline

Week 4

Source: Dr.Mai Ahmad

cyspera® PIGMENT CORRECTION

Part 4

CYSPERA

effects on **ACNE**

Effects on Active Acne of IBA Cysteamine Complex

Baseline	3 days	2 Weeks

Post-Acne PIH

Protocol: 1) Intensive (15min); 2) Neutralize (rinse-off); 3) Boost (day & night)

Data on file

cyspera® PIGMENT CORRECTION

Effects on PIH of IBA Cysteamine Complex

Baseline

Week 12

Cyspera Cysteamine 5% in combination therapy with tarazotene .1% cream (Tazorac®)

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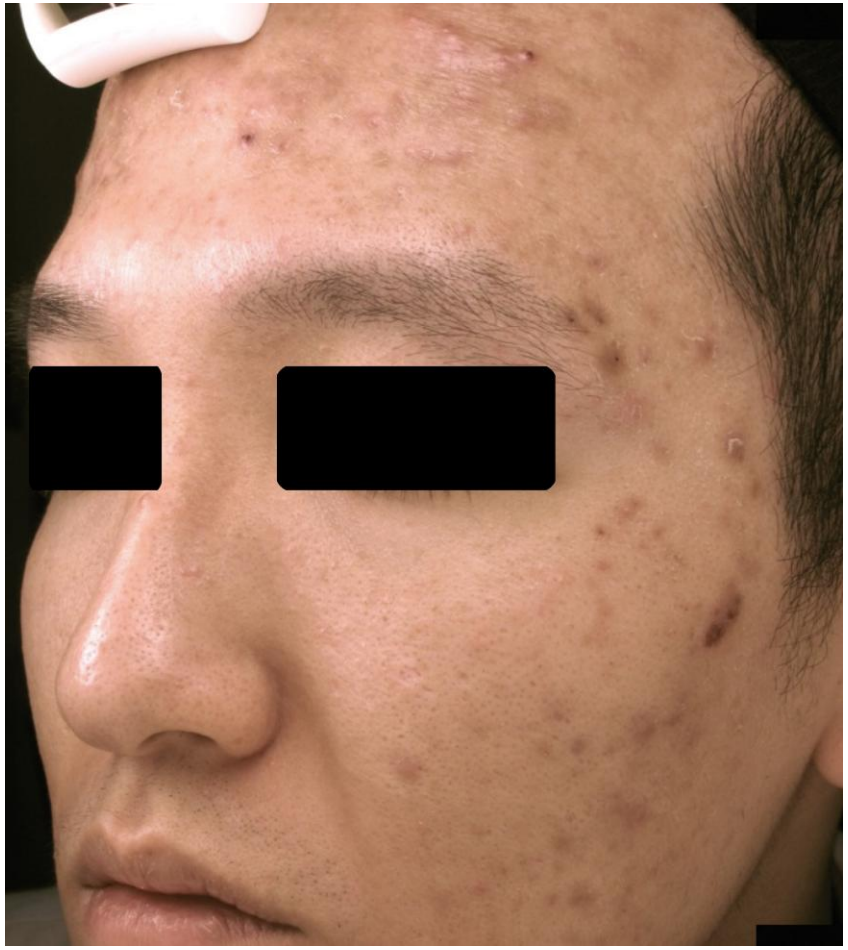
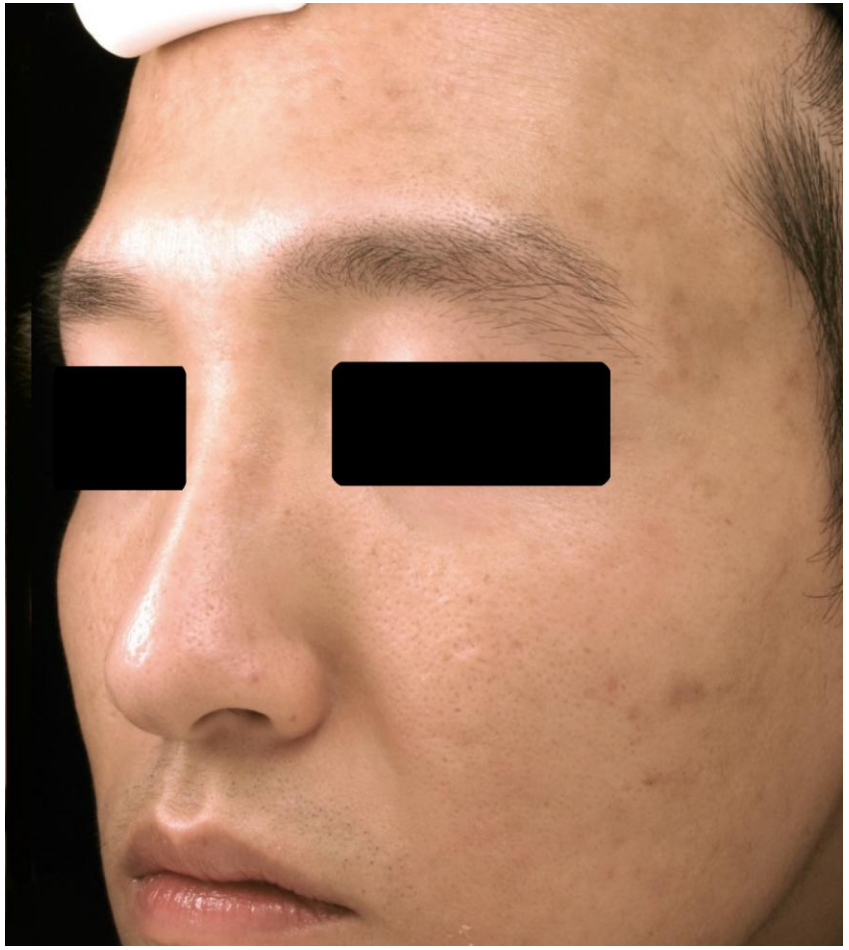
Effects on PIH of IBA Cysteamine Complex



Baseline



Week 16

Courtesy of Dr Chau Yee Ng (Taiwan)

Liu RT, Tsai T, Lai Y, Ng, CY. Efficacy and safety of cysteamine-isobionicamide complex in postinflammatory hyperpigmentation: A 16-week, randomized, double-blinded, vehicle-controlled trial. *Dermatologica Sinica*.2023;41(4)222-230.

Fast results on PIH within week 4, Cysteamine IBA Complex, conjunction with RX retinoids

Baseline

Week 4

Dr. Corey Hartman skin wellness DERMATOLOGY

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Fast results on PIH within week 4, Cysteamine IBA Complex, conjunction with RX retinoids

Baseline

Week 4

Dr. Corey Hartman skin wellness DERMATOLOGY

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Significant efficacy in Managing PIH with Cyspera®

A double blind, randomized and placebo-controlled study to investigate the **safety and efficacy** of Cysteamine Isobionic-Amide Depigmenting Complex in managing PIH.

- ✓ **Cyspera® Intensive** System= Isobionic-Amide Cysteamine depigmenting complex (N=20)
- ✓ **Placebo** (N=20)

Dermatologica Sinica

journal homepage: http://journals.lww.com/DERS

Original Article

Efficacy and safety of cysteamine-isobionicamide complex in postinflammatory hyperpigmentation: A 16-week, randomized, double-blinded, vehicle-controlled trial

Rosalie Tzu-Li Liu[1,2], Tsung-Fu Tsai[1,2,3], Yi-Jing Lai[1,2,3,4], Chau Yee Ng[1,2,3,4*]

[1]Department of Dermatology, Chang Gung Memorial Hospital, Linkou, Taoyuan, Taiwan, [2]School of Medicine, College of Medicine, Chang Gung University, Taoyuan, Taiwan, [3]Vitiligo Clinic and Pigment Research Center, Chang Gung Memorial Hospital, Linkou, Taoyuan, Taiwan, [4]Department of Dermatology and Aesthetic Medicine Center, Jen Ai Hospital, Tai-Chung, Taiwan

Inclusion Criteria
N=40

- 20 years old in age and
- experienced more than 12 weeks of acquired hyperpigmentation following acne or laser therapy

Exclusion Criteria

- patients with ongoing inflammatory symptoms, and/or under anti-inflammatory medications,
- pregnant patients
- patients undergoing hormone therapy and/or oral contraceptives,
- patients presenting with dermal hyperpigmentation without epidermal involvement, and
- patients with a known history of allergic reactions to the product.

Rosalie Tzu-Li Liu et al. 2023. Dermatologica Sinica, 41 (4), 222-230

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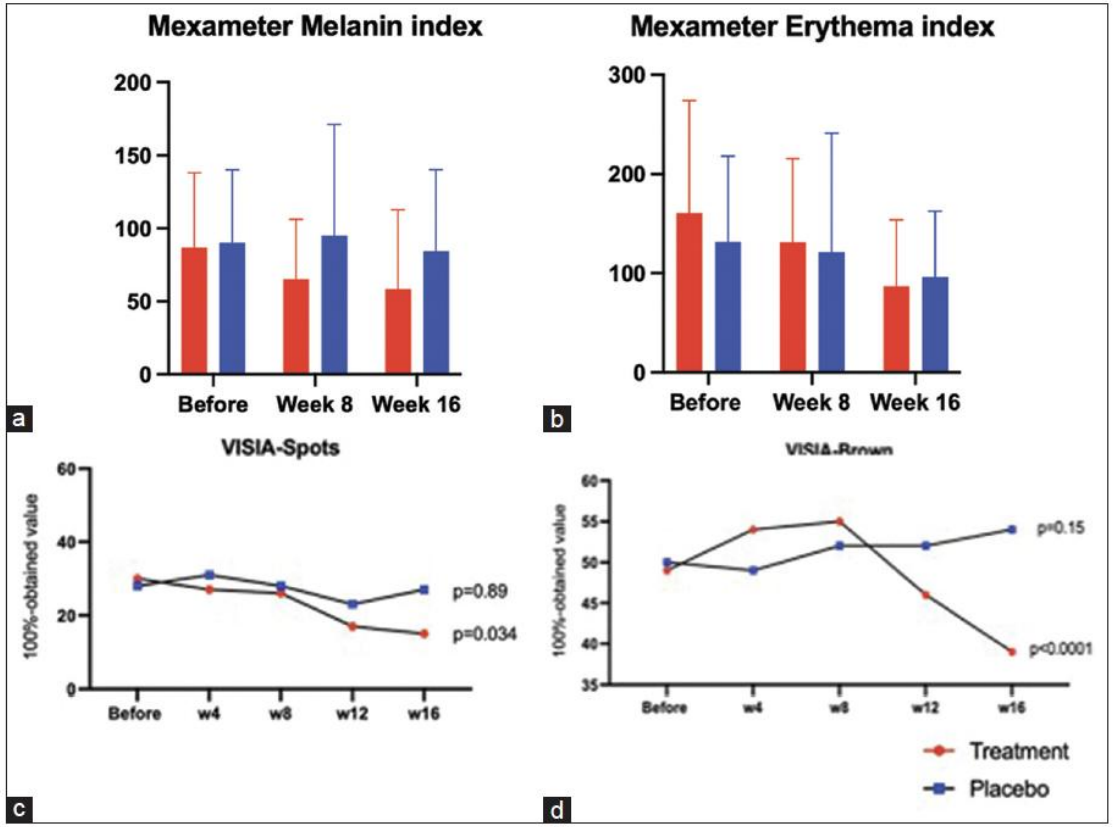
Significant improvements of Mexameter Melanin Index, Investigator assessments and Patient scores with Cyspera **on Managing PIH**



eter® and skin imaging analysis (VISIA skin analyzer) for the efficacy of cysteamine-isobionicamide complex in hyperpigmentation (a) Mexameter melanin index; (b) Mexameter erythema index; (c) VISIA skin analysis – surface s skin analysis – brown spots absolute scores.

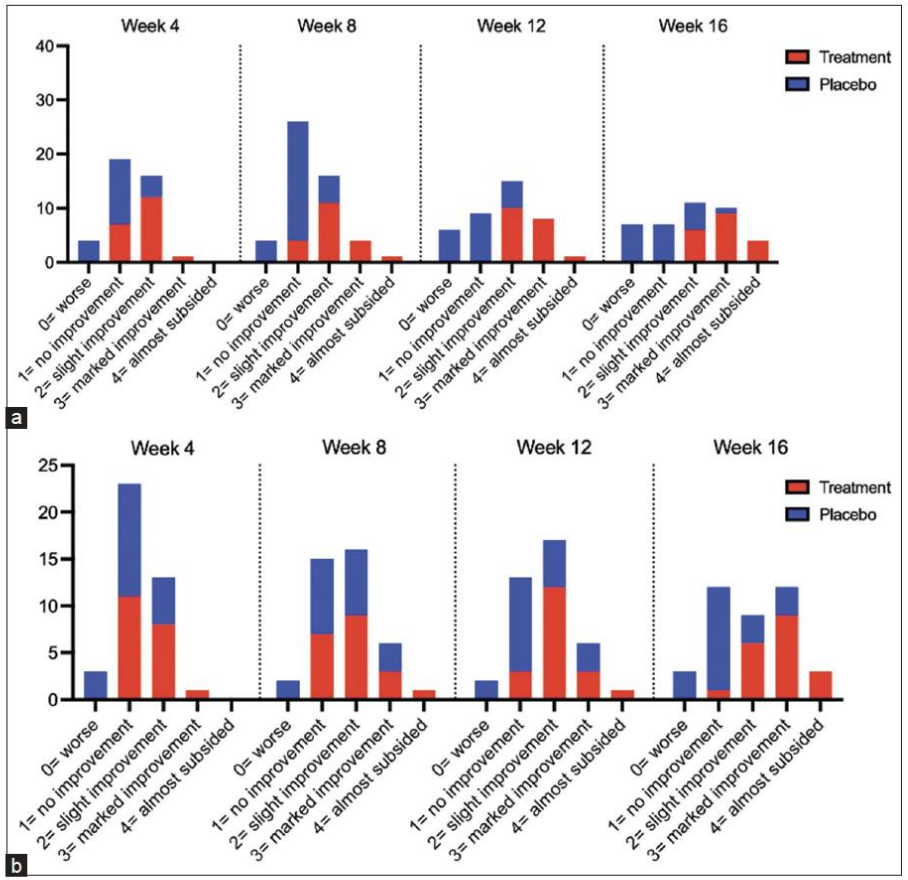


Figure 2: (a) Investigator global assessment. A significant improvement in postinflammatory hyperpigmentation was found for week 4 of treatment 4, $P < 0.05$, week 8, $P < 0.001$). (b) Patient Global Assessment. A significant improvement in postinflammatory hyperpigmentation was fou week 12 of treatment (week 12, $P < 0.05$, week 8, $P < 0.001$).

Rosalie Tzu-Li Liu et al. 2023. Dermatalogica Sinica, 41 (4), 222-230

cyspera® PIGMENT CORRECTION

Significant efficacy in Managing Acne-induced PIH with Cyspera®

A investigator blind, randomized and controlled study to investigate the safety and efficacy of Cysteamine vs. HQ in Treating Acne-induced Post-inflammatory hyperpigmentation

- ✓ **Cyspera®** Cysteamine 5% (N=13)
- ✓ **Hydroquinone 4%/ ascorbic acid 3%** (N=15)

Assessing the Effectiveness of Stabilized Cysteamine 5% Cream Compared to Hydroquinone 4%/Ascorbic Acid 3% Combination Cream in Treating Acne-induced Post-inflammatory Hyperpigmentation: A Randomized, Controlled Study

by KOOROSH AHMADI, MD; AMIR MIRI, MD; ZEINAB BIZAVAL, MD; MOZHDEH SEPASKHAH, MD; SARA RANJBAR, MSc; ZAHRA BAGHERI, PhD; and BEHROOZ KASRAEE, MD

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J Clin Aesthet Dermatol. 2024;17(4):37–41.

OBJECTIVE: Postinflammatory hyperpigmentation (PIH) is a common sequela of acne vulgaris. Topical treatment with hydroquinone is the standard treatment, but may be associated with complications. Cysteamine is a relatively safe depigmenting agent with an observed depigmenting effect. We designed this study to assess the efficacy of a cysteamine 5% cream in treating acne-induced PIH. **METHODS:** Twenty-eight out of 32 participants finalized this investigator-blind, randomized, and controlled trial (registered in Iranian Registry of Clinical Trials [IRCTID: IRCT20140212016557N5]). We randomized the patients to apply either cysteamine 5% or hydroquinone 4%/ascorbic acid 3% (HC) cream. Postacne hyperpigmentation index (PAHPI) and melanin index were the assessment measures after four months of treatment. We evaluated the quality of life by the Dermatology Life Quality Index (DLQI) questionnaire. **RESULTS:** Both cysteamine and HC cream significantly decreased the PAHPI score and melanin index of acne-induced PIH patients ($p<0.05$). The decrease in PAHPI score and melanin index were not significantly different in treatment groups after four months ($p>0.05$). Quality of life ameliorated significantly only with cysteamine treatment. However, no significant change in quality of life was observed between groups. **LIMITATIONS:** Limitations of our study include the relatively small sample size and absence of follow-up. **CONCLUSION:** Cysteamine cream is an effective treatment of post-acne PIH, with similar efficacy to the accepted treatment of PIH, i.e., hydroquinone cream. **KEYWORDS:** Acne vulgaris, hyperpigmentation, drug therapy, cysteamine, hydroquinone, ascorbic acid, administration, topical

Inclusion Criteria
N=28 of 32

- *patients between 14 and 40 years of age who had*
- *no active inflammatory acne lesions after receiving any kind of antiacne treatment*

Exclusion Criteria

- *patients receiving any depigmenting agent two months before being recruited in the study,*
- *patients with a history of hypersensitivity to ingredients of either drug*
- *pregnant or lactating patients.*

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Gold Standard Efficacy with Cyspera®

TABLE 2. Effect of treatment on different variables and comparison of the therapeutic effects in cysteamine cream and Hydroquinone 4%/ascorbic acid 3% cream-treated acne-induced post-inflammatory hyperpigmentation patients, based on both intention-to treat and per-protocol approaches

VARIABLES	CYSTEAMINE				HYDROQUINONE 4%/ASCORBIC ACID 3%				*P*-VALUE[b]
	BEFORE	AFTER	*P*-VALUE[w]	DELTA*	BEFORE	AFTER	*P*-VALUE[w]	DELTA*	
ITT RESULTS	MEAN±SD	MEAN±SD		MEAN±SD	MEAN±SD	MEAN±SD		MEAN±SD	
PAHPI score	11.39 ± 3.01	8.97 ± 3.32	0.049	2.41 ± 4.51	9.50 ± 2.64	6.59 ± 2.64	0.004	2.90 ± 3.76	0.732
Melanin index	123.04 ± 58.69	77.09 ± 22.55	0.005	45.94 ± 56.05	103 ± 66.70	57.19 ± 30.33	0.015	46.80 ± 73.29	0.970
DLQI	7.56 ± 6.63	3.94 ± 3.97	0.013	3.61 ± 5.16	3.94 ± 4.88	1.95 ± 2.35	0.058	1.98 ± 4.15	0.316
Per-protocol results									
PAHPI score	11.54 ± 2.87	8.92 ± 2.56	0.014	2.62 ± 3.28	9.33 ± 2.84	7.13 ± 2.06	0.033	2.20 ± 3.61	0.754
Melanin index	117.78 ± 55.62	72.36 ± 21.18	0.012	45.41 ± 55.74	106.71 ± 71.52	55.37 ± 27.79	0.019	51.34 ± 75.10	0.817
DLQI	8.07 ± 6.86	3.71 ± 3.73	0.007	4.36 ± 5.04	4.00 ± 5.19	1.94 ± 2.48	0.082	2.06 ± 4.41	0.195

ITT: Intention-to-treat; PAHPI: postacne hyperpigmentation index; DLQI: Dermatology Life Quality Index; SD: Standard deviation
*Difference of variables before and after treatment
p-value[w]: *p*-value based on paired samples *t*-test for comparing variables before and after study,
p-value[b]: *p*-value based on independent two-sample *t*-test for comparing Delta score between two groups.

- *Both cysteamine and HC cream significantly reduced the PAHPI score and melanin index of acne-induced PIH patients in ITT and PP approaches (Table 2).*
- *no significant decrease was observed in delta scores of PAHPI and melanin index between the two treatment groups after four months of treatment (Table 2).*
- *Quality of life improved significantly after treatment with cysteamine, but the improvement was not significant after HC cream therapy (Table 2).*
- *the difference in improvement of DLQI between the treatment groups was not statistically significant (Table 2).*
- *Post-treatment patient global assessment (Month 4) was 3.46±0.87 in the cysteamine group and 4.07±1.03 in the HC cream group and was not different between groups (p=0.068).*

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Part 6:

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Sensitive Pigment Correction

for mild pigmentation and sensitive skin

ORIGINAL+

Cysteamine 5%
Isobionic-Amide 5%

30ml

Rinse-off

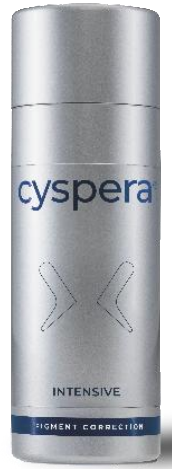
or

INTENSIVE

Cysteamine 7%
Isobionic-Amide 3.5%

30ml

Rinse-off

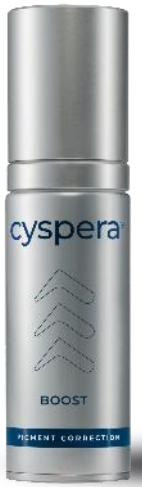


Intensive Pigment Correction

for moderate to severe pigmentation concerns

X

Regenerative activity on **hyperpigmentation** and **inflammation**



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scientis
THE PIGMENTATION AUTHORITY

Dr Behrooz Kasraee, MD
Dermatologist
Chief Scientific Officer, Scientis SA

Courtesy of Dr Chau Yee Ng (Taiwan)