



**Annual Fall
Scientific Meeting
of SMSNA**

October 17-20, 2024 • Scottsdale, AZ

Topical Administration of MED3000 Gel Significantly Improves Self-Esteem and Relationships in Men With Erectile Dysfunction: Results From Two Clinical Trials

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Disclosures

- All authors are advisors to Haleon

Introduction and methods

- Erectile dysfunction (ED) negatively impacts self-esteem, confidence, relationships, and quality of life while effective treatment of ED improves these measures.
- MED3000 is a FDA-cleared, topical treatment for ED that has been shown to be efficacious and well tolerated but the effects on psychosocial outcomes have not been previously reported.

Study 1

A multi-center, randomized, double-blind, parallel-group* study of MED3000 in 250 men with ED over 12-weeks

Study 2

A multi-center, randomized, open-label, parallel-group study where MED3000 was compared with 5 mg oral tadalafil over 24 weeks in 96 men with ED

Self-esteem and relationship assessments included:

- Subjects completed a 14-item Self-esteem and Relationship (SEAR) questionnaire every 4 weeks during the study periods.
- Individual scores were combined and transformed into domain and total scores (1-100, higher scores indicating more favorable responses) and a mean change from baseline was determined every 4 weeks for the 12- or 24-week durations.
- Significance ($P < 0.005$ with Bonferroni correction) of mean changes from baseline were assessed using paired t-tests.

ED, erectile dysfunction; GTN, glyceryl trinitrate.

*The study contained 3 other experimental arms, MED3000 with 0.2%/0.4%/0.6% GTN respectively (no significant differences shown in efficacy data to the MED3000 without GTN arm so are not shown here).

Results

	Study 1 (N=250)			Study 2 (N=48)		
	Baseline	Change from baseline over the 12-week period	P-value	Baseline	Change from baseline over the 24-week period	P-value
Total Score	38.7±15.9	14.7±18.6	<0.001	44.6±17.5	12.5±16.8	<0.001
Sexual Relationship and Satisfaction Domain	38.1±17.1	15.6±19.9	<0.001	41.9±19.6	13.8±17.9	<0.001
Confidence Domain	39.4±15.9	13.6±18.9	<0.001	48.2±16.1	10.8±16.6	<0.005
Self-esteem Domain	38.2±15.4	11.8±17.4	<0.001	42.6±14.6	11.1±18.3	<0.001
Overall Relationship Satisfaction Domain (MCMI not defined)*	41.9±23.4	17.1±28.1	<0.001	59.4±27.2	10.1±24.5	0.009

- All change scores exceed the defined thresholds for minimal clinically meaningful improvement (>10 points)*
- At the end of the trial periods, 81.2% of men in Study 1 and 85.4% in Study 2 felt that sex could be spontaneous



*MCMI has been defined as a 10-point change for most SEAR components (Overall Score, Sexual Relationship, Confidence, Self-Esteem). MCMI for Overall Relationship remains undefined (Cappelleri 2007).

Safety

- Safety results from the two studies have been previously reported at AUA 2024 (see table below)¹

	Pooled results from Study 1 and 2	Study 2 (N=47)
Adverse events (Men)	MED3000 patients (N=297)	Tadalafil patients (N=47)
Headache	9 (3.0%)	9 (19.1%)
Penile burning	3 (1.0%)	0 (0)
Nausea	2 (0.7%)	0 (0)
Back pain	0 (0)	2 (4.3%)
Non-cardiac chest pain	0 (0)	2 (4.3%)



1. Hellstrom WJG. Efficacy and safety of MED3000, a novel topical therapy for the treatment of erectile dysfunction. Oral presentation at AUA 2024, 3-6 May, San Antonio, TX, US.

Discussion and conclusions

MED3000 administration has shown statistically significant and clinically meaningful improvements in self-esteem and relationships as reflected by SEAR total and domain scores.

These findings provide further support of the benefits of MED3000 use in men with ED.

The availability of MED3000 over the counter should improve access to well-tolerated and effective therapy for an otherwise undertreated patient population.

