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Topical Administration of MED3000 Gel Significantly Improves Erectile Function in Men With Mild, Moderate, or Severe Erectile Dysfunction:

Results From Two Multicenter Clinical Trials

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Disclosures

- All authors are advisors to Haleon

Introduction

- Treatment of patients with erectile dysfunction (ED) has been dominated by phosphodiesterase type 5 inhibitors (PDE5i) which have been repeatedly shown to be safe and effective in men with erectile dysfunction of differing severity[1]
- However, about one-third of men are not successfully treated with these agents, many men discontinue therapy and an additional 5% cannot tolerate them[2–4]
- A relatively large group of men with ED symptoms remain either sub-optimally treated or not treated at all,[5] creating an unmet need which could benefit from **novel topical treatments** and new approaches to delivery of established therapies

MED3000 is a FDA-cleared, topical over-the-counter (OTC) treatment for ED that is available for patients regardless of degree of ED severity. The purpose of this study was to assess efficacy across a broad range of these subgroups

1. Wang CM et al. Front Endocrinol (Lausanne). 2023;14:1148834. 2. Cheng E. J Sex Med. 2007;4(2):432–439. 3. Kim SC et al. Int J Impot Res. 2014;26(3):87–93. 4. Zucchi A et al. Andrology. 2019;7(6):804-817. 5. Rasmussen S et al. BMC Fam Pract. 2020;21(1):166

Methods

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

Efficacy assessments included:

- Subjects completed the International Index of Erectile Function – Erectile Function (IIEF-EF) every 4-weeks and in only Study 1 answered Sexual Encounter Profile (SEP) Q2 and Q3 after each intercourse attempt.
- IIEF-EF domain changes from baseline were averaged to provide a mean change from baseline over 12 or 24 weeks, respectively (primary endpoint for both studies).
- The changes from baseline for percentages of patients responding “Yes” to SEP Q2 or Q3 were averaged to provide a mean change from baseline over the 12- week study period (dual primary endpoint for Study 1).
- Significance (with Bonferroni correction, $P<0.004$ for Study 1 and $P<0.0125$ for Study 2) 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 not shown here).

Baseline characteristics

	Study 1	Study 2	
	MED3000	MED3000	Tadalafil
	(N=250)	(N=48)	(N=48)
Countries	Poland, Czech Republic, Slovakia, Hungary, Georgia, Bulgaria, Latvia, Russia, Ukraine	United States, Bulgaria, Poland, Georgia	
Age (years), mean (SD)	46.8 (12.5)	46.1 (13.5)	41.5 (11.5)
Race			
Asian	1 (0.4)	-	-
White/Caucasian	249 (99.6)	44 (91.7)	43 (89.6)
Black/African-American	-	4 (8.3)	5 (10.4)
BMI (kg/m^2), mean (SD)	27.5 (3.6)	27.6 (4.3)	27.5 (4.4)
Duration of ED (months), mean (SD)	27.5 (36.5)	28.9 (32.3)	27.3 (24.8)
ED Severity, number (%)			
Mild	148 (59.2)	19 (39.6)	19 (39.6)
Moderate	70 (28.0)	17 (35.4)	17 (35.4)
Severe	32 (12.8)	12 (25.0)	12 (25.0)
Baseline IIEF-EF, mean (SD)	16.6 (4.7)	14.8 (5.4)	14.5 (4.8)

ED, erectile dysfunction; IIEF-EF, International Index of Erectile Function Erectile Function; SD, standard deviation.

Results (MED3000)

	Study 1 (N=250)			Study 2 (N=48)					
	MED3000			MED3000			Tadalafil		
	Baseline	Change from Baseline over the 12-week Period	P-value	Baseline	Change from Baseline over the 24-week Period	P-value	Baseline	Change from Baseline over the 24-week Period	P-value
IIEF-EF domain (mean ± score for total of 6 questions each scored 1-5, with higher scores indicating better sexual function)									
Overall	16.6±4.7	5.1±5.6	<0.001	14.8±5.4	5.5±5.2	<0.001	14.5±4.8	9.2±5.0	<0.001
Mild	19.9±2.1	3.2±4.3	<0.001	20.2±2.2	3.1±3.9	0.003	19.2±2.0	6.5±2.9	<0.001
Moderate	13.4±1.6	5.8±5.2	<0.001	13.5±1.9	5.6±5.0	<0.001	13.8±1.5	10.2±4.6	<0.001
Severe	8.0±1.6	12.2±5.7	<0.001	7.9±2.0	9.0±5.5	<0.001	7.9±1.6	11.7±6.3	<0.001
SEP Q2 Were you able to insert your penis into your partner's vagina? (% Yes)									
Overall	61.8±39.5	24.3±37.8	<0.001						
Mild	78.4±31.4	12.3±28.5	<0.001						
Moderate	46.5±38.1	31.7±42.4	<0.001						
Severe	16.5±26.4	64.4±35.3	<0.001						
SEP Q3 Did your erection last long enough for you to have successful intercourse? (% Yes)									
Overall	21.5±28.5	37.1±38.3	<0.001						
Mild	29.3±31.5	36.5±40.4	<0.001						
Moderate	12.9±20.8	33.3±34.6	<0.001						
Severe	3.2±7.5	48.8±34.6	<0.001						

Changes from baseline for IIEF-EF scores in both studies exceeded the minimal clinically important differences (MCID) for mild (2 points), moderate (5 points), and severe (7 points) ED. From Study 1, MCID for SEP Q2 (21.4%) and Q3 (23.0%) was exceeded in all subgroups except mild severity for Q2.

Discussion/conclusions

In June 2023, MED3000 became the first OTC topical gel for ED to be granted marketing authorization by the FDA.

MED3000 has demonstrated statistically significant improvements from baseline for IIEF-EF domain scores (in both studies) and, SEP Q2 and Q3 scores (Study 1 only) in patients with mild, moderate and severe ED.

These results demonstrate that MED3000 is a therapy option for men with ED, regardless of severity.