25TH Annual Fall Scientific Meeting of SMSNA

October 17-20, 2024 • Scottsdale, AZ

Topical Administration of MED3000 Gel Significantly Improves All Aspects of the Sexual Encounter Profile for Both Men and Their Partners

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Introduction

There is a significant unmet need for an erectile dysfunction (ED) treatment that is efficacious and well-tolerated, works quickly, and facilitates intimacy.[1]

MED3000 is a, FDA-cleared, over-the-counter topical gel that is applied to the glans penis by the patient or partner.[2]

The clinically proven safety and efficacy of MED3000, using IIEF-EF and time to onset measures, from two phase 3 clinical trials has previously been presented.[3]

The principal role of any ED therapy is to improve the sex life of men and their partners and not just enhance the rigidity and durability of an erection.[4]

A partner's support and acceptance of treatment are also important factors in helping maintain treatment adherence.[4]

It is therefore important to assess the impact any new therapy has on the sex life of both men and their partners.

Aim

To assess the responses to MED3000 in both men and their partners by using the Sexual Encounter Profile (SEP).

Method

MED3000 was tested in a 12-week, multi-center study that included subjects with a clinical diagnosis of ED for >3 months and had IIEF-EF scores of ≤25 during the screening period.

- Subjects were enrolled from Poland, Czech Republic, Slovakia, Hungary, Georgia, Bulgaria, Latvia, Russia and Ukraine
- MED3000 was instructed to be applied by the subjects or their partners immediately prior to sexual intercourse and they were required to have at least 4 intercourse attempts in each of the three 4-weekly periods during treatment (weeks 1-4, 5-8, and 9-12)
- Both the subjects and their partners were instructed to complete the SEP after each sexual intercourse attempt
- Mean percentages of subjects and partners answering "yes" at baseline were determined, as were mean values and changes from baseline for each 4-week period and for the entire 12-week study
- Baseline results and those from the entire 12-week study were compared using paired t-tests. With Bonferroni correction, P<0.005 was accepted for statistical significance
- Efficacy analyses were conducted using all subjects who had made use of the treatment at least once

SEP Questions:

1. Were you/Was your partner able to achieve at least some erection (some enlargement of the penis)?
2. Were you/Was your partner able to insert your/his penis into her/your vagina?
3. Did your (partners) erection last long enough for you to have successful intercourse?
4. Were you satisfied with the hardness of your (partners) erection?
5. Were you satisfied overall with this sexual experience?

Results

A total of 250 subjects were treated with MED3000 and all were included in the analysis.

- For subjects, 249 were White and 1 was Asian
- Mean age ± standard deviation (SD) = 46.8 ± 12.5 years
- Duration of ED = 27.5 ± 36.5 months
- 59.2%, 28.0%, and 12.8% with mild, moderate, or severe ED, respectively
- Baseline IIEF-EF of 16.6 ± 4.7
- For partners, 249 were White and 1 was Asian and the mean age was 43.4 ± 11.9 years

Use of MED3000 resulted in significant improvements in all 5 SEP questions for both subjects and partners over 12 weeks, P<0.001 (Graph/Table 1 and 2).

- Improvements in the percentage answering 'yes' from baseline for all SEP questions for both subjects and their partners achieved statistical significance by 4 weeks and were maintained at 8 weeks, P<0.001

In addition, changes from baseline to week 12 for SEP questions 2 and 3 for men and their partners exceeded the minimum clinically important difference (MCID), a change in percentage answering 'yes' of 21.4% for Q2 and 23.0% for Q3,[5] respectively for these questions.

- Improvements in the percentage answering 'yes' from baseline for SEP questions 2 and 3 for both subjects and their partners exceeded MCID by 4 weeks and were maintained at 8 weeks

References

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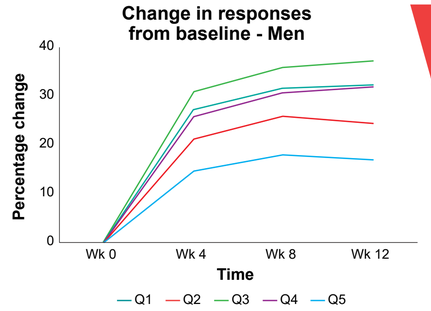
Acknowledgements

All authors are advisors to Haleon.

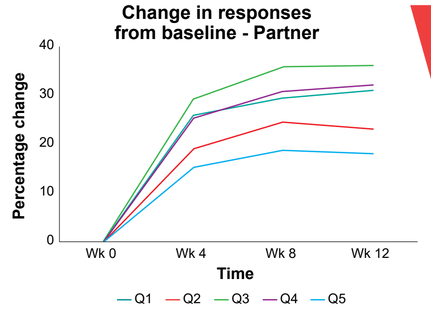
Results



Graph 1. Men SEP Results, Percent Answering "Yes"

SEP	Q1	Q2	Q3	Q4	Q5
Wk 4	±33.5	±37.4	±40.8	±38.1	±40.2
Wk 8	±39.2	±41.3	±42.8	±40.9	±41.1
Wk 12	±36.2	±37.8	±38.3	±36.7	±36.2

Table 1. Men SEP Results, SD to the means



Graph 2. Partner SEP Results, Percent Answering "Yes"

SEP	Q1	Q2	Q3	Q4	Q5
Wk 4	±33.9	±36.9	±40.3	±36.6	±37.8
Wk 8	±39	±41.4	±43.9	±39.6	±40.7
Wk 12	±36.7	±38.1	±39	±35.9	±35.9

Table 2. Partner SEP Results, SD to the means

Conclusions

This multi-center study shows that for both subjects and their partners the use of MED3000 resulted in:

- a statistically significant improvement from baseline for all SEP questions at 4, 8 and 12 weeks
- changes from baseline for SEP questions 2 and 3 for men which exceeded the MCID at 4, 8 and 12 weeks

MED3000 provides an efficacious ED treatment option that is inclusive of the partner.