The COUPLES-project: a pooled analysis of patient and partner treatment satisfaction scale (TSS) outcomes following vardenafil treatment

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Accepted for publication 17 November 2006

OBJECTIVE

To assess the influence of vardenafil on treatment satisfaction in men with erectile dysfunction (ED) and their female partners.

PATIENTS AND METHODS

This was a pooled analysis of three randomized, double-blind, placebo-controlled, 12-week studies of flexible-dose vardenafil vs placebo, in men with ED for ≥6 months (n = 788) and their untreated female partners. Measures of efficacy included the Treatment Satisfaction Scale (TSS), International Index of Erectile Function, Erectile Function domain (IIEF-EF), and Sexual Encounter Profile (SEP) questions 2 and 3 (SEP-2, ‘Were you able to insert your penis into your partner’s vagina?’; and SEP-3, ‘Did your erection last long enough for you to have sexual intercourse?’). In addition to the overall analysis, there was a subgroup analysis for potential moderators of response, e.g. whether patients who had undergone previous phosphodiesterase type 5 (PDE-5) treatment.

RESULTS

At baseline, least-squares (LS) mean scores for all TSS domains were similar in the vardenafil and placebo groups. After 12 weeks of treatment, vardenafil significantly improved the LS mean score for all domains compared with placebo, among both patients and their female partners (P < 0.0001, last-observation-carried-forward analysis). Absolute between-group differences in LS mean TSS scores (vardenafil – placebo) were: ease of erection (patients 23.4, partners 24.9), erectile function satisfaction (36.7 and 32.9), pleasure from sexual activity (23.0, 23.7), satisfaction with orgasm (27.6, 21.8), confidence to complete sexual activity (28.2, 32.5), and satisfaction with medication (37.4, 35.6). The benefits of vardenafil were greater in men who had undergone previous PDE-5-inhibitor treatment and men aged <45 years, while the overall pattern of benefit was similar in all examined subgroups. There were significant benefits with vardenafil in all other variables (IIEF-EF scores and positive response rates to SEP-2 and SEP-3).

CONCLUSIONS

Vardenafil significantly improved treatment satisfaction in men with ED, and in their partners. The results provide further evidence of the validity of the TSS.
KEYWORDS
erectile dysfunction, sexual partner, placebo-controlled trial, pooled analysis, treatment satisfaction

INTRODUCTION
Erectile dysfunction (ED) has a major negative impact on men, and significantly impairs their sexual health and overall quality of life [1,2]. Moreover, the female partners of men with ED also have reduced sexual desire, arousal and satisfaction [3,4]. Therefore, when assessing the effectiveness of ED therapy, it is also important to consider improvement in the partner’s quality of life.

A number of different scales have been developed to assess ED and its effect on sexual well-being and quality of life, but few such measures provide a comprehensive assessment of the sexual satisfaction of the patient and his partner before and after treatment; e.g. the International Index of Erectile Function (IIEF) does not include a measurement of treatment satisfaction or the impact of ED on partners, and neither the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITs) nor the Sexual Life Quality Questionnaire (SLQQ) were designed specifically for prospective assessment of change between the untreated and treated states.

The Treatment Satisfaction Scale (TSS) was developed to provide a comprehensive insight into the sexual satisfaction of men with ED, and of their partners [5]. This multidimensional scale has good internal consistency, reliability and concurrent validity with the IIEF, is highly responsive to change over time [5], and is brief and practical to use. The TSS has been translated into 15 languages other than English, and the different versions have been validated for use in multinational trials [6].

Phosphodiesterase type 5 (PDE-5) inhibitors are recommended as first-line treatment for ED [7], although not for men with risk factors such as significant hypotension, uncontrolled hypertension, unstable angina, severe cardiac failure, or stroke or myocardial infarction within the previous 6–8 weeks [8]. Vardenafil is a PDE-5 inhibitor with proven efficacy in a wide range of men with ED, regardless of disease severity or classification [9]. It is also effective in cases that are considered difficult to treat, e.g. men with a history of non-response to sildenafil [10], or men with comorbidities such as depression or hypertension [11,12]. Vardenafil has a rapid onset of action and, while it is recommended that it is taken =60 min before intercourse [8], a significantly higher likelihood of completing successful intercourse has been reported as early as 10–15 min after dosing [13,14]. In previous studies, the efficacy of vardenafil has been shown to extend to the female partners of men receiving treatment, e.g. vardenafil elicited a significant improvement in partners’ SLQQ quality of life scores [15], and improved the women’s total Female Sexual Function Index score, and sexual desire, subjective arousal, lubrication, orgasm and satisfaction domains [16].

In the present study, we analysed all previous randomized, placebo-controlled studies of vardenafil that included the TSS as an outcome measure, i.e. the ‘Pooled Analysis of Combined Outcomes of Patient and Partner Satisfaction following Levitra Treatment’ (COUPLES) project. Our aim was to confirm treatment satisfaction among both patients receiving vardenafil and their partners.

PATIENTS AND METHODS
We searched the literature for randomized, placebo-controlled studies of vardenafil that included the TSS as an outcome measure. Three studies were identified, all of which were multicentre, double-blind, flexible-dose clinical studies. The methods were similar in all three studies, with a 12-week treatment period in men with ED, and their untreated female partners. The study protocols were approved by Institutional Review Boards and all patients provided signed written consent.

Study 1 was conducted at 26 centres in nine European countries, study 2 at 29 centres in six European countries and study 3 at 26 centres in the USA and Canada. After a 4-week run-in period with no treatment, men were randomized to placebo or flexible-dose vardenafil, the randomization ratio being 1 : 1 in studies 1 and 3, and 3 : 1 (vardenafil : placebo) in study 2. The initial dose was 10 mg, with optional dose titration (vardenafil 5, 10, 20 mg or matched placebo) after 4 and 8 weeks. The men in each study were told to take randomized study medication =1 h before intended sexual intercourse, no more than one dose per calendar day.

The inclusion and exclusion criteria for the three studies were described previously [16–18]. Briefly, all studies included men with: ED for ≥6 months according to National Institutes of Health criteria (i.e. inability to achieve or maintain a penile erection sufficient for satisfactory intercourse) [19]; a stable heterosexual relationship for ≥6 months; and at least half of attempts at sexual intercourse during a run-in period unsuccessful due to ED. Exclusion criteria included penile anatomical abnormalities, primary hypoaactive sexual desire, spinal injury resulting in ED, radical prostatectomy, unstable angina, poorly controlled diabetes, clinically significant hypertension, and liver or haematological disease. Men who had undergone previous PDE-5 treatment were excluded from study 2, and men previously unresponsive to sildenafil were excluded from study 3.

The TSS data were secondary efficacy endpoints in each of the three studies. The domains assessed in the patient TSS are ‘Ease of Erection’ (item 1), ‘Erectile Function (EF) Satisfaction’ (items 2, 3 and 4), ‘Pleasure from Sexual Activity’ (item 5), ‘Confidence with Orgasm’ (item 6), ‘Confidence to Complete Sexual Activity’ (items 7, 8) and ‘Satisfaction with Medication’ (items 9–13) (Appendix). The TSS domains for patients and partners capture identical information, except for the confidence domain, where the question ‘How confident did you feel about initiating sex?’ is asked of patients only.

Other measures of efficacy included the EF domain of the IIEF (IIEF-EF) score and the per-patient diary responses to the Sexual Encounter Profile (SEP) questions 2 and 3 (SEP-2, ‘Were you able to insert your penis into your partner’s vagina?’; and SEP-3, ‘Did your erection last long enough for you to have sexual intercourse?’). All three of these were assessed in patients only, and IIEF-EF and SEP-2 were co-primary endpoints in all of the three studies.

Overall analyses were followed by subgroup analysis of the TSS data, with subgroups defined by patient age (≤45, 45–64, or ≥65 years), previous exposure to PDE-5 medications, and geographical regions (North America, Southern Europe and Northern Europe).
The analysis population was based on patients valid for the intent-to-treat population (as defined in the individual studies) and their partners, who contributed a baseline and post-baseline TSS score after 12 weeks of treatment for a given domain. Because all of the TSS domains have good internal consistency, TSS domain scores were imputed for patients answering at least half of the items (imputed values based on the mean of completed items). Missing TSS or IIEF-EF domain scores at 12 weeks were accounted for by using a 'last' observation carried forward (LOCF) approach, based on available TSS domain scores at 12 weeks. The SEP-3 per-patient response rate is based on diary responses until week 12.

For all efficacy variables, analysis of covariance (ANCOVA), with model terms for treatment and study effects as covariates, was used to compare differences between the least-squares (LS) means at week 12. The results for subgroups were derived from similar ANCOVA/ANOVA models that included model terms to represent the subgroup and treatment combinations.

All significance tests of treatment differences from placebo were two-sided, with no adjustments to significance levels to account for multiple efficacy variables and subgroups. Although none of the analyses were formally pre-specified, the pooled-data analyses adhered closely to those pre-defined in the statistical analysis plans of the individual studies in terms of TSS domain scoring, time points and patient population.

# RESULTS

In all, 788 men from the three studies were valid for the intent-to-treat analysis. Of these, 458 received vardenafil and 330 placebo; the imbalance was due to the 3:1 randomization ratio used in one of the studies. The men were from the USA (24.5%), Canada (4.1%), France (17.0%), Germany (15.9%), Italy (7.6%) and Belgium (5.5%), and several other European countries.

The patients' baseline characteristics (Table 1) indicated only minor differences between the studies. In study 3, the men were slightly older and slightly heavier, and more were non-white. In study 2, the likelihood of smoking was lower, the likelihood of light/moderate alcohol consumption was higher, and the duration of ED was shorter than in the other studies (none of the men in study 2 had undergone previous PDE-5 treatment). Three times as many men in study 2 received vardenafil than placebo, so the pooled vardenafil treatment group contained proportionately more patients from study 2 than the placebo group. As a result, the pooled vardenafil group had a shorter duration of ED symptoms and reduced previous sildenafil use vs placebo. Otherwise, for the pooled population, there was little difference between the vardenafil and placebo groups. Considering the pooled population, patients had a variety of...
coexistent medical conditions, e.g. hypertension (36% of the pooled population), hyperlipidaemia (22%), diabetes mellitus (22%), cardiovascular disease (13%) and pulmonary disease (3%).

TSS results for the pooled analysis are shown in Fig. 1. There were no significant differences between placebo and vardenafil groups at baseline for any TSS domain, for either patients or their partners. At 12 weeks, there were significant differences in favour of vardenafil for all six TSS domains (ease of erection, EF satisfaction, pleasure from sexual activity, satisfaction with orgasm, confidence to complete sexual activity, and satisfaction with medication). In all domains, there were significant differences for both patients and partners. For men assigned to placebo and their partners, there were minimal changes in all of the TSS domains at 12 weeks vs baseline.

FIG. 1. The TSS results for vardenafil vs placebo.

Vardenafil was also compared with placebo by profiling the between-group difference for the six TSS domains (Fig. 2). For all subgroups considered, including partners, there was little difference in the overall pattern. In most cases, the greatest benefits with vardenafil were evident with the domains of EF satisfaction, medication satisfaction and confidence to complete sexual activity, respectively. The only exceptions were for men aged ≥65 years, where the domain showing the third greatest benefit was orgasm satisfaction instead of confidence to complete sexual activity, and for men aged <45 years, where the vardenafil benefits were the same for both orgasm satisfaction and confidence to complete sexual intercourse. These two domains also showed very similar benefits from vardenafil in men who had undergone previous PDE-5 treatment. Across all domains, the benefits with vardenafil vs placebo were greater in men who had undergone previous PDE-5 treatment and in men aged <45 years.

FIG. 2. The profile of the difference between vardenafil and placebo across the six TSS domains, for subgroups from the analysis (12 weeks, LOCF).

There were also significant benefits with vardenafil vs placebo in terms of the secondary efficacy variables, with no significant between-group differences at baseline (Table 2). This was true for the IIEF-EF mean score (12 weeks), as well as the proportion of positive responses to SEP-2 and SEP-3 (diary entries: 0–12 weeks). The only one of these three variables indicating any improvement from baseline with placebo was SEP-3.

DISCUSSION

After 12 weeks of treatment, vardenafil significantly improved the LS mean score for all six TSS domains, vs placebo. Patients’ and
Partners’ results were similar, as were findings across all patient subgroups, indicating the consistent relevance and sensitivity of the TSS measures to these groups. Consistent improvements were also seen in terms of IIEF-EF, SEP-2 and SEP-3, indicating a broad agreement between the TSS and the other variables.

Notably, there were very similar benefits with vardenafil treatment for both men and their partners in the present analysis, indicating that vardenafil treatment is likely to benefit both partners in a relationship when treatment for ED is sought. The extension of the treatment effect to the partners of men with ED might not occur to the same extent with all PDE-5 inhibitors, e.g. it was reported that sildenafil has no impact on partners’ desire, arousal or orgasm experience [20], although a subsequent sildenafil study indicated a significant improvement in the partners’ sexual function [21]. Several randomized studies have provided evidence that vardenafil provides significant benefits to partners as well as patients [15–17,22]; the improvements were of similar magnitude to those in the present pooled analysis, in terms of improvements vs placebo in IIEF-EF, SEP-2 and SEP-3 outcomes, e.g. at 12 weeks the IIEF-EF scores in one of the studies were 22.8 with vardenafil vs 12.7 with placebo [15], compared with 23.1 and 14.4 in the present analysis. One of the studies, published after the present pooled analysis, reported TSS improvements with vardenafil in both patients and partners [22]. This was a comparison of vardenafil vs sildenafil, which indicated superiority with vardenafil in 12 of 19 patient TSS questions (nominal significance, P < 0.005), and a trend in favour of vardenafil in 14 of 18 partner TSS questions.

The TSS provides a multidimensional perspective on the treatment response, as it incorporates satisfaction with medication, satisfaction with EF, ease of obtaining an erection, sexual confidence, and satisfaction with orgasm and sexual pleasure [5]. This provides a high degree of validity and interpretability that is not achieved with other scales that include patients’ satisfaction with medication (SLQQ and EDITS, both of which have limited dimensionality). The TSS is also the only measure of treatment satisfaction that allows the change from baseline to be assessed prospectively [6]. Furthermore, the extensive similarity between questions in the patient and partner TSS questionnaires allows a meaningful analysis of differences and similarities in patient and partner satisfaction. The present results suggest equivalence between the improvements for patients and their partners. This is a novel concept that might warrant further exploration.

The present results are consistent with a previous study of >300 men with ED that showed a correlation between the IIEF and TSS [5]. Specifically, all patient TSS domains were significantly correlated with three domains of the IIEF (EF, intercourse satisfaction and overall satisfaction), the strongest relationship being between the TSS-EF domain and IIEF-EF. This study also demonstrated a significant correlation between men’s IIEF-EF results and the six partner TSS domains [5].

Further evidence of the validity of the TSS is provided by the similarity in the profile of domain scores across all patient subgroups. This also confirms the consistent benefits of vardenafil in the broad range of men included in this pooled analysis, regardless of age, previous PDE-5 treatment and geographical location. There were some differences between subgroups in the overall magnitude of benefit with vardenafil, with more benefit for men who had undergone previous PDE-5 treatment and for men aged <45 years. Considering the first of these groups, the increased benefit might be attributable to the selection of men for whom sexual activity is more important. For the second group, younger men might have potential for greater improvement, as sexual activity is more likely to be of major importance; in addition, younger men might be less impaired. Apparent geographical differences should be interpreted with caution, as cultural differences preclude a direct comparison of different regions.

The broad efficacy of vardenafil was indicated by overall success in the varied pooled-patient population, e.g. the pooled analysis included men with a wide age range, residence in a number of different countries (socioeconomic and sociocultural variation), and a variety of comorbidities were present, such as hypertension, diabetes, cardiovascular disease and pulmonary disease. The results of the individual (unpooled) studies were consistent with the present outcomes, with vardenafil providing significant benefits vs placebo in a variety of efficacy variables [16–18,23]. Earlier studies also showed the efficacy of vardenafil in a wide range of patients, including men with diabetes, mild depression, or previous radical prostatectomy [24]. These data indicate that vardenafil is well suited for use in clinical practice, with few restrictions in patient profile. Additionally, men in the present studies were given flexible dosing, ensuring that the results have maximum relevance to clinical practice.

In the present analysis, nominal P values are reported. Multiple comparisons and subgroup analyses accumulate to a total of 72 comparisons vs placebo. When applying the conservative Bonferroni method to control for multiplicity, a nominal α level of 0.05/72 = 0.00069 would result. The P values for all 72 comparisons were below this level, so that an overall significance at the 0.05 level is clearly obtained.

In conclusion, the present pooled analysis confirms the efficacy of vardenafil in a broad range of patients and their partners, and confirms the validity and sensitivity of the TSS.

### Table 2: Efficacy results: secondary variables; values are LS mean (SEM)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline Vardenafil</th>
<th>Placebo</th>
<th>During treatment Vardenafil</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIEF-EF*</td>
<td>13.1 (0.26)</td>
<td>13.4 (0.31)</td>
<td>23.1 (0.33)†</td>
<td>14.4 (0.40)</td>
</tr>
<tr>
<td>SEP-2</td>
<td>43.7 (1.79)</td>
<td>47.0 (2.14)</td>
<td>78.9 (1.36)†</td>
<td>49.4 (1.61)</td>
</tr>
<tr>
<td>SEP-3</td>
<td>17.1 (1.10)</td>
<td>19.7 (1.32)</td>
<td>67.6 (1.46)†</td>
<td>31.4 (1.75)</td>
</tr>
</tbody>
</table>

*During treatment values recorded at 12 weeks (LOCF); †P < 0.0001 vs placebo.

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R. Rosen and W. Fisher are paid consultants to Bayer; M. Beneke, M. Homering and T. Evers are employees of the sponsor. Source of funding: Bayer Pharmaceuticals.
REFERENCES


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Abbreviations: COUPLES, ‘Pooled Analysis of Combined Outcomes of Patient and Partner Satisfaction following Levitra Treatment’ project; ED, erectile dysfunction; TSS, Treatment Satisfaction Scale; IIEF-ED, International Index of Erectile Function, Erectile Function domain, SEPE(–)3, Sexual Encounter Profile questions 2 and 3; LS, least-squares; LOCF, ‘last’ observation carried forward analysis; PDE-5, phosphodiesterase type 5; EDITS, Erectile Dysfunction Inventory of Treatment Satisfaction; SLQQ, Sexual Life Quality Questionnaire; ANCOVA, analysis of covariance.
Appendix: Treatment Satisfaction Scale (TSS) Questionnaire

This is a self-administered questionnaire that the patient and his partner complete. The patient and partner should complete the TSS separately. The partner need not be present at the centre to complete the partner module of the TSS: this can be mailed out and returned via mail. The partner should complete the questionnaire on the same date as the patient, i.e. on the date of the clinic visit.

Patient

Baseline Module

Instructions

To answer the following questions, please think about the past four weeks only.

Please check or mark an “x” in one box only per question.

Important: When answering the questions keep in mind that "sexual activity" includes intercourse, caressing, foreplay, masturbation, etc., "sexual stimulation" includes situations such as foreplay with a partner, looking at erotic pictures, etc.

Over the past four weeks:

<table>
<thead>
<tr>
<th>Question</th>
<th>Rating Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How easy was it for you to get an erection when stimulated?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
<tr>
<td>2. How satisfied were you with the amount of time it took before you could get an erection?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
<tr>
<td>3. How satisfied were you with how long your erections lasted?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
<tr>
<td>4. How satisfied were you with the hardness of your erections?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
<tr>
<td>5. How much pleasure did you get from your sexual activity?</td>
<td>None 1 A little 2 Some 3 A lot 4 Extreme 5</td>
</tr>
<tr>
<td>6. How satisfied were you with your orgasms?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
<tr>
<td>7. How confident did you feel about initiating sex?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
<tr>
<td>8. How confident were you that you could complete your sexual activity?</td>
<td>Not at all 1 A little 2 Somewhat 3 Very 4 Extremely 5</td>
</tr>
</tbody>
</table>
PATIENT

ACTIVE MEDICATION MODULE

Instructions

To answer the following questions, please think about the past four weeks only.

Please check or mark an "x" in one box only per question.

IMPORTANT: When answering the questions keep in mind that "sexual activity" includes intercourse, caressing, foreplay, masturbation, etc., "sexual stimulation" includes situations like foreplay with a partner, looking at erotic pictures, etc.

Over the past four weeks:

1. How easy was it for you to get an erection when stimulated?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

2. How satisfied were you with the amount of time it took before you could get an erection after taking this medication?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

3. How satisfied were you with how long your erections lasted?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

4. How satisfied were you with the hardness of your erections?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

5. How much pleasure did you get from your sexual activity?
   □ 1 None  □ 2 A little  □ 3 Some  □ 4 A lot  □ 5 Extreme

6. How satisfied were you with your orgasms?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

7. How confident did you feel about initiating sex?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

8. How confident were you that you could complete your sexual activity?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

9. How confident were you that the medication would work every time?
   □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

10. How satisfied were you with how long the medication could help you to get an erection?
    □ 1 Not at all  □ 2 A little  □ 3 Somewhat  □ 4 Very  □ 5 Extremely

11. To what degree has this medication met your expectations?
    □ 1 Did not meet my expectations at all  □ 2 Did not quite meet my expectations  □ 3 Met my expectations  □ 4 Somewhat exceeded my expectations  □ 5 Greatly exceeded my expectations
12. Overall, how satisfied are you with this medication?

- Not at all
- A little
- Somewhat
- Very
- Extremely

13. Would you like to continue using this medication?

- Definitely not
- Probably not
- Do not know
- Probably yes
- Definitely yes

**PARTNER**

**BASELINE MODULE**

*Instructions*

To answer the following questions, please think about the past four weeks only.

Please check or mark an “x” in one box only per question.

**IMPORTANT:** When answering the questions keep in mind that “sexual activity” includes intercourse, caressing, foreplay, masturbation, etc., “sexual stimulation” includes situations such as foreplay with a partner, looking at erotic pictures, etc.

**Over the past four weeks:**

1. How easy was it for your partner to get an erection when you stimulated him?

- Not at all
- A little
- Somewhat
- Very
- Extremely

2. How satisfied were you with the amount of time it took before your partner could get an erection?

- Not at all
- A little
- Somewhat
- Very
- Extremely

3. How satisfied were you with how long your partner’s erections lasted?

- Not at all
- A little
- Somewhat
- Very
- Extremely

4. How satisfied were you with the hardness of your partner’s erections?

- Not at all
- A little
- Somewhat
- Very
- Extremely

5. How much pleasure did you get from your sexual activity?

- None
- A little
- Some
- A lot
- Extreme

6. How satisfied were you with your orgasms?

- Not at all
- A little
- Somewhat
- Very
- Extremely

7. How confident were you that your partner could complete his sexual activity?

- Not at all
- A little
- Somewhat
- Very
- Extremely
PARTNER

ACTIVE MEDICATION MODULE

Instructions

To answer the following questions, please think about the past four weeks only.

Please check or mark an "x" in one box only per question.

IMPORTANT: When answering the questions keep in mind that “sexual activity” includes intercourse, caressing, foreplay, masturbation, etc., “sexual stimulation” includes situations such as foreplay with a partner, looking at erotic pictures, etc.

Over the past four weeks:

1. How easy was it for your partner to get an erection when you stimulated him?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

2. How satisfied were you with the amount of time it took before your partner could get an erection after taking his medication?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

3. How satisfied were you with how long your partner’s erections lasted?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

4. How satisfied were you with the hardness of your partner’s erections?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

5. How much pleasure did you get from your sexual activity?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   None  A little  Some  A lot  Extreme

6. How satisfied were you with your orgasms?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

7. How confident were you that your partner could complete his sexual activity?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

8. How confident were you that your partner’s medication would work every time?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

9. How satisfied were you with how long the medication could help your partner to get an erection?
   ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
   Not at all  A little  Somewhat  Very  Extremely

10. To what degree has your partner’s medication met your expectations?
    ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5
    Did not meet my expectations at all  Did not quite meet my expectations  Met my expectations  Somewhat exceeded my expectations  Greatly exceeded my expectations
11. Overall, how satisfied are you with your partner’s medication?

☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5

Not at all  A little  Somewhat  Very  Extremely

12. Would you like your partner to continue using his medication?

☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5

Definitely not  Probably not  Do not know  Probably yes  Definitely yes