



## **PRESS RELEASE**

**Monday 6 April 2009**

### **Premature ejaculation spray enables men to last six times longer after penetration**

Men with premature ejaculation who used a topical spray five minutes before intercourse were able to delay their orgasm six times longer than normal, according to a study in the April issue of **BJU International**.

Three hundred men with clinically diagnosed lifelong premature ejaculation (PE) from 31 centres in the UK, Czech Republic, Hungary and Poland, were randomised into two groups. Two hundred used the PSD502 spray, which contains 7.5mg of lidocaine and 2.5mg of prilocaine, and 100 used a placebo spray with no active ingredients.

Every time they had intercourse during the three-month study period, each couple measured the time from vaginal penetration to ejaculation with a stopwatch. The men were asked to abstain from sexual activity or masturbation for 24 hours before each recorded encounter.

The time from penetration to ejaculation increased from an average of 0.6 minutes to 3.8 minutes in the medicated group and to just 1.1 minutes in the placebo group.

When these figures were adjusted to take account of any variations between the two groups, these showed that the treatment group were able to last 6.3 times longer after penetration when they used the spray. The placebo group lasted 1.7 times longer.

“Premature ejaculation can be a very distressing condition for men and can cause distress, frustration and make them avoid sexual intimacy” says lead researcher Professor W Wallace Dinsmore from the Royal Victoria Hospital, Belfast, UK.

The research team used the evidence-based definition of lifelong PE developed by the International Society for Sexual Medicine to select their study subjects. This

states that ejaculation occurs within about one minute of vaginal penetration in the majority of encounters.

“Because this definition was only launched in 2008, studies have yet to determine the prevalence of lifelong PE in the male population” says Professor Dinsmore. “But previous research suggests that as many as 40% of men will experience premature ejaculation at some time in their lives.”

The 300 men who took part in the phase three, multicentre, double-blind, randomised study had an average age of 35. The majority had used other treatments before, the most common being oral antidepressants.

After three months of treatment the researchers reported that:

- 90% of the men in the treatment group were able to delay ejaculation for more than one minute following vaginal penetration, compared with 54% in the placebo group.
- 74% of men in the treatment group managed to last more than two minutes before ejaculation, compared with 22% in the placebo group.
- 62% of men in the treatment group said their orgasms were ‘good’ or ‘very good’ after three months, compared with 20% before the study started. The figures for the placebo group were slightly lower at the end (19%) than at the start (21%).
- 66% of men in the treatment group said the medication was ‘good’ or ‘excellent’ compared with 15% in the placebo group.
- A significantly higher percentage of the patients and partners in the treatment group reported improvements when it came to perceived control, personal distress, satisfaction with sexual intercourse and interpersonal difficulties.
- There were no serious adverse events reported during the study. Adverse treatment-related reactions were reported by five men and six women from the treatment group and one man from the placebo group. The most common problems were loss of erection and a burning sensation in the vagina.

“Our study shows that when the PSD502 spray was applied to the man’s penis five minutes before intercourse it improved both sexual performance and sexual satisfaction, which are key factors in treating premature ejaculation” says Professor Dinsmore.

“It was well tolerated by both patients and their partners, with no systemic side effects and a low incidence of localised effects and was rated favourably by the majority of users.

“We believe that this shows that PSD502 offers significant advantages over other therapies being developed for the treatment of premature ejaculation.”

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### Notes to editors

- PSD502 improves ejaculatory latency, control and sexual satisfaction when applied topically 5 min before intercourse in men with premature ejaculation: results of a phase III, multicentre, double-blind, placebo-controlled study. Dinsmore et al. **BJU International**. 103, 940-949 (April 2009).
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- **Phase three studies** are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people. Source: [www.fda.gov](http://www.fda.gov)