



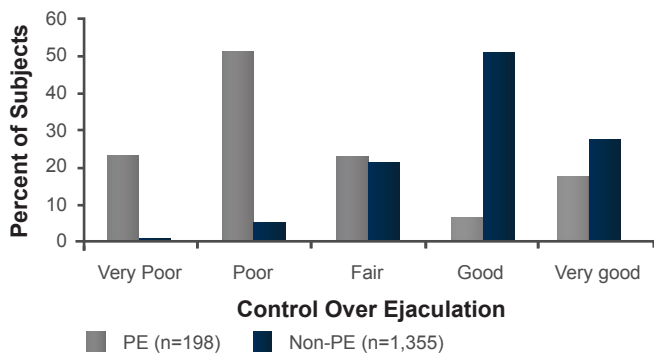
# PROMESCENT® Product Monograph

## Clinical Presentation of Premature Ejaculation

The clinical definition of PE is quite specific. According to the ISSM, premature ejaculation is: ejaculation which generally occurs within one minute of vaginal penetration, and the inability to delay ejaculation on all or nearly all vaginal penetrations, and negative personal consequences, such as distress, bother, frustration, and/or the avoidance of sexual intimacy.

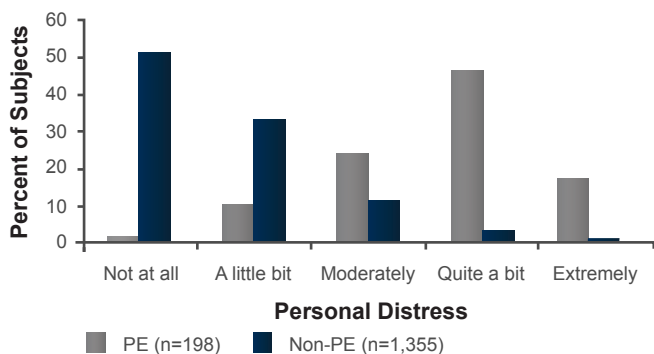
Using only the time component of this definition (ejaculation which generally occurs within one minute of vaginal penetration) available studies suggest that as few as 1 to 3% of men would meet the diagnostic criteria for premature ejaculation.

### The Control Criterion Leads to a Distinct Separation Between PE and Non-PE Men



Patrick et al J Sex Med 2005 2:358-67

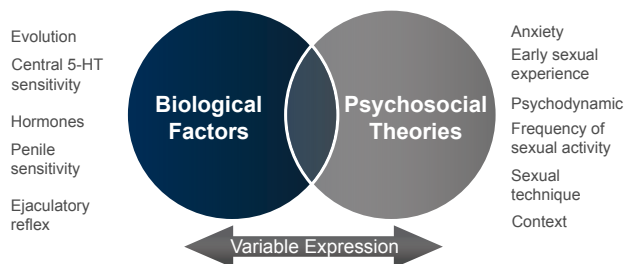
### The Distress Criterion Also Leads to a Separation Between PE and Non-PE Men



Patrick et al J Sex Med 2005 2:358-67

However, when considering the additional diagnostic criteria -- the inability to delay ejaculation on all or nearly all vaginal penetrations as well as negative personal consequences, such as distress, bother, frustration, and/or the avoidance of sexual intimacy-- patient reported data indicates a significantly higher prevalence of PE in the range of 20% to 30% that may be unrelated to the timed duration of intercourse.

## Multifactorial Etiology of PE



Perelman MA, et al. Atlas of Male Sexual Dysfunction. Philadelphia, Pa: Current Medicine, Inc; 2004.

Given the wide ranging prevalence estimates, and the degree to which self-reported negative personal consequences can affect a patient's motivation for treatment, the ISSM recommends that all men presenting with complaints of premature ejaculation should be evaluated and considered candidates for treatment.

While many men may not talk about premature ejaculation or extending the duration of their intercourse, their desire to last longer can affect their emotional and sexual well being.



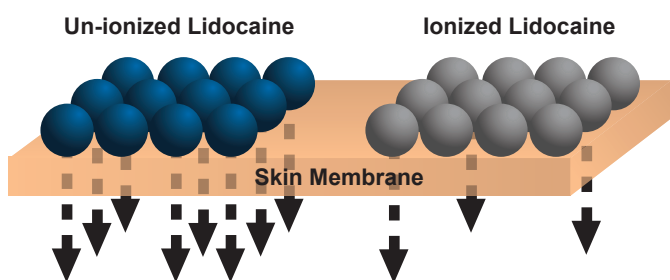
## Medical Treatment Options

The off-label use of selective serotonin reuptake inhibitors (SSRIs), may be considered for some men but these medications generally require daily dosing for optimal efficacy and have potentially significant side effects. Aside from the concerns caused by off-label use, patient compliance is a major limitation to this form of treatment. Data from Salonia et al. indicates that 30% of patients refused to begin treatment with SSRIs and 30% of those who started treatment discontinued it.<sup>1</sup>

The use of topical anesthetics such as lidocaine to reduce the sensitivity of the penis dates back to as early as 1943 and has been shown to be an effective treatment for PE. Unlike most systemic forms of treatment, the topical anesthetics can be used "on demand" with a minimal risk of significant side-effects. Unfortunately, there are limitations to the successful use of the topical anesthetics.

Specifically, the poor formulations of these products makes proper dosing difficult and the limited transdermal absorption of lidocaine in these products necessitates application at least 20-30 minutes before intercourse. This limited transdermal absorption may also require that the man use a condom to protect his partner from the vaginal numbness that can occur if topical anesthetic is transferred to his partner during intercourse.

## How PROMESCENT Works



PROMESCENT is a eutectic mixture with lidocaine in an un-ionized form that effectively penetrates the skin membrane. Ionized forms of lidocaine may not penetrate the skin or may take significant time to penetrate the skin, making them less appealing for use in PE.

## Real Medicine That Really Works

PROMESCENT is a unique eutectic mixture that allows for effective absorption of topical lidocaine. Developed with a leading U.S. university's school of pharmacy, PROMESCENT's absorption technology, in conjunction with the metered-dose spray bottle, enables men to deliver a specific and reproducible amount of lidocaine through the stratum corneum of the penile skin to the dermis and control ejaculation latency. PROMESCENT allows men to easily manage penile sensitivity in order to maintain optimum sexual satisfaction. PROMESCENT conforms to 21 CFR Section 348.10 Subpart B (a)(2) and is produced in the United States by a pharmaceutical manufacturing company meeting or exceeding Good Manufacturing Practices (GMP) established by the FDA.

PROMESCENT takes effect in as little as 10 minutes and use of a condom is not required. It absorbs and dries in just a few minutes and can be easily washed off prior to intercourse so that transmission is not an issue. The reduced sensitivity typically lasts at least 30 minutes to more than one hour depending upon the dose and sensitivity.

## Important Safety Information

Premature Ejaculation may be due to a condition requiring medical supervision. PROMESCENT should not be used if the man or his partner are allergic to lidocaine or topical anesthetics. Patients should be instructed to discontinue use if the man or his partner develop a rash or irritation such as burning or itching. PROMESCENT should not be applied to irritated or broken skin. For topical use only. If swallowed, contact a poison control center or go to the nearest emergency room. Avoid contact with eyes. Dosing must be individualized and should not exceed 10 sprays per use. Excess numbness may cause a temporary loss of erection. If symptoms persist, consult a doctor. PROMESCENT will not stop the spread of sexually transmitted disease. Results may vary with each individual.



PROMESCENT®

MAKE LOVE LONGER

1. Salonia A, Rocchini L, Sacca A, Pellucchi F, Ferrari M, Carro UD, Ribotto P, Gallina A, Zanni G, Deho F, Rigatti P, Montorsi F. Acceptance of and discontinuation rate from paroxetine treatment in patients with lifelong premature ejaculation. J Sex Med 2009;6:2868-77.