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DRUG REVIEW

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Clinical efficacy and safety of Vitaros©/Virirec© (Alprostadil cream) for the treatment of erectile dysfunction

Ignacio Moncada[1], Béatrice Cuzin[2]

[1] Hospital La Zarzuela c/Pléyades, Madrid - Spain
[2] Department of Urology and Transplantation, Universitary E Herriot Hospital, Lyon Cedex - France

ABSTRACT

Erectile dysfunction (ED) is a very common disorder with a deep impact on patients and their partners. Several options are now available for treating ED; oral pharmacotherapy with phosphodiesterase-5 (PDE5) inhibitors currently represents the first-line option for many ED patients. Vitaros©/Virirec© is new topical, non-invasive treatment for ED that offers the combination of an active drug (alprostadil, a synthetic PGE1) with a skin enhancer that improves its local absorption directly at the site of action. Vitaros©/Virirec© has a favorable pharmacodynamic profile and is poorly absorbed in systemic circulation. This makes it suitable in any circumstances and results in a reduced risk of adverse events (AEs), being systemic AEs reported in only 3% of the treated population. Its clinical efficacy has been demonstrated in both phase II and III trials, showing a global efficacy up to 83% with the 300 µg dose in patients with severe ED significantly better than placebo. Its fast onset of action together with its favorable toxicity profile and lack of interactions with other drugs makes Vitaros©/Virirec© a first-line therapeutic option for patients with ED, particularly for individuals who are reluctant to take systemic treatments or with AEs. It may also have an important role in patients not responding to PDE5 inhibitors, particularly those with ED after radical prostatectomy.

Keywords: Alprostadil, Erectile dysfunction, Topic application, Vitaros©/Virirec©

Introduction

Erectile dysfunction (ED) can be defined as the consistent inability to obtain and maintain an adequate penile erection sufficient for a satisfactory sexual activity (1). It is a common disorder, with increasing incidence in men over 40 years of age. The prevalence of ED has been estimated to be between 2 and 10% in men aged between 40 and 50 years, 30 and 40% in men 60-70 years, and more than 50% in men over the age of 70 (2-4).

Due to the increase in healthy aging population, ED is becoming a serious health problem. Apart from pathophysiological implications of the disorder, several pathologies are also associated with ED [cardiovascular (CV) disease, diabetes, prostatectomy], further increasing the proportion of individuals affected. ED strongly contributes to an unsatisfactory sexual life and, as a consequence, the quality of life of both affected men and their partners is also greatly impaired (5).

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Corresponding author:
Ignacio Moncada, MD
Hospital La Zarzuela
c/Pléyades, 25
28023 Aravaca
Madrid, Spain
ignacio@moncada.name

Treatment of ED has been shown to have a positive effect on the quality of life and overall satisfaction for both patients and their partners (6). The guidelines of the European Association of Urology recommend psychosexual counseling and phosphodiesterase-5 (PDE5) inhibitors as first-line treatment for ED (5). However, this class of drugs is associated with treatment failure in 11-44% of patients depending on the patient population under study (7). In addition, PDE5 inhibitors have several pharmacological interactions for which they are contraindicated, such as patients taking nitrates. Also, PDE5 inhibitors have numerous side effects that can cause treatment discontinuation, particularly headache, visual disturbances, muscular pain, and dyspepsia (8). Local treatment modalities (intracavernosal injection therapy, intraurethral alprostadil, vacuum erection devices) have been used as an alternative or in combination with PDE5 inhibitors.

Herein, we present the pharmacology, clinical efficacy data, and safety profile of Vitaros©/Virirec©, a new alprostadil cream formulated with a novel skin permeation enhancing drug delivery system.

Molecular mechanism and pathophysiology of erectile dysfunction

Penile erection is mostly governed by the tone of the penis smooth muscle (which represents roughly half of the volume of the corpus cavernosum) through its control of different hemodynamic events (9). Proper levels of agonists and