



This drug has been "archived" and will not be actively updated except for a compelling reason or request (August 2006).

ALPROSTADIL

SUMMARY SHEET

TRADE NAME: Caverject, Viridal 20®

For the treatment of erectile dysfunction

Licensed Indication:

Treatment of erectile dysfunction.

An adjunct to other diagnostic tests in the diagnosis of erectile dysfunction.

Background information

Erectile dysfunction is defined as the consistent inability to achieve or maintain an erection of sufficient rigidity for vaginal penetration in sexual intercourse. It is distinctly different from loss of libido, premature ejaculation or the absence of orgasm. Erectile dysfunction is an age and disease dependent disorder with an incidence of 1.9% at 40 years and 25% at 65 years.¹

Current treatment options include vacuum devices, intracavernosal injection therapy, surgical implantation of penile prosthesis, venous and/or arterial surgery and psychotherapy.

Alprostadil is the first drug to be licensed in the UK for the treatment of impotence by direct intracavernosal injection. Papaverine has been used for a number of years but is **not licensed** for this indication.

Clinical Efficacy

There have been numerous controlled and uncontrolled trials of alprostadil for the treatment of impotence. Dose response studies and open labelled trials have shown that approximately 80% of patients achieve a satisfactory erection with 20mcg alprostadil or less. Generally patients with neurogenic or psychogenic impotence responded to lower doses, those with vasculogenic impotence requiring larger doses. A response is usually seen with 15 minutes, and with careful dose titration lasts no more than one hour.^{2,3}

Controlled trials have compared intracavernous alprostadil with papaverine ± phentolamine. These have demonstrated that alprostadil is at least as effective as papaverine ± phentolamine in producing a satisfactory erection in impotent men. A few patients however only responded to alprostadil and others only to papaverine.^{4,5,6}

Alprostadil has also been shown to be an effective treatment for men who are refractory to or inappropriate for treatment with papaverine ± phentolamine.⁷

Adverse Effects

Pain in the penis during erection with/without a burning sensation or tension is seen in approximately 20% of patients treated with intracavernous alprostadil.⁸

Less common side effects include haematoma (1.5%), erythema (7%), penile deviation (4%), and perineal pain (4%).⁸

Systemic side effects have also been reported but in some instances are considered to be related to the injection procedure itself rather than the pharmacological effects of alprostadil. These include increased blood pressure (9%), decreased blood pressure (15%), cardiac arrhythmias (3%), postural hypotension (3%), collapse (1%) and vagal shock (1%).⁸

Priapism has been recorded in approximately 1% of patients. An erection lasting 6 hours or more requires treatment. This involves penile aspiration or intracavernous injection of μ adrenergic medication. Alprostadil is contra-indicated in patients with a predisposition to priapism such as those with sickle-cell anaemia, multiple myeloma or leukaemia.⁸

Costs

At current prices one month's treatment with alprostadil 20mcg three times a week costs approximately £120. Doses and frequency of injection will vary between patients. Administration more than 3 times a week is not advised.

Summary

Alprostadil by intracavernosal injection is an effective treatment for erectile dysfunction, response being greatest in men with psychogenic and neurogenic impotence. Expertise is required before initiating treatment, patients need to be carefully selected and trained. General practitioners should only prescribe this drug if they are comfortable with the training and supervision of these patients. The Department of Health has recently issued guidance on the restricted prescribing of impotence drugs on the NHS.

References

1. Lerner SE, Melman A & Christ G. A Review of Erectile Dysfunction: New Insights and More Questions. *J. Urol.* 1993; 149: 1246-1255.
2. Schramek P, Dorninger R, Waldhauser M, Konecny P & Porpaczy P. Prostaglandin E₁ in Erectile Dysfunction - Efficiency and Incidence of Priapism. *Br. J. Urol.* 1990; 65: 68-71.
3. Ishii N, Watanabe H, Irisawa C, Kikuchi Y, Kubota Y et al. Intracavernous Injection of Prostaglandin E₁ for the Treatment of Erectile Impotence. *J. Urol.* 1989; 141: 323-325.
4. Chen J, Hwang TIS & Yang C. Comparison of Effects following the Intracorporeal Injection of Papaverine and Prostaglandin E₁. *Br. J. Urol.* 1992; 69: 404-407.
5. Earle CM, Keogh EJ, Wisniewski ST, Tulloch AG, Lord DJ et al. Prostaglandin E₁ Therapy for Impotence, Comparison with Papaverine. *J. Urol.* 1990; 143: 57-59.
6. Mahmoud KZ, El Dakhli MR, Fahmi IM & Abdel-Aziz AB. Comparative Value of Prostaglandin E₁ and Papaverine in Treatment of Erectile Failure: Double-Blind Crossover Study Among Egyptian Patients. *J. Urol.* 1992; 147: 623-626.
7. Armstrong DKB, Convery A, Dinsmore WW. Prostaglandin E₁ in the Medical Management of Erectile Dysfunction in Genito-Urinary Medicine. *Ulster Med. J.* 1993; 63: 18-22.
8. Anon. Caverject. ABPI Datasheet Compendium 1995-96.

THIS SUMMARY SHEET REPLACES SS96/24 which should be removed and DESTROYED

