Alprostadil

Presentation A white to off-white lyophilised powder, containing alprostadil 20 micrograms. The powder also contains lactose and sodium citrate. The diluent solution is 1 ml bacteriostatic water for injections (benzyl alcohol 0.9% w/v).

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

Dosage and Administration The initial dose of alprostadil is 2.5 micrograms and can be increased in increments of 2.5 micrograms to a maximum of 60 micrograms. The usual dose is 10-20 micrograms. The recommended frequency of injection is no more than once daily and no more than three times weekly.
The first injection of alprostadil must be done by medically trained personnel. After proper training and instruction, alprostadil may be self-injected.
The dose should provide the patient with an erection that is satisfactory for sexual intercourse. It is recommended that the dose administered produces a duration of the erection not exceeding one hour.

Contra-indications, warnings, etc *Contra-indications:* Known hypersensitivity to alprostadil, benzyl alcohol, or any of the other constituents. Patients with sickle cell anaemia, multiple myeloma, or leukaemia (risk of priapism).

Warnings: Prolonged erection and/or priapism. Patients with an erection lasting 4 hours or more should report to a physician for consideration of detumescent therapy.
Painful erection is more likely to occur in patients with anatomical deformations of the penis.
patients on anticoagulants such as warfarin or heparin may have increased propensity for bleeding after the intracavernous injection.
use of intracavernous alprostadil offers no protection from the transmission of sexually transmitted diseases. Individuals should be counselled about the spread of sexually transmitted diseases, including HIV.

Pregnancy and lactation: Not applicable. (High doses of alprostadil (0.5 to 2.0 mg/kg subcutaneously) had an adverse effect on the reproductive potential of male rats, although this was not seen with lower doses (0.05 to 0.2 mg/kg). Alprostadil did not affect rat spermatogenesis at doses 200 times greater than the proposed human intrapenile dose.)

Side-effects: Pain in the penis during erection (16.8%). Haematoma at the site of injection (1.5%). Other rarely reported adverse reactions are: fibrosis, erythema, testicular or perineal pain, penile deviations, hemosiderin deposits in the penis, injection into the urethra as a result of faulty injection technique, and systemic medical events. The systemic medical events that have been reported are: changes in blood pressure, postural hypotension, cardiac arrhythmias, dizziness, headaches, vagel shock, and collapse (these may be related to the procedure rather than alprostadil).

Interactions: None Known. Not intended for co-administration with any other agent for the treatment of erectile dysfunction.

Incompatibilities: None Known. Only the supplied diluent should be used to prepare solutions.

Pharmaceutical precautions Caverject must be stored in a refrigerator until dispensed. It may then be stored below 25°C for up to 3 months. Reconstituted solutions should be used immediately and not stored. Do not store the unused pack or reconstituted solution in a freezer.

Legal category POM

Package quantities Single packs containing a vial of Caverject powder and a vial of diluent.

Product licence numbers
PL 0032/0188 Caverject Powder for Injection
PL 0032/0193 Bacteriostatic Water for Injections diluent

Holder of product licences Upjohn Limited, Fleming Way, Crawley, West Sussex, RH10 2LZ.

Date of preparation or last review July 1994

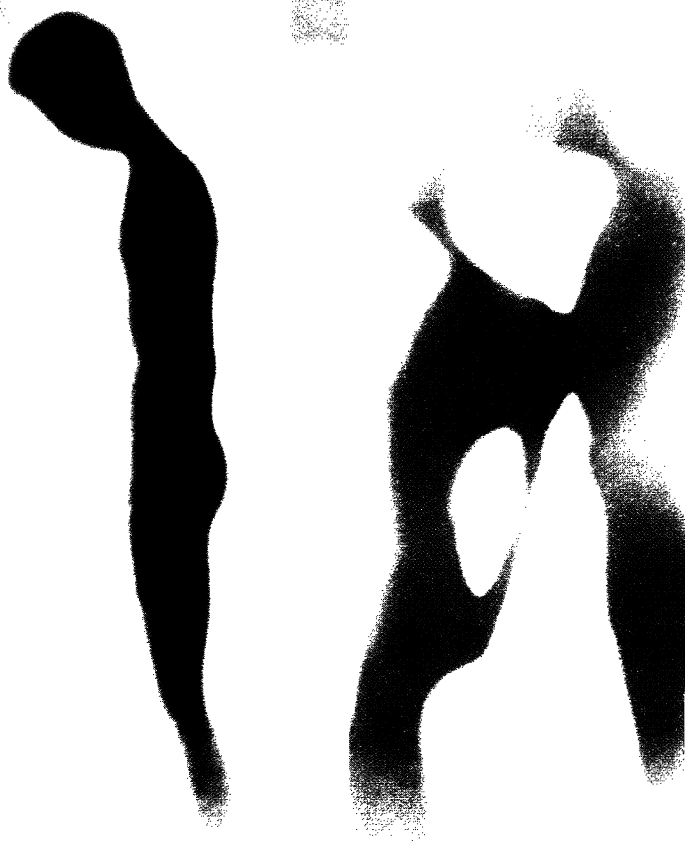
Pricing information £9.95 per pack

Trademark: Caverject

As a result of customer feedback we have changed the storage requirement of Caverject to allow patients to keep Caverject where it is most easily accessible for them.

The new recommendations are 21 months refrigerated (below 8°C) prior to dispensing plus 3 months at room temperature (below 25°C) following dispensing.

Please remember to write the 'Use-by' date in the space provided on the carton for the patient and please note Caverject should not be dispensed within 3 months of its expiry date.



New

alprostadil sterile powder

powder for injection

The only licensed product for intracavernous treatment of erectile dysfunction in the UK

Effective in up to 100% of neurogenic and psychogenic cases[1] and over 70% of other cases[2]

Well tolerated,[3] and rated highly in terms of therapeutic satisfaction for both patient and partner[4]

Clinically and scientifically documented

Fifth Meeting of the
European Neurological Society

June 17–21, 1995 · Munich / Germany
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Teaching courses: Saturday, June 17 to Sunday, June 18, 1995

Vertigo and Vestibular Disorders
Th. Brandt, M. Gresty

Anatomy and Imaging of Nervous System
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Movement Disorders
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Clinical Neuroimmunology
O. Abramsky, H. P. Hartung

Neurological Emergencies
D. Bates, W. Pfister

Epilepsy
H. Wieser, P. Jallon

Peripheral Neuropathy
G. Said, F. G. A. van der Meché

Muscle Disorders
L. Angelini, H. Kwiecinski

Headache
H. C. Diener, K. J. Jenssen

Multiple Sclerosis
W. I. McDonald, Ch. Confavreux

Symposia: Monday, June 19 to Wednesday, June 21, 1995

Motor Neuron Diseases
Chairman: G. Scarlato, Milano

Unstable Mutations in Neurological Disease
Chairpersons: A. E. Harding, London
and M. MacDonald, Boston

Pain Mechanisms and Management
Chairmen: W. Janig, Kiel and J. W. Scadding, London

Animal Models of Neurological Disease
Chairmen: W. Oertel, Munich and A. Aguzzi, Zurich

Amyloid and the Nervous System
Chairmen: P. Coutinho, Porto
and M. N. Rossor, London