

PACKAGE LEAFLET

DESIGNATION

CAVERJECT®

(Alprostadilum)

COMPOSITION

CAVERJECT® 5 µg powder for preparation of an injection solution + solvent in single-use syringe
I. Alprostadil. 5 µg - Lactose. - Sodium. citrate - Hydrochloric acid. diluted. - Sodium. hydroxide.
II. Benzyl alcohol. - Water for injection. sufficient quantity. to 1 ml.

CAVERJECT® 10 µg Powder for preparation of injection solution + Solvent in Single-use syringe
I. Alprostadil. 10 µg - Lactose. - Sodium. citrate - Hydrochloric acid. diluted. - Sodium. hydroxide.
II. Benzyl alcohol. - Water for injection. q.s. ad 1 ml.

CAVERJECT® 20 µg powder for preparation of an injection solution + solvent in single-use syringe
I. Alprostadil. 20 µg - Lactose. - Sodium. citrate - Hydrochloric acid. diluted. - Sodium. hydroxide.
II. Benzyl alcohol. - Aqua ad inject. q.s. ad 1 ml.

PHARMACEUTICAL FORM AND OTHER PACKAGE SIZES

Solution for injection: it is produced by mixing the dry substance with the solvent. Package sizes:

CAVERJECT® 5 µg powder for preparation of an injection solution + solvent in single-use syringe:

1 package size of: 1 Vial of 5 ml with dry substance + 1 pre-filled syringe with 1 ml solvent + 2 needles (27 G 1/2 inch and 22 G 1 1/2 inch) + 2 alcohol swabs

CAVERJECT® 10 µg powder for preparation of Injection solution + Solvent in Single-use syringe:
1 and 5 Package sizes of: 1 Injection vial of 5 ml with Dry substance + 1 pre-filled Syringe with 1 ml solvent + 2 needles (27 G 1/2 inch and 22 G 1 1/2 inch) + 2 alcohol swabs

CAVERJECT® 20 µg powder for preparation of injection solution + solvent in single-use syringe:
1 and 5 Package sizes of: 1 vial of 5 ml with dry substance + 1 pre-filled syringe with 1 ml solvent + 2 needles (27 G 1/2 inch and 22 G 1 1/2 inch) + 2 alcohol swabs
Dispensing regulation: prescription only.

MEDICINAL PRODUCT GROUP

The active ingredient Alprostadil (Prostaglandin E1) is chemically considered a fatty acid, which occurs in the body naturally .. Alprostadil causes among others a dilation of the blood vessels and inhibits the activity of the platelets. By injection into the corpus cavernosum of the penis is a Erection induced.

HOLDER OF THE MARKETING AUTHORIZATION, MANUFACTURER

Pfizer S.A., Boulevard de la Plaine 17, 1050 Brussels

Manufacturer: Pfizer Manufacturing Belgium, Rijksweg 12, 2870 Puurs, Belgium

TO BE USED FOR

Treatment of erectile dysfunction, whose cause is the nervous system or the circulation attributable is, or whose origin psychological nature is. The cause can also be of different nature. Diagnosis of erectile dysfunction.

CIRCUMSTANCES UNDER WHICH TREATMENT WITH THIS MEDICINE SHOULD BE AVOIDED CAVERJECT® must not be in the following patients used : become:

Patients with hypersensitivity to alprostadil or any of the other components of CAVERJECT®.

Patients with tendency to persistent erection as a result of sickle cell anemia, latent sickle cell disease or blood cancer (leukemia,, multiple myeloma).

Patients with certain deviations of the penis (curvature, phimosis and Peyronie's disease).

Patients with penile prosthesis.

Patients, in which sexual activity not indicated is.

CAVERJECT® must women, children and newborns not administered be.

SPECIAL PRECAUTIONS

Before starting a treatment with CAVERJECT® your doctor will determine the cause of erectile dysfunction and, if necessary, treat.

After injection of CAVERJECT® a persistent erection may occur. An erection that lasts longer than 4 hours, must always your doctor informed should be. Before starting a treatment with CAVERJECT® your doctor will determine, which measures in this Case must be taken must.

A regular check-up and a careful examination of the penis must be performed, so that an increase of the connective tissue in penis in time detected can be. The treatment with CAVERJECT® must be discontinued if when there are deviations in the shape of the penis or indurations in penis occur.

Alprostadil offers after injection into the corpus cavernosum of the penis no protection against sexually transmitted diseases. Use you the necessary protective measures against the spread of sexually transmitted diseases, such as AIDS (HIV virus). An injection of CAVERJECT® can also cause small Bleeding at the injection site (see "Adverse Effects") cause, so that you with these conditions Diseases lighter infect can.

CAVERJECT® must not together with a other medication for treatment of erectile dysfunction injected be.

This medication was you as part of a specific medical treatment prescribed. It must neither by other people nor for other complaints used .

INTERACTIONS WITH OTHER MEDICINES AND FOODS

If You medicines for inhibition of blood coagulation (such as Warfarin or Heparin) use, can a tendency to bleeding increase strengthen.

APPLICATION: HOW AND HOW MUCH

Depending on, from which reason the erectile dysfunction exists, your doctor will determine ,which amount is injected injected will should.

Follow you therefore carefully the instructions of your doctor.

The initial dose is usually at 1.25 - 5 micrograms (μg) alprostadil. After this Hereupon is the dosage gradually increased, until the correct dose is reached .. this dose causes an erection , which lasts 1hour . persists. If the erection lasts longer, consult your doctor .. the erection occurs within 10 - 30 minutes after the injection the Injection a.

In general the usual dose between 1.25 and 20 micrograms per injection. The use of more than 60 micrograms per Injection is not recommended.

CAVERJECT® should not more often than once per day and three times per week used be. The consultation Your doctor is every three to four months recommended. If necessary or desired, however only in consultation with your doctor, can the dosage gradually adjusted be. Follow your exactly the instructions of your doctor.

Consult your doctor or pharmacist, Pharmacist, if you questions about the use this medication have.

PREPARATION OF THE SOLUTION

The preparation of the solution must sterile be. Procedure You after the recommendations your doctor

and follow you the here below specified procedure.

1. Wash you yourself the hands and dry you them with a fresh towel off.
2. Remove the plastic cap of the vial (the cap remains always on the bottle). Disinfect the top of the lid with one of the two disinfection wipes , whichyou then dispose of ..
3. Depending on the type of packaging, that you use, proceed as follows : CAVERJECT®
package: Bottlewith powder + single-use syringe Disposable syringe with solvent
 - Remove you the long needle (22 G 1 ½ inch) from the packaging under consideration, that the plastic cover on the needle remains.
 - Turn You the white seal of the syringe, so that this is broken ..
 - the needle with the plastic cover the Plastic protection on the syringe, by you this onto it turn.
 - Remove you the plastic cover of the needle.
4. Insert you now the needle through the disinfected rubber cap of the vial and inject you the entire liquid from the syringe into the powder.
5. The Vial lightly shake (without the syringe withdrawing), until the powder completely dissolved is.

This solution is now ready to use and can injected will be. They contains 5, 10 or 20 μg Alprostadil per ml. After that must no other products of the solution added be. The solution must clear and colorless be. Otherwise may you it not inject. When stored in the original vial is the prepared solution at room temperature (15 - 25 °C) 24 Hours long shelf life. The solution must not be frozen .

INJECTION OF THE SOLUTION INTO THE PENIS

The first injection should be administered by your doctor . In doing so you should the procedure for injection taught will be. Follow you exactly this procedure, when you yourself CAVERJECT® administer administer. You can in this Step by step following guidelines observe.

1. Draw you the for you recommended amount of solution into the syringe.
2. Interrupt you the Connection between needle and syringe (the needle remains in vial).
3. Bring the injection needle (it is (it concerns short needle for the Needle, 27 G 1/2 inch) on the syringe at and remove you the protective cover.
4. Hold you the syringe with the needle up above and press you gently on the plunger, until a drop from the tip of the needle emerges. Afterwards place You the syringe on a hard, flat sur face and make sure, that the needle does not come into contact with objects Touch comes.
5. The injection itself is done easily.

If you are right-handed , holdyou your penis with the left hand, flat flat behind the glans. If you are not circumcised ,make sure that theforeskin is as far as possible so as far as possible over the tip of the glans back pulled is. Pull you now the penis against your left thigh. At the top of the penis see you a bulge, that to the left yields, as soon as you press harder. This is one of the two corpora cavernosa, and here into must the injection given be (shaded areas on the diagram).

With the second disinfection cloth disinfect you now with the right hand the the right hand the Skin over the corpus cavernosum, into which you inject will and let it dry for a few seconds ..

the penis with with the left hand during the injection well stretched. With the right hand insert you the needle at a right angle through the skin until to Corpora cavernosa. Avoid you hereby superficial blood vessels or other noticeable structures.

Inject you now the contents of the syringe completely in. If this does not immediately succeed, pull you the needle slightly back and try it again.

Pull you then the Needle completely back and press you the disinfectant wipe on the injection site. By you your penis massage, apply you to at, that the medication well distributed is.

It is recommended, the injection site to change, as your Your Doctor it you taught has.

6. The solution is only for single use suitable. Any residues should be disposed of . In Cases, that you the CAVERJECT®-packaging use, which consists of the vial with powder and the single-use syringeconsists , insert everything into the package, do the package up and close it finally with the red tab . SIDE EFFECTS.

others than those here

Also other than those here below listed side effects may occur. Talk to your doctor or pharmacist , if problems occur, that in your opinion are a possible side effect of this medication be could. -

Genital side effects

In one of three injections can it mild to moderate Pain in penis during the erection occur. This is occasionally described as a burning sensation or as a feeling of tension described. Mostly impairs this the sexual relationships not. In rare cases (3%) bruises have around the injection site occurred, an increase of connective tissue in penis can occur. After injection of CAVERJECT® can a prolonged erection of a duration of 4 to 6 hours occur. A erection of 6 hours or longer occurs only rarely .. erection thatlasts longer than 4 hours lasts, must you always your doctor inform.

Local side effects

The following local side effects may in rare cases (1 - 1.5%) occur: Small blue Spots at the injection site, rash, fluid accumulation and increase of the connective tissue in the penis.

Side effects in the area of the heart and the Blood vessels

A Dosage of more than 20 µg can lead to a reduction of blood pressure cause. At more than 30 µg can a increased heartbeat occur.

Other side effects

Your doctor is also about other undesirable effects, which very rarely (< 1%) occur could, informs.

STORAGE

At room temperature (15 °C - 25 °C) store.

The expiry date (month/year) is on the package printed after "EXP." (EXP. = expiry date). After expiration of the expiry date should this medication not be used anymore. When stored in the original container remains the prepared solution at room temperature (15°C - 25°C) 24 hours, usable. The prepared solution must not be frozen . Medicines out of reach of children store.

STATUS OF THE PACKAGE LEAFLET

March 2004

The information provided information is as detailed and specific as in the limited scope of this package leaflet possible. Medical terms are explained as far. If you have any further questions ,your doctor will assist you or Pharmacist gladly assist.