

Package leaflet: Information for the user

Caverject[®] 5, 10 or 20 micrograms Powder and Solvent for Solution for Injection

Alprostadil

PFIZER

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Caverject is and what it is used for
2. What you need to know before you use Caverject
3. How to use Caverject
4. Possible side effects
5. How to store Caverject
6. Contents of the pack and other information

1. What Caverject is and what it is used for

Caverject contains alprostadil which is similar to the natural substance in your body called prostaglandin E1. It widens blood vessels so that blood can flow in your penis more easily. This makes it easier for you to have an erection.

Caverject is used for “erectile dysfunction” including weak erections or impotence. Your doctor may also use it to help find the exact cause of your erectile dysfunction along with other tests.

Caverject is not suitable for children under 18 years of age.

2. What you need to know before you use Caverject

Do not use Caverject:

- if you are allergic (hypersensitive) to Caverject or any other medicines containing alprostadil or any of the other ingredients of Caverject (listed in section 6).
- if you have sickle cell anaemia (a blood disease), leukaemia (cancer of the blood), multiple myeloma (bone cancer) or any other problem which increases the risk of getting “priapism”. This is a painful condition when your penis continues to remain erect.

- if you have a penis which is scarred or not straight which may sometimes be referred to as Peyronie's disease.
- if you have abnormal fibrous tissue in the erectile tissue of the penis (cavernosal fibrosis).
- if you have an implant in your penis.
- if you have a condition (such as severe heart disease) in which sexual activity should be avoided.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Caverject.

Before prescribing Caverject to you your doctor will have checked that there are no other medical causes for the signs of illness that you have.

Take special care with Caverject

- if you have a tight foreskin
- if you have lung, chest or heart problems (in these cases you should engage in sexual activity with caution)
- if you have a history of mental illness or addiction
- if you have had a mini stroke (transient ischaemic attack).

If you experience a prolonged erection such as for 4 hours, tell your doctor immediately. If you experience this outside of your doctors working hours, seek advice from your nearest casualty department straight away.

If you develop angulation of the penis, stop using Caverject and tell your doctor.

Reconstituted solutions of Caverject are intended for single use only, they should be used immediately and not stored.

Sexually transmitted diseases

Caverject will not protect you or your partner from sexually transmitted diseases like AIDS, herpes and gonorrhoea. Injection of Caverject can start a small amount of bleeding where the needle enters. This could increase the risk of transmission of such diseases. Condoms can protect against sexually transmitted diseases. If you need advice about contraception or 'safe sex' speak to your doctor or contact your local Family Planning Clinic.

Other medicines and Caverject

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you have bought for yourself.

The following medicines may affect Caverject

- other medicines for erectile dysfunction such as sildenafil or papaverine as this may cause a prolonged erection
- medicines to thin your blood such as warfarin or heparin, as you might bleed more at the site of injection
- medicines to treat high blood pressure (antihypertensives)
- medicines used for respiratory and heart disease (sympathomimetics)
- medicines that widen blood vessels (vasodilative agents).

Pregnancy, breast-feeding and fertility

Caverject can be used by couples wishing to conceive and with a partner who is pregnant or breast-feeding. It will not protect your partner from pregnancy, so you should use a reliable contraceptive if appropriate.

Driving and using machines

Caverject should not affect your ability to drive or use machines.

Caverject contains benzyl alcohol and sodium

Benzyl alcohol may cause toxic reactions and allergic reactions and has been associated with serious side effects including the “gasping syndrome” and death in children.

This medicine contains less than 1 mmol sodium (23 mg) per dose and is essentially ‘sodium-free’.

3. How to use Caverject

Always take this medicine exactly as described in the leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

A doctor or nurse will show you how to do the injection for **at least** the first time. Do not try to do it yourself until you have learnt the correct way or if you can’t remember what to do, see your trainer again. These instructions are a reminder only. Keep the antiseptic swab away from the eyes.

How much Caverject should you inject?

Different people need different amounts of Caverject to treat erectile dysfunction. Your doctor will advise on the right dose for you and monitor you regularly to check how it is working. The starting dose is 2.5 micrograms. Most men find that a dose of 5 - 20 micrograms is right for them; however some men may require a higher dose. To minimise the risk of prolonged painful erection, your doctor will select the lowest effective dose.

You should never use more than 60 micrograms.

If Caverject is being used to find the reason for your erectile dysfunction, the dose will be 5 - 20 micrograms.

If the dose that has been prescribed for you does not work well enough, tell your doctor. Do not change your dose unless your doctor tells you to. If you forget how much to use, read the label on the pack or speak to your doctor.

You and your partner

You may like your partner to be involved in preparing and/or giving the injection. If so, you should speak to your doctor about training for your partner. Wash your hands. Dry them on a clean towel. If your partner wishes to be involved in preparing or giving the injection, they should wash their hands too.

1. Check your pack

Make sure that the vial is the correct strength and the expiry date is still valid. The vial, syringe and needles all have protective covers. The flip-off cap on the vial can rotate; this is normal. Check that all the covers are on firmly and if they are not on properly, do not use them – take the whole pack back to your pharmacist. There are two needles in the pack:

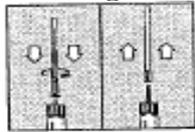
- The larger 22 gauge needle with the grey end is used to mix the solution and Caverject Powder.
- The smaller and finer 30 gauge needle with the yellow end is used to inject the mixture into your penis.

2. To prepare the vial



Flip the plastic cap off the vial. Wipe the rubbery top with one of the wet antiseptic pads.

3. Fitting the needle to the syringe



Hold the syringe and twist the white tamper evident cap to break the seal. Take the foil off the larger needle, (22 gauge) with the grey end, keeping the cover on. Join the needle to the syringe by turning the needle clockwise tightly onto the syringe, then remove the needle cover by pushing it away from the syringe with your thumb and forefinger.

4. Mixing the solution with the powder



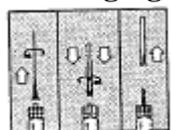
Push the needle through the rubbery middle of the vial top. Press the plunger down firmly to squirt all the solution onto the powder. Gently swirl the vial until all the powder has dissolved. If the mixture is cloudy or does not dissolve completely, do not use it. Never use tap water or any liquid other than the one supplied in the syringe.

5. Filling the syringe



With the needle still inserted, turn the vial upside down. The needle should support the vial unaided. Make sure the needle tip is underneath the level of the liquid. Gently pull the plunger to draw all the mixture into the syringe. Pull the needle out of the vial.

6. Changing to the injecting needle



Gently twist the larger needle anticlockwise off the syringe. Discard it carefully in a special “sharps” bin (please refer to **How to throw away the syringe and needle safely**). Please ask your doctor or pharmacist if you are unsure about how to dispose of needles. Remove the smaller injecting needle, (30 gauge) with the yellow end from its package, keeping the cover

on. Twist the needle clockwise tightly onto the syringe, then remove the needle cover by pushing it away from the syringe with your thumb and forefinger.

7. Setting the dose



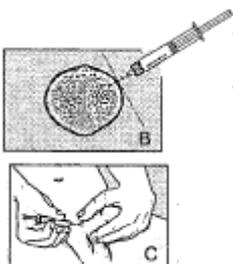
Tap the syringe gently to send any air bubbles to the top, then push the plunger to squeeze the air bubbles out, ensuring that at least one drop of solution comes out of the needle. Continue pushing until the plunger is exactly at the right mark for your dose. Your doctor will have shown you where this is.

How do you do the injection?

- Get undressed and make yourself comfortable. Take some time to relax yourself and your partner. If your prescriber has recommended use of the second antiseptic pad, open it now.
- Make sure that the injection needle is **not** bent. A bent and re-straightened needle is predisposed to breakage. Needle breakage, with a portion of the needle remaining in the penis, has been reported and, in some cases, required hospitalisation and surgical removal. If ~~it~~ the needle is **bent**, **do not** use it and throw it away. **Do not** attempt to straighten it out. Attach a new, unused sterile needle to the syringe.
- Take hold of the penis from the front, with the first two fingers underneath close to the testicles and the thumb on top. Gently squeeze the penis between your thumb and finger so that the injection site bulges out. If there is a foreskin on the penis, make sure it is stretched. The injection will go into the part of the penis shown as the shaded area in diagram A.



- If recommended by your prescriber wipe the skin over this area with the second pad and let it dry.
- Keeping a firm grip on the penis and taking the syringe in your free hand, push the needle straight through the skin all the way into the bulgy part avoiding veins or other obvious blood vessels. The angle is shown in diagrams B and C. Push the plunger firmly and if the Caverject does not come out fairly easily, move the needle slightly and try again. **Do not** force the Caverject liquid from the syringe.



- Pull the needle out. On the needle mark, press gently with the pad of your thumb, as recommended by your prescriber. Massage the penis to help the Caverject spread through it.
- Do not keep any mixture in the syringe to use for a second injection.

How to throw away the syringe and needle safely

Never throw away needles, vials or syringes with your ordinary household rubbish. When you have finished with a needle you must discard it carefully to prevent accidental injury and so that no-one will be able to use it. Put the needle, syringe and vial into a container for needles called a sharps bin (available from your doctor or pharmacist). Ask your doctor or pharmacist for instructions on how to properly dispose of the sharps bin after use if you are at all unsure.

How often can you use Caverject?

Do not use Caverject more than once in 24 hours or more than three times in a week. Change the exact place and side of the penis that you inject Caverject each time you use it.

Your erection after injecting Caverject

It will take a little while for your erection to come on after the injection. With the right dose of Caverject, your erection should be strong enough for you and your partner to enjoy lovemaking. Usually, your erection should not last longer than an hour. If you would like it to last longer, talk to your doctor.

If your erection lasts longer than four hours you should seek medical advice (see the section on side effects).

If you use more Caverject than you should

Tell your doctor straight away as you may need treatment, particularly if you experience an erection that lasts for longer than four hours. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if your erection goes on for longer than 4 hours.

If you cannot contact your doctor, go to a hospital casualty department **immediately** as treatment should be started within 6 hours.

Very common side effects

(may affect more than 1 in 10 people)

- Pain in the penis

Common side effects

(may affect up to 1 in 10 people)

- Penis can become bruised, scarred, bent or kinked, particularly after long term use. **Tell your doctor** if this happens as you may need to stop using Caverject.
- You may get uncomfortable, painful or prolonged erections and your ejaculation may change
- Other problems with your penis such as bleeding, swelling, rash
- Swelling and skin discolouration or bruising at the site of injection. You may find this happening when you first use Caverject but it should occur less often with practice.
- Headache, feeling sick, dry mouth, increased blood pressure
- Inflamed sinuses, chest or lung infections, cold or flu-like symptoms
- Muscle spasm, pain in the leg, buttocks, genitals, stomach or general abdominal pain
- Prostate problems

- Abnormal masses or growths on the skin.

Uncommon side effects

(may affect up to 1 in 100 people)

- The area injected becomes irritated, inflamed or swollen and may itch or bleed, or feel numb, warm, tender or painful
- The testes or scrotum could become red, swollen or painful, or develop lumps called spermatocele, which are cysts containing sperm. The penis could feel numb
- You may get no erection at all, your foreskin could feel tight or swollen, as well as the head of your penis
- The desire to pass urine more urgently or frequently than normal or you may have pain or difficulty in urinating. Some blood may appear in the urine or at the end of the penis especially if Caverject is injected by mistake into the tube which carries urine out through the penis (urethra)
- Pelvic pain, weakness, sweating, swollen legs or arms, having a common cold, blocked nose or fungal infection
- Changes in blood pressure and heart rhythm, faintness, shallow breathing and collapse could occur because of the injection itself
- Skin itching, redness, rash, increased sweating, eye sensitivity to bright light or excessive dilation of the pupil (blown pupil), impaired or enhanced sense of touch, leg cramps, back pain cold hands and feet, venous problems including bleeding (bleeding from vein(s))
- If you have a blood test you may have raised levels of creatinine (a substance found in your muscles).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Caverject

- Keep the syringe, needles and Caverject out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
- When you have mixed the Caverject Powder with the solution, use it straight away. After reconstitution the product is a clear solution. Do not keep it to use later on.
- For single use only. Any unused Caverject should be discarded.
- Do not use Caverject if the injection is cloudy or contains particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Caverject contains

The active ingredient in Caverject is alprostadil. Each vial contains 5, 10 or 20 micrograms of alprostadil. When reconstituted, each 1 mL delivers a dose of 5, 10 or 20 micrograms of alprostadil.

Caverject 5 micrograms: The other ingredients are lactose, sodium citrate, hydrochloric acid and sodium hydroxide.

Caverject 10 or 20 micrograms: The other ingredients are lactose monohydrate, sodium citrate anhydrous, α -cyclodextrine, hydrochloric acid and sodium hydroxide.

The syringe contains benzyl alcohol (7.96 mg/mL) and water for injections.

The antiseptic pads are soaked in isopropyl alcohol.

What Caverject looks like and contents of the pack

In the Caverject box you will find 5 items:

1. One glass vial containing Caverject 5, 10 or 20 micrograms as a white to off-white powder
2. One glass syringe containing 1 mL of a clear solution
3. One larger 22 gauge needle - 1½ inches long with a grey plastic end
4. One small 30 gauge needle - 0.5 inch long with a yellow plastic end
5. Two antiseptic pads

Marketing Authorisation Holder

Pfizer Healthcare Ireland, 9 Riverwalk,
National Digital Park,
Citywest Business Campus, Dublin 24, Ireland

Manufacturer

Caverject is made by Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

Company Contact Address

For further information on your medicine contact Medical Information at the following address:

Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus,
Dublin 24, Ireland.

Telephone 1800 633 363.

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