

This medicine is dispensed with a doctor's prescription only

Caverject® 10 mcg

Each ml contains: alprostadil 10 mcg



Caverject® 20 mcg

Each ml contains: alprostadil 20 mcg

Solution for injection (after dissolving the powder)

List of inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

The medicine is intended for men. The medicine is not intended for children.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is used to diagnose and treat erectile dysfunction (impaired sexual function) that is due to different reasons in men.

Therapeutic group: medicines for erectile dysfunction.

The active ingredient in this medicine is similar to a natural substance in your body (prostaglandin E1). This substance widens blood vessels when the medicine is injected, so that blood flows more easily in the penis making it easier to have an erection.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to Caverject® or to any other medicine that contains alprostadil, or to any of the other ingredients in this medicine (see section 6).
 - You have sickle cell anaemia (a blood disease), multiple myeloma (bone marrow cancer), leukaemia (cancer of the blood), or any other problem which with combined treatment with this medicine may cause prolonged erection, "priapism" (a possibly painful condition in which the penis continues to remain in prolonged erection).
 - You have an implant in your penis.
 - You have a penis which is scarred or curved (not straight).
 - You have a condition (such as severe heart disease) in which sexual activity should be avoided.
 - You have a tight foreskin.
- Do not use this medicine in children.
Do not use this medicine until your doctor decides that it is right for you.

Special warnings regarding use of the medicine

Before treatment with Caverject®, tell your doctor if:

- You have lung, chest or heart function disorders (in these cases you should engage in sexual activity with caution)
- You have a history of mental illness or addiction
- You have had a mini-stroke (transient ischaemic attack)
- You have one or more cardiovascular risk factors (these might include high blood pressure, tobacco use (smoking), raised blood sugar level, raised blood cholesterol levels, being overweight and obesity)
- You have one or more risk factors for stroke (these might include high blood pressure, raised blood cholesterol levels, coronary heart disease, heart rhythm disorder, diabetes)

Sexually transmitted diseases

Using this medicine will not protect you or your partner from various sexually transmitted diseases like AIDS, herpes and gonorrhoea. Injection of this medicine can cause a small bleeding in the injection site which could increase the risk of transmission of these diseases. The use of condoms can protect against contagious sexually transmitted diseases of this sort. If you are not sure, ask the doctor for advice about having safe sex or contraception.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

Tell the doctor if you are taking any of the following medicines **before** you start using this medicine:

- medicines for treating high blood pressure
- medicines for treating respiratory tract and heart problems
- medicines that widen blood vessels
- other medicines for treating erectile dysfunction such as sildenafil or papaverine
- medicines to thin your blood such as heparin or warfarin, as you might bleed more when you do the injection.

Pregnancy, breast-feeding and fertility

This medicine can be used when you and your partner are trying to conceive and when your partner is pregnant or breast-feeding. This medicine does not protect your partner from pregnancy, so you should use reliable contraceptives if appropriate.

Driving and using machines

This medicine should not affect your ability to drive or use machines.

Important information about some of this medicine's ingredients

This medicine contains benzyl alcohol 8.4 mg/mL (not including 5% overage). Benzyl alcohol may cause allergic reactions.

Using large amounts of Caverject® may cause a build-up of benzyl alcohol resulting in an increased level of acid in your blood (a condition called metabolic acidosis).

Patients with liver or kidney disease need to be especially cautious and consult their doctor.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children.

This medicine is not intended for use in children.

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Different patients need different dosages of this medicine to treat erectile dysfunction. The doctor will decide on the right dose for you and monitor you regularly to check how effective your treatment is. This is **after the dose was individualized for each patient, by injecting the medicine for the first time at the doctor's clinic and under his supervision.** Do not try to do it yourself until you have learnt the correct way, or if you can't remember what to do, consult the doctor again. These instructions are a reminder only.

If the dose you were prescribed does not work well for you, tell the doctor. Do not change your dose unless your doctor tells you to. If you forget how much to take, speak to the doctor.

Do not use this medicine more than once in 24 hours or more than three times a week.

Do not exceed the recommended dose.

Instructions for use:

Before using Caverject®

- Make sure that the vial is the correct strength and that according to the expiry date the medicine is still valid.
- The vial, syringe, and needles all have protective covers. Check that the covers are on firmly (the vial cover can be turned). If they are not on properly, do not use the medicine.
- Wash your hands and dry them before using Caverject®. If your partner wishes to be involved in preparing or giving the injection they should be trained, and they should wash and dry their hands too.
- It is important to carefully follow the instructions for preparing and injecting Caverject®.
- Keep the antiseptic pad away from the eyes.

Part I Preparing the medicine

1. To prepare the syringe

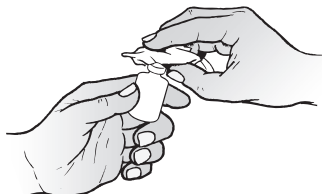
Prepare the syringe only just before use.

There are two needles in the pack.

- The large needle (22G) is used to add diluent for dissolving the powder.
- The small, fine needle (30G) is used to inject the dissolved solution into the penis. If a needle is bent do not use it.

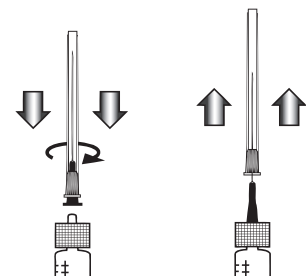
2. To prepare the vial

- Take the plastic cap off the vial.
- Wipe the rubber top with one of the antiseptic pads. Discard the used pad.



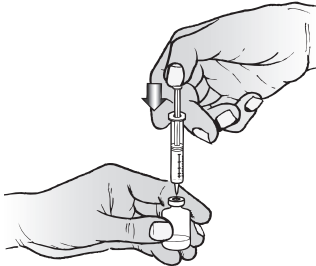
3. Fitting the needle

- Hold the syringe, twist the white plastic tamper-evident cap to break the seal, and remove by rocking the cap up and down and pulling.
- Twist the base of the cover on the larger needle (22G) and remove it.
- Keep the needle cover on the needle.
- Join the needle firmly to the syringe by turning the needle clockwise. **Do not twist too tightly.**
- Remove the needle cover by pushing it away from the syringe with your thumb and forefinger. Do not touch the exposed needle.



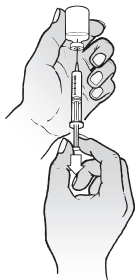
4. Dissolving the powder with the supplied diluent

- Push the needle through the rubber middle of the vial top.
 - Press the plunger down firmly to squirt all the liquid into the powder.
 - The reconstituted solution may appear cloudy at first.
 - Without removing the syringe from the vial, gently shake the vial until all the powder has dissolved.
 - If the solution is cloudy or does not dissolve completely, do not use it.
- Do not use tap water or any liquid other than the one supplied in the pack.



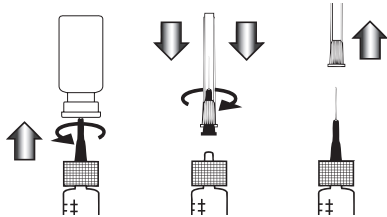
5. Filling the syringe

- With the needle still inserted, turn the vial upside down. Make sure the needle tip is underneath the level of the liquid. If the plunger has moved while you turned the vial upside down, push it back into its original position.
- Gently pull the plunger to draw all the mixture into the syringe. Make sure the gap in the rubber top of the vial is facing you, so you can check the position of the needle tip so that all the liquid can be withdrawn from the vial.



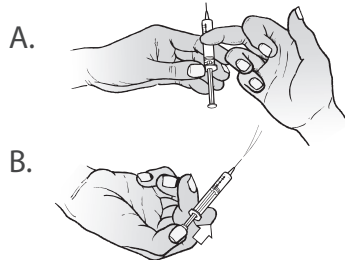
6. Changing from the 22G needle to the 30G needle

- Hold the sides of the syringe (not the plunger or the white cap) and remove the needle from the syringe by twisting it anticlockwise. The needle must stay in the vial.
- Do not pull the needle out of the vial.
- Remove the wrapper from the small injecting needle (30G), keeping the needle cover in place.
- Firmly attach the needle by twisting the needle clockwise, then remove the needle cover by pushing it away from the syringe with your thumb and forefinger.



7. Withdrawing the dose

- Tap the syringe gently to move any air bubbles to the top of the syringe (A).
- Push the plunger to squeeze the air bubbles out, ensuring that a drop of solution comes out of the needle (B).



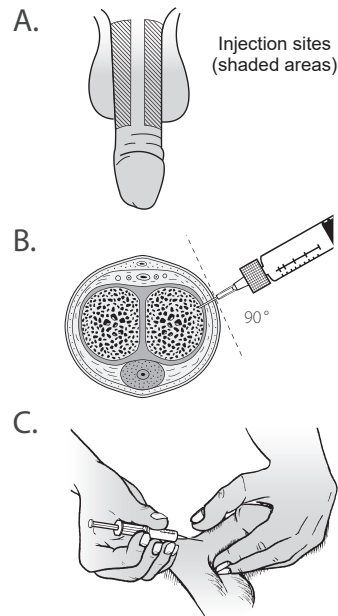
Checking the dose

Continue pushing until the plunger is exactly at the right mark for your dose. Your doctor will have shown you where this is marked.

PART II Injecting the solution

The prepared solution is injected into one of the 2 areas (corpora cavernosa) described below.

- Get undressed and make yourself comfortable. If your doctor has recommended use of the second antiseptic pad, open it now.
- Make sure that the needle is not bent. A bent needle is more likely to break. 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 the needle is bent, do not use it and throw it to a closed, puncture-resistant container. Do not attempt to straighten it out. Attach a new, unused sterile needle to the syringe. Hold the head of your penis with your thumb and forefinger and squeeze gently as shown in diagram C. The injection site will then bulge out.
- Hold the penis from the front, with two fingers underneath close to the testicles and the thumb on top. Gently squeeze the penis between your thumb and forefinger so that the injection site bulges out. If you are uncircumcised, pull back the foreskin.
- The injection will go into the shaded area, see diagram A.
- If recommended by your doctor, disinfect the injection area with the second antiseptic pad and let the area dry.
- Keeping a firm grip on the penis, hold the syringe in your other hand between your thumb and forefinger. Do not push the plunger. Gently rest the needle on the penis.
- With a steady, continuous motion, insert the entire length of the needle at an angle into the injection site (see diagrams B and C).
- Push the plunger firmly and if the solution does not come out easily, move the needle slightly and try again. **Do not** try to force the medicine from the syringe.
- Withdraw the needle from your penis. Apply pressure to the injection site with the antiseptic pad as recommended by your doctor.
- Massage the penis to help the medicine spread through it.
- Do not keep any remaining solution for re-use.
- Carefully dispose of the used syringe, vial, and needles as instructed by your doctor or pharmacist, preferably in a puncture-resistant container.



Change the injection site every time you use Caverject®; choose one side of your penis for this injection, choose the other side next time and so on. Within each area, the actual point of injection should also be changed each time.

Your erection after injecting the medicine

It will take a little while for your erection to come on after injecting the medicine. 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 help** (see the section about side effects below).

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Tell your doctor immediately because you may need treatment, particularly if you experience an erection that lasts longer than four hours.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them. **If you have any further questions about using this medicine, consult your doctor or pharmacist.**

4. SIDE EFFECTS

As with any medicine, use of Caverject® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately if:

your erection goes on for longer than 4 hours. If you cannot contact your doctor, go to a hospital emergency room **immediately** as treatment should be given within 6 hours.

Very common side effects (may affect more than 1 in every 10 people):

- Pain in the penis.

Common side effects (may affect up to 1 in every 10 people):

- Penis can become bruised, scarred, bent or kinked, particularly after long term use.
- Tell your doctor** if this happens to you, as you may need to stop using this medicine.
- Prolonged erection.
- Other problems with your penis.
- Swelling and skin discolouration or bruising at the site of injection. This may happen with the first injection and will occur less often with the next injections.
- Muscle spasms.

Uncommon side effects (may affect up to 1 in 100 people):

- The area injected becomes irritated, inflamed or swollen and may also itch or bleed, or feel numb, warm, tender or painful.
- The testes or scrotum could become red, swollen or painful, or develop lumps called spermatoceles (cysts containing sperm). The penis could feel numb.
- You may get uncomfortable, painful or prolonged erections or none at all, your ejaculation may change or your foreskin could feel tight or swollen, as well as the head of your penis.
- Passing urine more urgently and frequently than normal, pain or difficulty in urinating, blood in the urine or at the end of the penis especially if the medicine is injected by mistake into the urethra (the tube which carries urine out through the penis).
- Pelvic pain, weakness, sweating, nausea, swollen arms or legs, common cold, dry mouth, yeast infection.
- Changes in blood pressure and heart rhythm, faintness and shallow to stopped breathing could occur because of the injection itself.
- Skin itching, redness of the skin at site of injection, rash or skin growth, increased sweating, dilation of the pupils or eye sensitivity to bright light, changes in sense of touch, leg cramps, cold hands and feet, problems with venous blood vessels including bleeding from veins.
- Raised levels of blood creatinine (a substance found in your muscles) in blood tests.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- insufficient blood flow to the heart muscle via the coronary arteries.
- stroke.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.
- For use immediately after preparation.
- For single use only. Discard any unused medicine.
- Do not use this medicine if the solution appears cloudy or contains particles.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

alpha cyclodextrine, lactose monohydrate, sodium citrate, hydrochloric acid, sodium hydroxide.

The syringe contains benzyl alcohol 8.4 mg/mL (not including 5% overage) and water for injections. See section 2.

The antiseptic pads contain isopropyl alcohol.

This medicine contains 173 mg/mL lactose monohydrate.

What the medicine looks like and contents of the pack:

- Caverject® 10 mcg or 20 mcg packs contain:
 - 1 glass vial containing 10 mcg or 20 mcg of sterile white to off-white powder.
 - 1 glass syringe containing 1mL of a clear liquid.
 - 2 needles.
 - 2 alcohol antiseptic pads, used before injecting.

Registration holder's name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry: Caverject® 10 mcg: 101-08-28542
Caverject® 20 mcg: 068-13-28275

Revised in 11/2021 according to MOH guidelines.