

PATIENT INFORMATION LEAFLET

Caverject® Dual Chamber 10 and 20 micrograms
Powder and solvent for solution for injection
Alprostadil

Pfizer logo

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Caverject Dual Chamber is and what it is used for
2. Before you use Caverject Dual Chamber
3. How to use Caverject Dual Chamber
4. Possible side effects
5. How to store Caverject Dual Chamber
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1. What Caverject Dual Chamber is and what it is used for

Caverject Dual Chamber contains alprostadil which is similar to the natural substance in your body called prostaglandin E1. It widens blood vessels, increasing blood flow to your penis making it easier for you to have an erection. Caverject Dual Chamber 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.

2. Before you use Caverject Dual Chamber

Do not use Caverject Dual Chamber if you:

- are allergic (hypersensitive) to Caverject Dual Chamber, any other medicines containing alprostadil or any of the other ingredients of Caverject Dual Chamber.
- have sickle cell (a blood disease), leukaemia (cancer of the blood), multiple myeloma (bone cancer) or any other problem which increases risk of getting “priapism”. This is when your erection lasts for a long time.
- have an implant in your penis.
- have a condition (such as severe heart disease) in which sexual activity should be avoided.
- have a penis which is scarred or not straight.

- have a tight foreskin.

Take special care with Caverject Dual Chamber

Tell your doctor **before** using Caverject Dual Chamber if you:

- have a lung, chest or heart disorder
- have a history of mental illness or addiction
- have had a mini- stroke (transient ischaemic attack)

Sexually transmitted diseases

Caverject Dual Chamber will not protect you or your partner from sexually transmitted diseases like AIDS, herpes or gonorrhoea. The injection of Caverject Dual Chamber 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.

Taking other medicines

Tell your doctor if you are taking any of the following medicines **before** you start using Caverject Dual Chamber:

- Antihypertensives (used for treating high blood pressure)
- Sympathomimetics (used for respiratory and heart disease)
- Vasodilative agents (drugs that widen blood vessels)
- Anticoagulants (blood-thinning agents)
- Other treatments for erectile dysfunction (e.g. sildenafil or papaverine)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast feeding

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

Driving and using machines

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

Important information about some of the ingredients of Caverject Dual Chamber

Caverject Dual Chamber contains benzyl alcohol which may cause allergic reactions. This medicine contains less than 1 mmol sodium (23 mg) per dose and is essentially 'sodium-free'.

3. How to use Caverject Dual Chamber

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 doctor again. These instructions are a reminder only.

How much Caverject Dual Chamber should you inject?

Different people need different amounts of Caverject Dual Chamber 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 in the clinic is 1.25-2.5 micrograms, although doses lower than 2.5 micrograms cannot be delivered with Caverject Dual Chamber. In this case, Caverject Powder for Injection will be used. Most men find that a dose of 5-20 micrograms works for them, however, some men may require a higher dose. **You should never use more than 40 micrograms.**

If Caverject Dual Chamber 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.

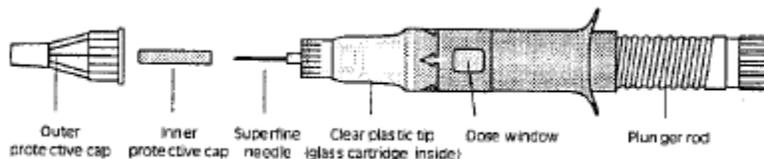
How do you use Caverject Dual Chamber?

These instructions are intended as a reminder only; you should follow your doctor's advice where it differs from this leaflet. If you are using Caverject Dual Chamber for the first time and you have previously used Caverject Powder for Injection, your doctor should have given you advice about using Caverject Dual Chamber.

You and your partner

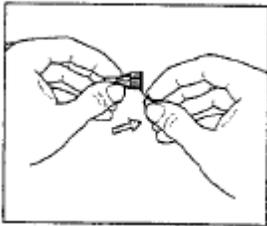
You may like your partner to be involved in preparing and/or giving the injection. If so, you should speak to your doctor about training for your partner.

The Caverject Dual Chamber device

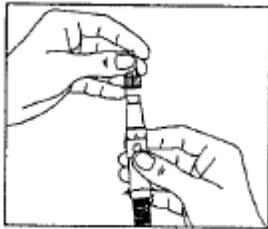


Preparing the injection

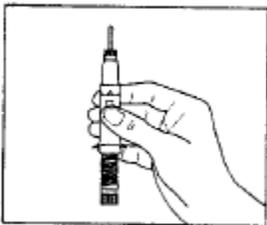
Wash your hands. Dry them with a clean towel. If your partner wishes to be involved in preparing or giving the injection, they should wash their hands too.



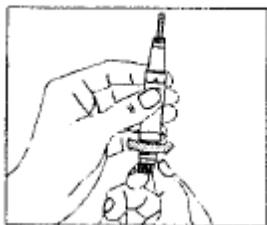
1. Remove one of the injection devices and needles from the box. Peel the foil cover from the needle.



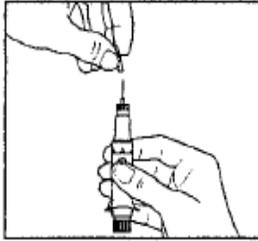
2. Attach the needle to the device by pushing the needle on to the tip of the device. Turn clockwise until it is firmly in place. Pull off the outer protective cap of the needle.



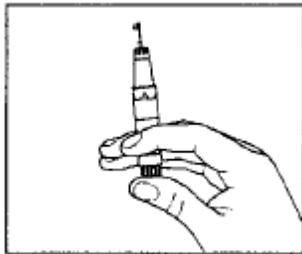
3. Hold the device with the needle pointing upwards. The plunger rod should be in the extended position.



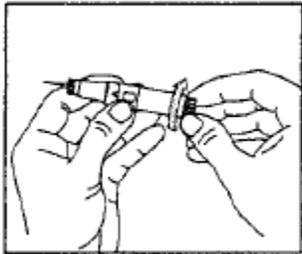
4. Turn the plunger rod clockwise until it stops. This mixes the powder and diluent. Gently shake to make sure that the solution is evenly mixed and the powder has dissolved. Do not use if it remains cloudy or contains particles.



5. Hold the device with the needle upwards. Carefully remove the inner protective cap from the needle. Make sure that the needle is **not** bent. If it is, **do not** use it and throw it away. **Do not** attempt to straighten it out.
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6. To remove any large bubbles from the solution, flick the cartridge with your finger until the bubbles disappear. Then, keeping the device upright, make sure that the plunger rod is fully turned to the stop by screwing it to the right (clockwise) then immediately press the plunger rod as far as it will go. A few drops will appear at the needle point. It is normal for there to be small bubbles at the side of the glass cartridge.

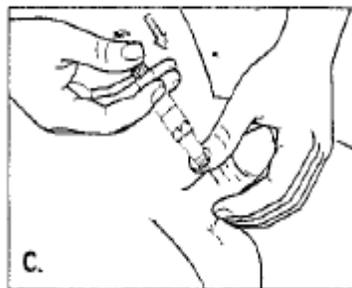
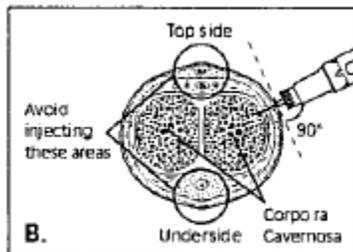
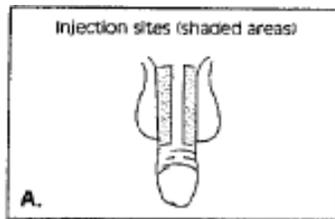


7. Turn the end of the plunger rod slowly clockwise to select your dose. There are four dosage options. Each option is one of four quarterly parts of a full dose delivered by the device. Your doctor will have told you what this should be. The number appearing in the window indicates the dose of the injection. If you make a mistake, continue to turn the plunger rod clockwise until you reach the correct dose.

You can prepare your injection up to 24 hours before using it, providing it is kept at room temperature.

How do you do the injection?

- Get undressed and make yourself comfortable. Take some time to relax yourself and your partner. If your doctor has recommended you use an alcohol cleansing pad, open one now.
- Make sure that the needle is **not** bent. If it is, **do not** use it and throw it away. **Do not** attempt to straighten it out.



- 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.
- Using the alcohol swab, wipe over the area and let it dry. Check or if necessary adjust so that the right dose is in the dose window.
- 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 solution does not come out fairly easily, move the needle slightly and try again. **Do not** force the Caverject Dual Chamber liquid from the syringe.

- Pull the needle out. On the needlemark, press gently with the alcohol swab. Massage the penis to help the alprostadil spread through it.
- **Do not** keep any mixture in the cartridge to use for a second injection. When you have finished with the needle, throw it away carefully as recommended by your doctor, so no-one will see it, use it, or prick themselves on it.

How often can you use Caverject Dual Chamber?

Do not use Caverject Dual Chamber 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 Dual Chamber each time you use it.

Your erection after injecting Caverject Dual Chamber

It will take a little while for your erection to come on after the injection. With the right dose of Caverject Dual Chamber, 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 immediately** (see section on side effects below).

If you use too much Caverject Dual Chamber

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 how to use this product, ask your doctor.

4. Possible side effects

As with all medicines, Caverject can sometimes cause side effects in some individuals. If any of the following side effects bother you or you notice any other unpleasant effects, tell your doctor or pharmacist before you use Caverject Dual Chamber again:

Very common conditions affect at least 1 in 10 patients. Pain in penis is a very common reaction and should -be discussed with your doctor.

Common conditions affect at least 100 in 10,000 patients taking CAVERJECT DUAL CHAMBER (this means that for every 10,000 patients, up to 9,900 are not expected to have these side effects).

These include:

- Swelling and skin discolouration at site of injection .You may find this happening the first time you use Caverject Dual Chamber but should occur less often with practice
- Prolonged and painful erections
- Tender lump in the penis
- Penis becoming scarred, bent or kinked

Other less common side effects have been seen in some patients taking CAVERJECT or other medicines of this kind. Not all of these effects have necessarily been linked to the use of these medicines.

Uncommon conditions affect fewer than 100 in 10,000 patients taking CAVERJECT (this means that for every 10,000 patients taking CAVERJECT, at least 9,900 are not expected to have these side effects).

These include:

- Excessive dilation of the pupil; nausea; dry mouth; skin irritation; sensation of warmth in the penis; blood in urine; decreased blood pressure; increase in heart rate; leg cramps, yeast infections; symptoms of common cold; impaired urination;

increased urinary frequency; urinary urgency; abnormal ejaculation; pain in the testes; scrotum and pelvic area; oedema of the testes and scrotum; skin rash; painful scrotal swelling; dizziness; back or pelvic pain; general weakness; dry mouth; changes in blood pressure and heart rhythm; faintness; shallow breathing and collapse; skin itching or rash; increased sweating; eye sensitivity to bright light; impaired sense of touch, cold hands and feet.

If you get any of these, or any other unusual effects, tell your doctor or pharmacist at once.

5. How to store Caverject Dual Chamber

- Keep the cartridge and needles out of the reach and sight of children.
- Do not use any Caverject Dual Chamber after the expiry date on the pack. The expiry date refers to the last day of that month.
- For single use only. Any unused contents of the syringe should be discarded.
- Do not use Caverject Dual Chamber if the injection is cloudy or contains particles.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Caverject Dual Chamber contains

The active ingredient in Caverject Dual Chamber is alprostadil. Depending on the strength you have been given, the front compartment of each cartridge delivers a maximum of 10 or 20 micrograms of alprostadil in 0.5ml.

The other ingredients are lactose monohydrate, alfadex, sodium citrate, hydrochloric acid and sodium hydroxide.

The diluent in the rear compartment is Bacteriostatic Water for Injection and contains 0.9% w/v benzyl alcohol and water for injections. The antiseptic pads are soaked in isopropyl alcohol.

What Caverject Dual Chamber looks like and contents of the pack

The product is a dual chamber glass cartridge assembled as a single unit in a disposable delivery device. The cartridge contains a powder in the front compartment and diluent in the rear compartment.

There are sufficient components in each box to enable two or ten separate injections of Caverject Dual Chamber. Not all pack sizes may be marketed.

In the Caverject Dual Chamber box you will find:

1. Two or ten single use injection devices each containing a dual chamber cartridge
2. Two or ten 29G needles
3. Alcohol cleaning swabs

Marketing Authorisation Holder

Pfizer Limited,
Ramsgate Road,
Sandwich, Kent
CT13 9NJ, UK.

Manufacturer

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

The needle is made by Becton Dickinson Consumer Products, Dublin, Ireland and is labelled with the number CE 0050.

This leaflet was last revised on September 2011

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