

Patient Information Leaflet

Caverject® Dual Chamber **10 and 20 micrograms**

Powder and solvent for solution for injection
Alprostadil

PHARMACIA

This leaflet is a summary of information about Caverject Dual Chamber. Please read it before you start using the product. If you have any questions after you have read it, speak to your doctor or pharmacist. Keep the leaflet safely as you may need it again. Caverject Dual Chamber can only be prescribed by a doctor. Do not let anyone else use your Caverject Dual Chamber even if they have the same problem as you.

Caverject Dual Chamber is a powder and diluent for solution for injection. The product is a dual chamber glass cartridge assembled as a single unit in a disposable delivery device. The cartridge contains a lyophilised powder in the front compartment and diluent in the rear compartment. The product licence holder is:

PL Holder: Pharmacia Limited, Davy Avenue, Milton Keynes, MK5 8PH, UK.

PA Holder: Pharmacia Ireland Limited, Airways Industrial Estate, Dublin 17, Ireland.

What is provided in the Caverject Dual Chamber box?

There are sufficient components in each box to enable two separate injections of Caverject Dual Chamber. In the Caverject Dual Chamber box you will find:

1. Two single use injection devices each containing a dual chamber cartridge

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 0.5 ml. This compartment also contains the inactive ingredients, lactose monohydrate, alfadex, sodium citrate, hydrochloric acid and sodium hydroxide. The diluent in the rear compartment is Bacteriostatic Water for Injection and contains benzyl alcohol and water for injections. Caverject Dual Chamber is made by Pharmacia AB, S-112 87 Stockholm, Sweden.

2. Two 29 gauge needles – 0.5 inch long

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

3. Two alcohol cleaning swabs.

How does Caverject Dual Chamber work?

The alprostadil in Caverject Dual Chamber 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.

What is Caverject Dual Chamber for?

Caverject Dual Chamber is 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.

Before you use Caverject Dual Chamber

Is Caverject Dual Chamber suitable for you?

You should not use this injection if you have:

- ever had a bad reaction to Caverject Dual Chamber, any other medicines containing alprostadil or any of the other ingredients listed above.
- sickle cell disease, leukaemia, multiple myeloma (bone cancer) or any other problem which means that you get "priapism". This is when your erection lasts for a long time.
- an implant in your penis.
- a condition (such as very severe heart disease) in which sexual activity should be avoided.
- a penis which is scarred or not straight.
- a tight foreskin.

Do not use any Caverject Dual Chamber until your doctor says that it is right for you.

Are you taking any other medicines?

Do not use other medicines for erectile dysfunction at the same time as Caverject Dual Chamber. Ask your doctor or pharmacist for advice if you are taking "anticoagulants" to thin your blood. You might bleed abnormally when you do the injection. Make sure that your doctor knows about any other medicines you are taking, including ones you have bought for yourself at the chemist, BEFORE you start using Caverject Dual Chamber.

Important information

Pregnancy

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.

Sexually transmitted diseases

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

Using 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. The starting dose in the clinic is 1.25–2.5 micrograms, although doses lower than 2.5 microgram can not be delivered with Caverject Dual Chamber. In this case, Caverject Powder for Injection will be used. Your doctor will investigate which is the right dose for you. 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 60 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?

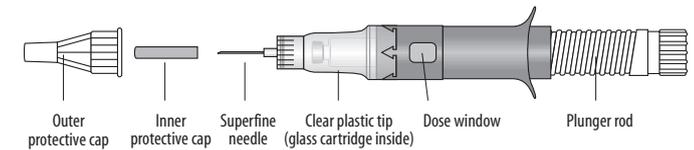
These instructions are intended as a guide only; you should follow your doctor's advice where it differs from this leaflet. If you are using Caverject Dual Chamber for the first time and you have previously used Caverject Powder for Injection, you should have received instructions from your doctor about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

You and your partner

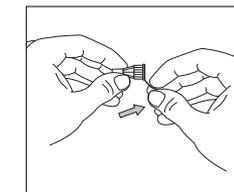
You may like your partner to be involved in preparing and/or giving the injection. If so, you should speak to your doctor about training for your partner.

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.

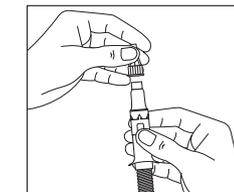
The Caverject Dual Chamber device



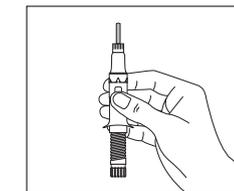
Preparing the injection



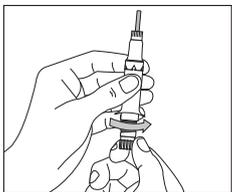
1. Remove one of the injection devices and needles from the box. Peel the foil cover from the needle.



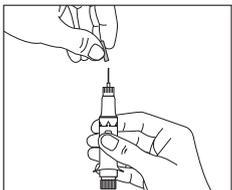
2. Attach the needle to the device by pushing the needle on to the tip of the device. Turn clockwise until it is firmly in place. Pull off the outer protective cap of the needle.



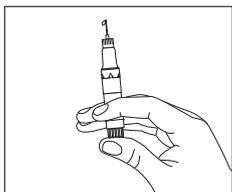
3. Hold the device with the needle pointing upwards. The white plunger rod is in the extended position.



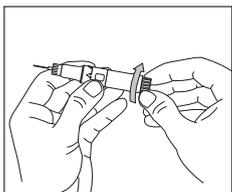
- Turn the plunger rod clockwise until it stops. This mixes the powder and diluent. Gently shake to make sure that the solution is evenly mixed. Do not use if it is cloudy or contains particles.



- Hold the device with the needle upwards. Carefully remove the inner protective cap from the needle.



- To remove any large bubbles from the solution, flick the cartridge with your finger. Then, keeping the device upright, 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 microbubbles at the side of the glass cartridge.

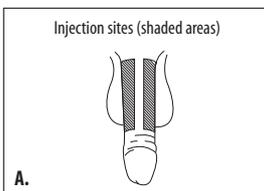


- Turn the end of the plunger rod slowly clockwise to select your dose. This is one of four quarterly increments of full dose delivered by the device. Your doctor will have told you what this should be. The number appearing in the window indicates the dose of the injection. If you make a mistake, continue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

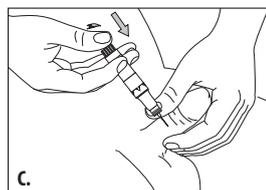
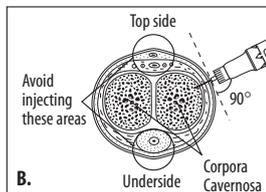
You can prepare your injection upto 24 hours before using it, providing it is kept at room temperature.

How do you do the injection?

- Get undressed and make yourself comfortable. Take some time to relax yourself and your partner. If your prescriber 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.
- 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.

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 (see section on side effects below).

How often can you use Caverject Dual Chamber?

You can use Caverject Dual Chamber up to once in 24 hours and up to three times in a week. Do not use it more often than this. Change the exact place that you inject Caverject Dual Chamber each time you use it.

What if you inject too much Caverject Dual Chamber?

Tell your doctor straight away if you experience an erection that lasts for longer than four hours, rapid breathing, feeling faint or weak, depression, soft stools or diarrhoea. You may need treatment.

Does Caverject Dual Chamber have side effects?

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.

Some people find that their erections are uncomfortable or painful when they use Caverject Dual Chamber, others may notice that their penis becomes scarred, bent or kinked. Also, when you first start using Caverject Dual Chamber, you may find the injection leaves a small bruise. This should happen less often with practice.

1% or less of users have found the following side effects with Caverject Dual Chamber:

- The area injected becomes inflamed or swollen and may itch, have a rash or bleed.
- The penis, testes or scrotum could be red, swollen or painful, or the penis could feel numb, your ejaculation may change or your foreskin could feel tight.

- The desire to pass urine more frequently than normal or difficulty in urinating. If Caverject Dual Chamber is injected by mistake into the tube which carries urine out through the penis, some blood may appear in the urine or at the end of the penis.
- Dizziness, back or pelvic pain, general weakness, sickness, dry mouth.
- Changes in blood pressure and heart rhythm, faintness, shallow breathing and collapse could occur because of the injection itself.
- Skin itching or rash, increased sweating, eye sensitivity to bright light, impaired sense of touch, cold hands and feet.

If your erection goes on for longer than 4 hours, speak to the doctor who prescribed Caverject Dual Chamber for you straight away. This may have been a doctor in a clinic or hospital, or your GP. If you cannot contact this doctor, go to a hospital casualty department.

How do you store Caverject Dual Chamber?

- Keep the cartridge and needles in a safe place where children can not reach them.
- Do not use any Caverject Dual Chamber after the "use-by" date on the pack.

This leaflet was last revised on 23 May 2003.