

## **PATIENT INFORMATION LEAFLET**

### **Caverject<sup>®</sup> Dual Chamber 20 mcg Powder and solvent for solution for injection Alprostadil**

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

#### **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. What you need to know before you use Caverject Dual Chamber**

##### **Do not use Caverject Dual Chamber:**

- If you are allergic to alprostadil or any of the other ingredients of this medicine (listed in section 6).

- If you have sickle cell anaemia (an abnormality of red blood cells), 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 longer than 6 hours.
- 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.
- If you have a penis which is scarred, bent or kinked, or Peyronie’s disease.
- If you have a tight foreskin.

Caverject Dual Chamber must not be given to children (see ‘Caverject Dual Chamber contains benzyl alcohol and sodium’).

### **Warnings and precautions**

If you experience an erection that lasts for longer than 4 hours seek medical advice **immediately** as treatment should be started within 6 hours. If you cannot contact your doctor go to the hospital emergency department.

Talk to your doctor or pharmacist before using Caverject Dual Chamber:

- If you have a lung, chest or heart disorder (in these cases you should also 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 have one or more cardiovascular risk factors (these might include high blood pressure, tobacco use, raised blood glucose, raised blood cholesterol, overweight and obesity)
- If you have one or more risk factors for stroke (these might include high blood pressure, raised blood cholesterol, coronary artery disease, heart arrhythmia, diabetes)

### **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.

### **Other medicines and Caverject Dual Chamber**

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)

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

### **Pregnancy and breast-feeding**

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

### **Caverject Dual Chamber contains benzyl alcohol and sodium**

This medicine contains benzyl alcohol 8.9 mg/ml.

Benzyl alcohol may cause allergic reactions.

Using large amounts of Caverject Dual Chamber may cause a build-up of benzyl alcohol in your body resulting in an increased amount of acid in your blood (called metabolic acidosis). Patients with liver or kidney disease need to be especially cautious and discuss with their doctor.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gaspings syndrome”) in young children. Caverject Dual Chamber is not for use in children.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say

essentially 'sodium-free'.

### **3. How to use Caverject Dual Chamber**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

A doctor 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 cannot 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. To minimise the risk of prolonged painful erection, your doctor will select the lowest effective 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?**

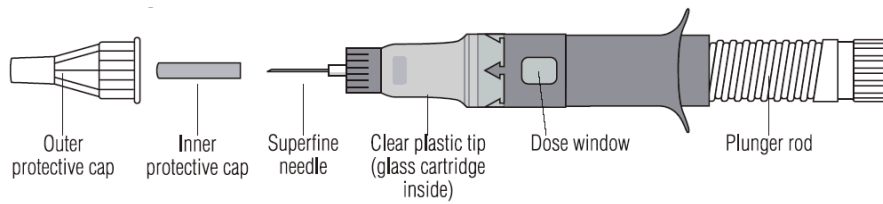
These instructions are intended as a reminder only; you should follow your doctor's advice where it differs from this leaflet. If you are using Caverject Dual Chamber for the first time and you have previously used Caverject Powder for Injection, your doctor should have given you advice about using Caverject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

#### **You and your partner**

You may like your partner to be involved in preparing and/or giving the injection. If

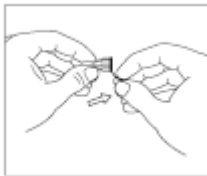
so, you should speak to your doctor about training for your partner.

### The Caverject Dual Chamber device

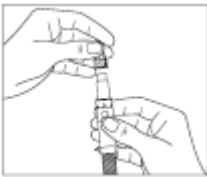


### Preparing the injection

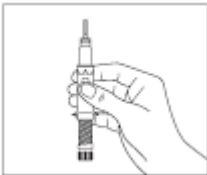
Wash your hands. Dry them with a clean towel. If your partner wishes to be involved in preparing or giving the injection, they should wash their hands too.



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. The injection needle is enclosed in 2 protective caps. 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.



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.

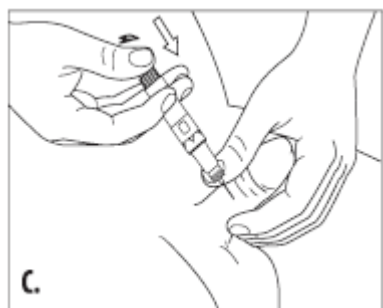
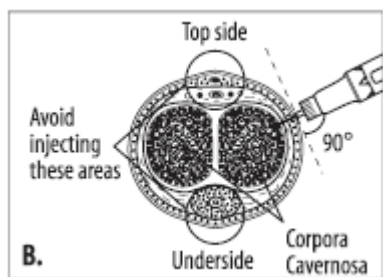
You can prepare your injection up to 24 hours before using it, providing it is kept at room temperature.

### 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. 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 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.



- 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. 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 Take special care with Caverject Dual Chamber).

### **If you use more Caverject Dual Chamber 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 or pharmacist.

#### **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.

Other side effects may include the following:

##### **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 Caverject Dual Chamber
- Prolonged erections
- Other problems with your penis
- Swelling and skin discolouration or bruising at site of injection. You may find this happening the first time you use Caverject Dual Chamber but should occur less often with practice
- Muscle spasms.

##### **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 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

- 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 specially if Caverject Dual Chamber is injected by mistake into the tube which carries urine out through the penis (urethra)
- Pelvic pain, weakness, sweating, feeling sick or swollen legs or arms, having a common cold or dry mouth. You may get a yeast infection (thrush)
- Changes in blood pressure and heart rhythm, faintness, shallow breathing and collapse could occur because of the injection itself
- Skin itching, redness of the skin at site of injection, rash or skin growth, increased sweating, eye sensitivity to bright light or excessive dilation of the pupil (blown pupil), impaired or enhanced sense of touch, leg cramps, 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).

#### **Not known**

(frequency cannot be estimated from available data)

- Insufficient blood flow to the heart muscle via the coronary arteries
- Stroke

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **5. How to store Caverject Dual Chamber**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the outer carton after 'EXP'.
- Refer to the outer carton for storage condition.
- You can prepare your injection up to 24 hours before using it, providing it is kept below or at 25°C.
- 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. Content of the pack and other 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 20 micrograms of alprostadil in 0.5 ml.

The other ingredients are lactose, 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 cleaning swabs are soaked in isopropyl alcohol.

### **What Caverject Dual Chamber looks like and contents of the pack**

This 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 separate injections of Caverject Dual Chamber.

In the Caverject Dual Chamber box you will find:

1. Two single use injection devices each containing a Caverject Dual Chamber cartridge
2. Two 29G needles
3. Alcohol cleaning swabs

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