

Caverject®**Powder for Injection 5, 10, 20 micrograms**

alprostadil

Production code area

Read all of this leaflet carefully before you start taking 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 is and what it is used for
2. Before you use Caverject
3. How to use Caverject
4. Possible side effects
5. How to store Caverject
6. Further 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.

2. 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.
- have sickle cell (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.
- an implant in your penis.
- a condition (such as 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 until your doctor says that it is right for you.

Take special care with Caverject**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.

Taking other medicines

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

- other medicines for erectile dysfunction such as sildenafil.
- medicines to thin your blood such as warfarin or heparin, as you might bleed more when you do the injection.

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 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 should not affect your ability to drive or use machines

Important information about some of the ingredients of Caverject

Caverject 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

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. 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 1.25 - 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.

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:

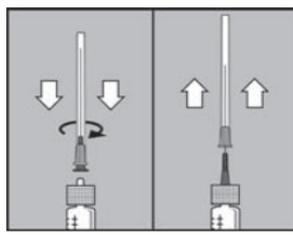
- The larger 22 gauge needle with the grey end is used to mix the solution and Caverject Powder.
- The smaller and finer 30 gauge needle with the yellow end is used to inject the mixture into your penis.

2. To prepare the vial

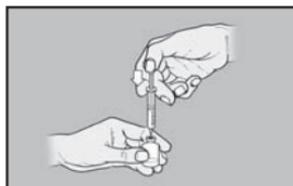
Flip the plastic cap off the vial. Wipe the rubbery top with one of the wet antiseptic pads.

**3. Fitting the needle to the syringe**

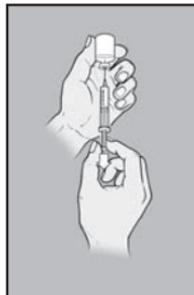
Hold the syringe and twist the white tamper evident cap to break the seal. Take the foil off the larger needle, (22 gauge) with the grey end, keeping the cover on. Join the needle to the syringe by turning the needle clockwise tightly onto the syringe, then remove the needle cover by pushing it away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

**4. Mixing the solution with the powder**

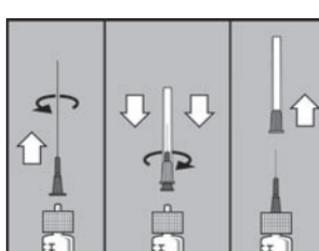
Push the needle through the rubbery middle of the vial top. Press the plunger down firmly to squirt all the solution onto the powder. Gently swirl the vial until all the powder has dissolved. If the mixture is cloudy or does not dissolve completely, do not use it. Never use tap water or any liquid other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

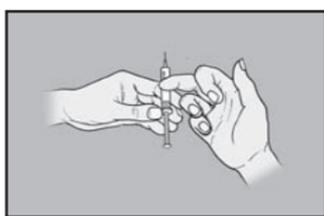
Gently twist the larger needle anticlockwise off the syringe. Put this and the empty vial in the blue box. Remove the smaller injecting needle, (30 gauge) with the yellow end from its package, keeping the cover on. Twist the needle clockwise tightly onto the syringe, then remove the needle cover by pushing it away from the syringe with your thumb and forefinger.



continued overleaf...

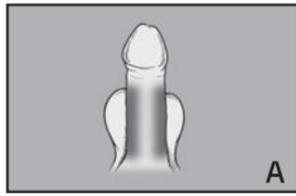
7. Setting the dose

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.

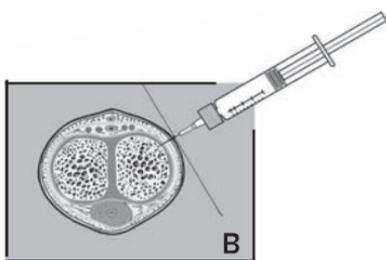


How do you do the injection?

- 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. 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.



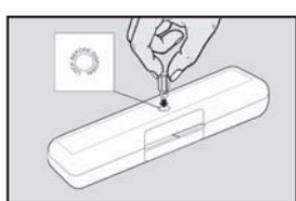
- If recommended by your prescriber wipe the skin over this area with the second pad and let it dry.
- Keeping a firm grip on the penis and taking the syringe in your free hand, push the needle straight through the skin all the way into the bulgy part avoiding veins or other obvious blood vessels. The 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 or 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?

Ensure that the syringe, vial and needles are placed in the blue box. Pull the red plug out of its holder. Close the blue box and push the red plug through the padlock symbol on the box. Make sure it locks in position and the box does not open. Put the box into a carrier bag and tie it up. Dispose of it as recommended by your prescriber.



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 Section 4 - Side effects).

What if you use too much Caverject

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

Like all medicines, Caverject 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.

Very common side effects (occurring in more than 1 in 10 patients)

- Pain in the penis

Common side effects

(occurring in less than 1 in 10 patients)

- Penis can become scarred, bent or kinked, particularly after long term use. **Tell your doctor** if this happens as you may need to stop Caverject.
- Headache or dizziness
- Increased blood pressure
- Cough, inflamed sinuses, cold or flu-like symptoms
- Pain in the leg, back, buttocks, genitals or stomach
- Prostate problems
- Swollen penis or rash on penis,

When you first start using Caverject, you may find the injection leaves a small bruise. This should happen less often with practice

Uncommon side effects

(occurring in less than 1 in 100 patients)

- The area injected becomes inflamed or swollen and may itch or bleed.
- The testes or scrotum could be red, swollen or painful, or the penis could feel numb. You may get uncomfortable, painful or prolonged erections, your ejaculation may change or your foreskin could feel tight. You may get a yeast infection (thrush).
- The desire to pass urine more frequently than normal or difficulty in urinating. If Caverject 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.
- Pelvic pain, weakness, sweating, feeling sick or, dry mouth.
- Changes in blood pressure and heart rhythm, faintness, shallow breathing and collapse could occur because of the injection itself.
- Skin itching, rash or skin growth, increased sweating, eye sensitivity to bright light, impaired sense of touch, leg cramps, cold hands and feet.
- If you have a blood test you may have raised levels of creatinine (a substance found in your muscles).

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.

5. How to store Caverject

- Do not store above 25°C.
- Keep the syringe and needles out of the reach and sight of children.
- When you have mixed the Caverject Powder with the solution, use it straight away. 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 use any Caverject after the 'use-by' date on the pack. The expiry date refers to the last day of that month.

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 contains

The active ingredient in Caverject is alprostadil. Each vial contains 5, 10 or 20 micrograms of alprostadil.

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

The syringe contains benzyl alcohol (8.4 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 blue box you will find 6 items.

- 1 One glass vial containing Caverject 5, 10 or 20 micrograms as an off-white powder
- 2 One glass syringe containing 1mL 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 (Medi-Swab skin cleansing wipes)
- 6 One red plastic plug

Marketing Authorisation Holder

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

Manufacturer

Caverject Powder is made by Pharmacia NV/SA, Puurs, Belgium.

The solution in the syringe is made by Pharmacia NV/SA Puurs, Belgium and Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany.

The larger 22 gauge needle is made by Becton Dickinson SA, 11 Rue Aristide Berges, Zone Industrielle, F-38800, Pont-de-Claix, France, and is labelled CE 0086.

The smaller 30 gauge needle is made by Becton Dickinson & Co. Ltd., Donore Road, Drogheda, Co. Louth, Ireland, and is labelled CE 0050.

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