

Caverject[®] powder for injection

Alprostadil, Prostaglandin E₁ (PGE₁) 10 and 20 micrograms

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Caverject.

This leaflet answers some common questions about Caverject.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Caverject against the expected benefits it will have for you.

Use Caverject as instructed and follow the advice given in this leaflet.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Caverject is used for

Caverject may be prescribed by your doctor for the treatment of erectile dysfunction (inability to maintain an erection to have sexual intercourse).

Caverject may also be used to help in the diagnosis of erectile dysfunction.

Caverject contains alprostadil as the active ingredient. Alprostadil is also known as prostaglandin E₁ (PGE₁) and is found naturally in many parts of your body.

Caverject works by increasing the blood flow to the penis. The increased blood flowing into the penis is trapped in the spongy erectile tissue of the penis called the corpora cavernosa. When these chambers fill with blood they swell and your penis becomes erect.

Caverject is injected into the side of the penis and should produce an erection in 5 to 20 minutes. The erection should last for about 30 to 60 minutes.

Caverject is available only with a doctor's prescription.

Your doctor may have prescribed Caverject for another reason. Ask your doctor if you have any questions about why Caverject has been prescribed for you.

Before you use Caverject

When you must not use Caverject

Do not use Caverject if you:

- have an allergy to alprostadil, the active ingredient in Caverject, or to any of the other ingredients listed at the end of this leaflet.
- have a penis which is scarred, not straight or if you experience painful erections (Peyronie's disease)
- have a penile implant
- have certain illnesses such as leukaemia, multiple myeloma, sickle cell anaemia or any other condition which means that your erection lasts for a long time (priapism)
- have abnormal thickening of the tissues of your penis.

Caverject is not for use in women, children or newborns.

Caverject should not be used by men who have been advised not to have sex.

Do not use Caverject if the packaging is torn or shows signs of tampering.

Do not use Caverject after the expiry date (EXP) printed on the carton.

If you are not sure whether any of these apply to you, check with your doctor.

Before you start using Caverject

Tell your doctor if:

- you are taking any medications used to stop your blood clotting. For example, heparin or warfarin.

Tell your doctor or your partner's obstetrician if your partner intends to become pregnant.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Note:

The use of Caverject offers no protection from sexually transmitted diseases or those caused by the human immunodeficiency virus (HIV) such as AIDS. Your doctor can give you more information about the type of protection you should use against these diseases.

You may also need to consider using appropriate contraception.

The injection of Caverject can cause a small amount of bleeding at the site of injection. If you have any diseases that can be passed by blood, eg hepatitis B, there could be a higher chance of passing them onto your partner.

How to use Caverject

How much to use

Your doctor will tell you how much Caverject to use. This depends on your condition and whether or not you are taking any other medicines.

You should use Caverject no more than once in a 24 hour period and not more than three times a week.

You should not use more than 3 vials for any one treatment.

You should not change your dosage without first talking to your doctor.

Follow all instructions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand these instructions, ask your doctor for help.

How to prepare solution from the powder

You must be properly instructed and trained in the injection technique by your doctor before using Caverject. It is important that you follow your doctor's instructions at all times. If you are not certain about the way to prepare your Caverject injection please contact your doctor; this leaflet is only intended to remind you about the instructions that your doctor has already given you.

To prepare your Caverject injection your pharmacist will give you a carton containing:

- A glass vial of Caverject powder
- A syringe filled with diluent (bacteriostatic water for injection)
- Two needles (a 22 gauge needle for adding diluent to dissolve the Caverject powder and a 27 gauge needle or 30 gauge needle for injection)
- Two alcohol swabs

How to prepare the injection

Note:

Follow these instructions exactly to prepare and inject a sterile dose of Caverject. If the needle is bent at any time, do not use it for injecting Caverject and do not attempt to straighten it prior to injecting Caverject. A bent and restraightened needle may be 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 while preparing for the injection, remove it from the syringe, discard and attach a new, unused sterile needle to the syringe as described in point 5 below.

1. Wash your hands thoroughly with soap and water.
2. Unpack the Caverject packaging.
3. Peel back the covers on the syringe and needle packet and open the swab.
4. Remove the plastic cap from the vial and wipe the rubber stopper with one alcohol swab. Discard this alcohol swab.
5. Unwrap the needle (22 gauge), keeping its plastic needle cover in place. Turn the upper part of the white-tamper-evident seal on the syringe by breaking the seal and remove the rubber cap. Join the needle to the syringe by turning it onto the neck of the syringe. Remove the needle cover by pulling it straight up. Do not touch the exposed needle.

6. Hold the syringe with the needle pointing upwards and push the plunger to the 1 mL mark on the syringe.
7. To dissolve the Caverject powder, pick up the vial and hold upright. Insert the needle through the rubber stopper of the vial. Then push the plunger all the way down to expel all 1 mL of the diluent into the vial.
8. Without removing the syringe from the vial **gently** shake the vial to mix the contents until dissolved. **Do not use the solution if it is cloudy, coloured or contains particles.**
9. To draw the solution from the vial, turn the vial upside down. Keep the needle tip below the level of the solution, slowly pull back on the syringe plunger and withdraw the solution.
10. If there are air bubbles, gently tap the sides of the syringe to allow them to float to the top of the solution. Holding the syringe upright, push the syringe plunger to the correct volume mark for the dose prescribed by your doctor.
11. Hold the sides of the syringe (not the plunger) and pull the needle/syringe from the vial in a straight line to avoid bending the needle. Throw away any unused solution left in the vial.
12. **To inject the solution, remove the needle from the syringe and replace the cover. Then attach the other needle (27 or 30 gauge) supplied.**

How to inject

Caverject injection is injected into either of two sections of the penis called the corpora cavernosa. Your doctor will show you these areas on the sides of your penis.

Follow these instructions carefully before proceeding with your Caverject injection.

DO NOT USE THE NEEDLE IF IT IS BENT (refer to notes under the subheading "How to prepare the injection").

1. Perform the self-injection procedure whilst sitting in an upright, slightly reclining or standing position.
2. Inject Caverject only in the areas (corpus cavernosum) as shown by your doctor. **Do not inject into any visible veins, the top or the underside of the penis.**
3. Alternate the injection site each time you use Caverject; choose one side of your penis for this injection, use the other side next time and so on. Within each area, the actual point of injection should also be changed each time.
4. Open the second alcohol swab packet.
5. Hold the head of your penis with your thumb and forefinger. Fully stretch your penis away from your body, straight ahead. If you are uncircumcised the foreskin must be pulled back before you inject the solution.
6. Clean the injection area with an alcohol swab and let it dry. Put the swab to one side.

Inserting the needle

7. Keeping a firm grip on your penis, take the syringe in your free hand. Gently rest the needle on your penis. With a steady, continuous motion, insert the entire length of the needle straight into the injection site.
8. Push the plunger firmly with your thumb. This may require some pressure.
9. Withdraw the needle from your penis. Apply pressure to the injection site for at least five minutes with the alcohol swab. If bleeding occurs, maintain this pressure on the injection site until the bleeding stops.

Massage the penis to help the Caverject spread through it.

10. If there is any solution left in the syringe DO NOT keep it to use for a second injection. The syringe is designed for single use only.
11. After using the contents of this pack, dispose of all materials safely. Do not reuse or share needles or syringes.

If you use too much Caverject (overdose)

Remember to only use the amount of Caverject that your doctor told you to use. If you use more Caverject than your doctor has prescribed, your erection may last longer than is medically safe and may require medical intervention. You should contact your doctor if your erection lasts for more than four (4) hours.

Telephone your doctor or National Poisons Centre (telephone 0800 764 766) immediately for advice or go to the Accident and Emergency (Casualty) Department at your nearest hospital if you think you or anyone else may have used too much Caverject.

While you are using Caverject

Things you must do

Tell your doctor, dentist and pharmacist who are treating you that you are using Caverject.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Caverject.

If your partner becomes pregnant while you are using Caverject, tell your doctor or your partner's obstetrician.

If you are being treated with warfarin or heparin (medicines that are used to stop your blood from clotting) you need to be aware of

an increased chance of bleeding after injection.

An injection with Caverject should produce an erection that lasts for 30 – 60 minutes and enables you to have sex. Tell your doctor if your erection lasts for more than 60 minutes. Your dose may need to be reduced.

Visit your doctor regularly. From time to time your doctor will need to examine the injection site to detect any abnormal thickening of the tissues of the penis and may need to change your dose of Caverject.

Always discuss with your doctor any problems or difficulties during or after using Caverject.

Things you must not do

Do not give Caverject to anyone else, even if they have the same condition as you.

Do not use Caverject to treat any other complaints unless your doctor or pharmacist tells you to.

Do not change your dose yourself without first asking your doctor for advice.

Do not use any mixture left in the syringe or vial for a second injection.

Do not use the needle to inject if it is bent (refer to notes under the subheading "How to prepare the injection").

Side effects

Check with your doctor as soon as possible if you have any problems while using Caverject, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like many medicines, Caverject may cause side effects. If they occur, they are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

These are common side effects of Caverject. Mostly these are mild and short lived:

- Pain in the penis during erection
- Bruising at the site of injection

Tell your doctor if you experience the following uncommon or rare side effects:

- redness, swelling, bleeding and itching at the site of injection
- localised pain (buttocks, leg, genital, back or pelvis)
- leg cramps
- numbness
- increased sweating
- increased feeling of pain or sensitivity, especially in the skin
- yeast infection
- inflammation of the head of the penis
- tight foreskin
- hardened areas developing at the site of injection. This can result in curvature of the penis
- prolonged erection (lasting 4 to 6 hours). See below.
- abnormal ejaculation or painful erection.
- swelling, redness, pain of the scrotum
- disorder of the testis (pain, warmth, swelling, thickening)
- changes in blood pressure
- changes in your heartbeat or palpitations
- dizziness and headache
- fainting
- nausea, dry mouth
- 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 (urethra), some blood may appear in the urine or at the end of the penis
- skin rash, redness, sensitivity, irritation, itchiness
- dilated pupil

Your doctor will check regularly that Caverject is not causing abnormal

thickening of the tissues of the penis. If this happens your treatment with Caverject will be stopped.

If your erection lasts for more than 1 hour you should tell your doctor as your dose may need to be reduced.

If your erection lasts for more than 2 hours try walking around, especially up and down stairs, emptying your bladder, or taking a hot or cold shower. You should avoid any further sexual activity.

Contact your doctor immediately if your erection lasts for 4 hours or more. This can be painful and may require medical treatment.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Caverject

Storage

Unused packs of Caverject vials should be stored below 25°C. Do not freeze or refrigerate.

After dissolving the Caverject powder, the solution of Caverject should be used as soon as possible. If storage is necessary then store at 2-8°C for not more than 24 hours after dissolving. Do not freeze the dissolved solution.

During travel, care should be taken to avoid allowing the product to be stored at temperatures above 25°C. Therefore, do not store in checked luggage during air travel.

Do not leave Caverject in the car on hot days or on window sills.

Do not store Caverject in the bathroom or near a sink.

Do not keep outdated Caverject.

Be sure that any discarded Caverject is out of reach of children.

Keep Caverject where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

After using Caverject, dispose of all injection material safely by placing them back into the plastic case. Your doctor or pharmacist will advise you on how to dispose of the used syringes and needles.

Product description

What it looks like

Caverject is available as a sterile freeze-dried powder. It is supplied in a clear glass vial. It is available in packs containing 1 vial in each of the following strengths:

10 micrograms
20 micrograms

Ingredients

Caverject powder for injection contains either 10 or 20 micrograms of the active ingredient, alprostadil (prostaglandin E₁; PGE₁) depending on the vial strength.

The other ingredients are:

- Lactose
- Sodium citrate
- Hydrochloric acid
- Sodium hydroxide

The diluent in Caverject contains water for injection and benzyl alcohol.

Supplier

Caverject is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland
New Zealand

Toll Free Number: 0800 736 363

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