

CAVERJECT®

Alprostadil, Prostaglandin E1 (PGE1) 10 and 20 micrograms

Consumer Medicine Information

What is in this leaflet

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 using CAVERJECT against the benefits it is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What CAVERJECT is used for

What CAVERJECT does

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. Alprostadil is also known as prostaglandin E1 (PGE1) and is found naturally in many parts of your body.

How CAVERJECT works

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 a specific area of the penis and should produce an erection in 5 to 20 minutes. The erection should last for about 30 to 60 minutes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed CAVERJECT for another reason.

This medicine is available only with a doctor's prescription.

Before you are given CAVERJECT

When you must not use it

Do not use CAVERJECT if you have an allergy to:

- any medicine containing alprostadil
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use CAVERJECT if you have or have had any of the following medical conditions:

- a penis which is scarred or not straight
- you have painful erections (Peyronie's disease)
- a penile implant
- certain illnesses such as leukaemia, multiple myeloma, sickle cell anaemia or any other condition which causes your erection to last for a long time (Priapism)
- abnormal thickening of the tissues of your penis
- been advised not to have sex.

Do not give this medicine to women.

Do not give CAVERJECT to children or newborns.

CAVERJECT contains an ingredient called benzyl alcohol (see list of ingredients at the end of this leaflet). Benzyl alcohol has been associated with serious side effects which can be fatal in children, especially premature and low weight infants. Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should use this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

If you have not told your doctor about any of the above, tell him/her before you start taking CAVERJECT.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by CAVERJECT or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicine used to prevent blood clots, e.g., warfarin or heparin.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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, e.g., hepatitis B, there could be a higher chance of passing them onto your partner.

How to use CAVERJECT

CAVERJECT is a single use device. The syringe device should only be used to administer one dose and then discarded.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions provided at the end of this leaflet, ask your doctor or pharmacist for help.

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.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it.

If you use too much (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.

Immediately telephone your doctor, or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much CAVERJECT

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using CAVERJECT

Things you must do

Before you start on any new medicine, tell your doctor, pharmacist and dentist that you are using CAVERJECT.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are using this medicine.

It may interfere with the results of some tests.

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.

Keep all of your doctor's appointments so that your progress can be checked.

From time to time your doctor will need to examine the injection site to detect any abnormal thickening of the tissues of the penis. If this happens, your treatment with CAVERJECT will be stopped.

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

Things you must not do

Do not use CAVERJECT to treat any other complaints unless your doctor tells you to.

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

Do not stop using your medicine or lower the dosage without checking with your doctor.

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 at the end of this leaflet under the subheading "Injecting the Caverject solution").

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). Additional instructions of what you can do if this happens are provided below.
- abnormal ejaculation or painful erection
- swelling, redness, pain of the scrotum
- disorder of the testis (pain, warmth, swelling, thickening)
- changes in your heartbeat or palpitations
- changes in blood pressure
- 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.

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

After using CAVERJECT

Storage

Keep your unused packs of CAVERJECT vials in a cool dry place where the temperature stays below 25°C. Do not freeze. After dissolving the CAVERJECT powder, the solution of CAVERJECT should be used as soon as possible. If storage is necessary, store at 2°C - 8°C (Refrigerate. Do not freeze.) for not more than 24 hours after dissolving.

Care should be taken to avoid storing the product at temperatures above 25°C even when you travel.

Do not store CAVERJECT in checked luggage during air travel.

Do not store CAVERJECT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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, put all the injection material back into its original box and ask your pharmacist to dispose them safely. If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

CAVERJECT 10 microgram or CAVERJECT 20 microgram is available as a sterile freeze-dried powder. It is supplied in a clear glass vial. CAVERJECT is available in packs containing 1, 5 or 10.

*Not all pack sizes are available.

Ingredients

CAVERJECT powder for injection contains either 10 micrograms or 20 micrograms of the active ingredient, apolprostadil (prostaglandin E1; PGE1).

The other ingredients are

- lactose,
- alfadex,
- sodium citrate,
- hydrochloric acid,
- sodium hydroxide.

The diluent in CAVERJECT contains Water for Injections and benzyl alcohol.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

CAVERJECT is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia
Toll Free number: 1800 675 229.

It is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand
Toll Free number: 0800 736 363.

Australian registration numbers

- CAVERJECT 10 micrograms, AUST R 202518.
- CAVERJECT 20 micrograms, AUST R 202519.

Date of preparation

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INSTRUCTIONS ON HOW TO USE CAVERJECT

My prescribed dose is

_____ microgram = _____ mL.

Before you use Caverject

- Wash and dry your hands before using Caverject. If your partner wishes to be involved in preparing or giving the injection, they should also wash and dry their hands.

- The remaining solution in the Caverject vial should be discarded after the dose is withdrawn.
- It is important that you follow the instructions carefully to prepare and inject Caverject.
- It is important that you also read the Consumer Medicine Information leaflet available from your pharmacist or at www.pfizer.com.au and follow your doctor's advice.

PART I Preparing the syringe

Prepare your syringe just before use. If storage is necessary, store at 2°C - 8°C (Refrigerate. Do not freeze.) for not more than 24 hours after dissolving.

There are two needles in the pack

- The larger 22 gauge needle is used for adding diluent to dissolve the Caverject powder.
- The smaller and finer 27 or 30 gauge needle is used to inject the dissolved solution into your penis.

1. Prepare the vial

- Flip the plastic cap off the vial.
- Wipe the rubber top with one of the alcohol swabs. Discard this alcohol swab.

2. Fitting the needle

- Hold the syringe, break the seal and remove by rocking the cap up and down and pulling.
- Twist the base of the cover on the larger needle (22 gauge) and remove.

- Keep the cover on the needle.

- Join the needle to the syringe by turning the needle clockwise tightly onto the syringe.

- **DO NOT TWIST TOO TIGHTLY.**

- Remove the needle cover by pushing it away from the syringe with your thumb and forefinger. Do not touch the exposed needle.

3. Dissolving the powder with the supplied diluent

- Push the needle through the rubber middle of the vial top.
- Press the plunger down firmly to squirt all the solution onto the powder.
- The reconstituted solution may appear cloudy at first.
- Without removing the syringe from the vial, gently shake the vial until all the powder has dissolved.
- If the solution 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.**

4. Filling the syringe

- With the needle still inserted, turn the vial upside down. Make sure the needle tip is underneath the level of the liquid. If the plunger has moved whilst turning the vial upside down, push back into its original position.
- Gently pull the plunger to draw all the mixture into the syringe. Make sure the gap in the rubber stopper in the vial is facing you so you can check the position of the needle tip so that all liquid can be withdrawn from the vial.

5. Changing the 22 gauge needle to the 27 or 30 gauge needle

- Hold the sides of the syringe (not the plunger or the white cap) and remove the needle from the syringe by twisting it in an anticlockwise direction. The needle stays in the vial.
- DO NOT pull the needle out of the vial.
- Remove the smaller injecting needle (27 or 30 gauge) 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.

6. Setting the dose

- Tap the syringe gently to send any air bubbles to the top.

- Push the plunger to squeeze the air bubbles out, ensuring that a drop of solution comes out of the needle.

7. Check your dose

- Continue pushing until the plunger is exactly at the right mark for your dose. Your doctor will have shown you where this is.

PART II Injecting the Caverject solution

The prepared Caverject solution is injected into either side of the penis shaded below (corpora cavernosa).

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.

8. Injecting the Caverject solution **DO NOT USE THE NEEDLE IF IT IS BENT.**

- Perform the self-injection procedure whilst sitting in an upright, slightly reclining or standing position.
- Hold the head of your penis with your thumb and forefinger and squeeze gently. The injection site will then bulge out.
- Stretch your penis tightly against your thigh so that it does not slip during the procedure. If you are uncircumcised the foreskin must be pulled back before you inject the solution.
- Clean the injection area with an alcohol swab. Put swab on one side.
- Hold the syringe between your thumb and index finger. Do not press on the plunger. Gently rest the needle on the penis.
- With a steady, continuous motion, insert the entire length of the needle at a 90 degree angle into the injection site.

- Withdraw the needle from your penis. Apply pressure to the injection site for at least 5 minutes with the alcohol swab or until the bleeding stops.
- Safely dispose of the used syringe, vial and needles as instructed by your doctor or pharmacist.