

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCAVERJECT® STERILE POWDER

alprostadil for injection

Read this carefully before you start using **CAVERJECT STERILE POWDER** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CAVERJECT STERILE POWDER**.

What is CAVERJECT STERILE POWDER used for?

CAVERJECT STERILE POWDER is used in adult males:

- in the treatment of erectile dysfunction. Erectile dysfunction is a condition when a man cannot achieve and/or maintain an erection.
- together with diagnostic tests to confirm erectile dysfunction

How does CAVERJECT STERILE POWDER work?

CAVERJECT STERILE POWDER relaxes the smooth muscles of the penis. This allows more blood to flow into the penis and helps to achieve and/or maintain an erection.

What are the ingredients in CAVERJECT STERILE POWDER?

Medicinal ingredients: alprostadil

Non-medicinal ingredients: benzyl alcohol, hydrochloric acid and/or sodium hydroxide to adjust the pH, lactose monohydrate, sodium citrate dihydrate

CAVERJECT STERILE POWDER comes in the following dosage forms:

Sterile powder: 20 mcg / vial

Do not use CAVERJECT STERILE POWDER if:

- you are allergic to alprostadil or any of the non-medicinal ingredients (see **What are the ingredients in CAVERJECT STERILE POWDER?**)
- you have sickle cell anemia or a family history of sickle cell anemia (abnormality of the red blood cells), multiple myeloma (cancer of the bone marrow) or leukemia (cancer of the blood)
- you have an erection that has lasted more than 4 hours
- you have a deformed penis or Peyronie's disease (a condition that causes the penis to curve)
- you have a penile implant
- you have been told you should not be sexually active
- you are a woman or are under the age of 18

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use CAVERJECT STERILE POWDER. Talk about any health conditions or problems you may have, including if you:

- have blood clotting problems or take medicines to prevent blood clotting such as warfarin or heparin
- have a disease that is carried in your blood. You could transmit this disease to your partner as there can be a small amount of bleeding where you inject CAVERJECT STERILE POWDER.

Other warnings you should know about:

You must be properly trained by your healthcare professional before you begin to self-inject CAVERJECT STERILE POWDER.

Prolonged erection: CAVERJECT STERILE POWDER may cause prolonged erection (4 to 6 hours) or priapism (over 6 hours):

- If you have an erection lasting longer than 2 hours, try to reduce the erection using the methods suggested by your healthcare professional. Do not wait, it is easier to reduce the erection if you treat it earlier rather than later.
- If your penis is still hard after 3 hours get immediate medical help. Write down the name of the medicine, the dose and the time you took it and bring this with you to the emergency room.
- Erections that last more than 6 hours can cause serious and permanent damage.

Injection site problems: Occasionally you may have problems at the injection site such as swelling, inflammation, bruising or bleeding or blood blisters. These are usually related to improper injection technique. If this happens, ask your healthcare professional to go over the self-injection techniques with you again.

Broken or bent needle: CAVERJECT STERILE POWDER is used with a very thin needle that could break easily. If the needle breaks during use and you can see and touch the broken end, remove it and talk to your healthcare professional immediately after. If you cannot remove the broken end, get immediate medical help.

If the needle is bent, do not use it and do not try to straighten it before using it. This could make it more likely to break. Remove it from the syringe, discard it, and attach a new needle to the syringe. See **How to use CAVERJECT STERILE POWDER**, below.

Sexually Transmitted Infections (STIs): CAVERJECT STERILE POWDER does NOT protect against STIs, including HIV/AIDS. For protection against STIs, use protective measures when having oral or penetrative sex, such as condoms.

Use in children: CAVERJECT STERILE POWDER is not to be used in children and newborns. It contains benzyl alcohol which can cause death in children, especially in babies born early, and in babies who have a low weight when they are born.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CAVERJECT STERILE POWDER:

- anticoagulants, medicines used to prevent blood clotting, such as warfarin or heparin. You may be more likely to bleed after injecting CAVERJECT STERILE POWDER.

How to use CAVERJECT STERILE POWDER:

- CAVERJECT STERILE POWDER is to be injected into either of the two areas of the corpora cavernosa (spongy tissue of penis).
- CAVERJECT STERILE POWDER must be given to you first by your healthcare professional in their office to determine a dose that works for you. This dose should help you achieve and/or maintain an erection not longer than 1 hour. This process is called dosage titration.
- When your dose has been selected, your healthcare professional will show you how to safely inject CAVERJECT STERILE POWDER. The instructions are provided below. Make sure you are familiar with the instructions before giving yourself an injection. If you have any questions, talk to your healthcare professional.
- Do NOT change your dose without talking to your healthcare professional.
- Do NOT inject CAVERJECT STERILE POWDER into an erect penis.
- DO NOT reuse needles or syringes. DO NOT give used needles or syringes to others.

Usual dose:

- CAVERJECT STERILE POWDER should not be used more than once daily or more than 3 times a week.
- You must wait at least 24 hours between each dose.
- The maximum daily dose should not be more than 60 mcg.

CAVERJECT STERILE POWDER case supplies (see Diagram 1):

CAVERJECT STERILE POWDER is supplied in boxes that contain five cases. One case has enough medicine for one injection. Each case contains the following:

- One 20 mcg vial of CAVERJECT STERILE POWDER.
- One pre-filled syringe containing bacteriostatic (bak-te-reo-stat-tik) water for injection. This is sterile water containing a preservative. It is used to dissolve CAVERJECT STERILE POWDER. This solution does not contain any medicinal ingredients. You will use this syringe after attaching the needle, to inject the prepared medicine into your penis.
- A 27-gauge, 0.5-inch needle. Keep the plastic cover on the needle until ready to inject.
- Two alcohol swabs. It is important to use the swabs to make sure the injection site is clean to prevent infection.

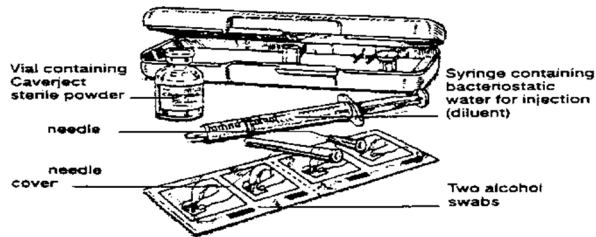


Diagram 1: Vial containing 20 mcg CAVERJECT STERILE POWDER.; Syringe containing bacteriostatic water for injection; Needle with cover; Two alcohol swabs

Instructions for self-injection of CAVERJECT STERILE POWDER

Preparing the medication:

1. Wash your hands thoroughly with soap and water.
2. Pull back on tabs of needle package to expose open end of needle. Do not let this end touch any surface.
3. Hold syringe tip upwards and remove rubber end cover. Continue to hold the syringe upright in one hand. With your free hand, pick up needle by covered end.
4. With the needle cover still on, attach the open end of the needle to the syringe tip by pushing down and twisting into place (see **Diagram 2**). Make sure the needle fits tightly.

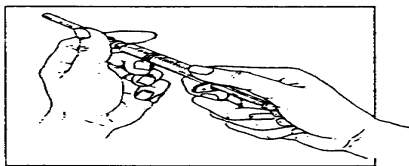


Diagram 2: Joining the needle to the syringe.

5. Remove the plastic cap from the vial.
6. Wipe the rubber stopper of the vial, using one of the swabs provided (see **Diagram 3**). Discard the used swab (the second swab is needed later).

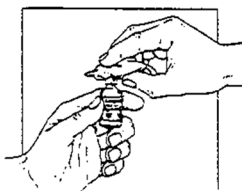


Diagram 3: Wiping the rubber stopper of the vial.

7. Handle the syringe by the barrel only. Remove the needle cover carefully from the syringe. Do not allow the needle to touch any surface.
8. Holding the syringe with the needle pointing upward, push plunger to the 1-cc (mL) line marked on the syringe. This will remove a slight amount of overfill in the syringe.
9. Pierce the needle through the center portion of the vial's rubber cap. Push down the

plunger and inject the entire contents of the syringe (bacteriostatic water) into the vial (see **Diagram 4**).

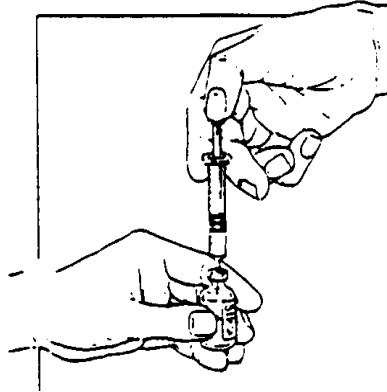
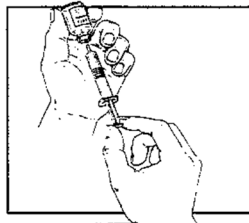


Diagram 4: Injecting bacteriostatic water into the vial.

10. Carefully hold the syringe and the vial as a unit, and gently swirl the two (do not shake) until the powder dissolves completely. DO NOT USE if the resulting solution is cloudy or coloured, or if it contains particles.

Withdrawing the medication:

1. To withdraw the medication, turn the vial (and syringe) upside down. Keep the tip of the needle below the level of the fluid. Then slowly withdraw the syringe plunger until the amount of solution is level with the line recommended by your healthcare professional (see **Diagram 5**).



Withdrawing the medication

Diagram 5: Withdrawing the medication.

2. If there are air bubbles in the syringe, tap the syringe gently to remove them, or inject the solution back into the vial and slowly withdraw again (see **Diagram 6**).

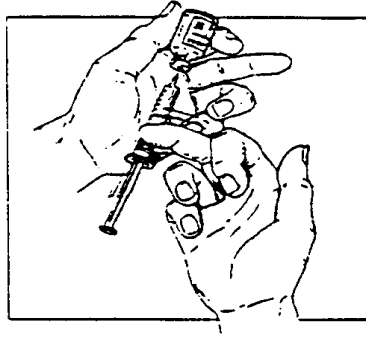


Diagram 6: Tapping the syringe to remove air bubbles.

3. Remove the needle from the bottle and carefully replace the needle cover. **DO NOT** puncture the vial more than once, you could contaminate the solution.

Diagram A. Cross-section of penis showing injection sites.

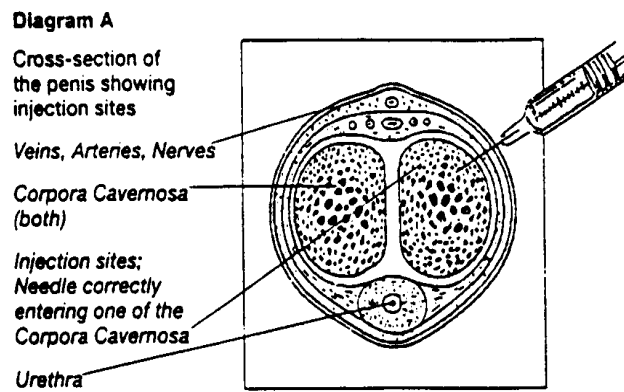
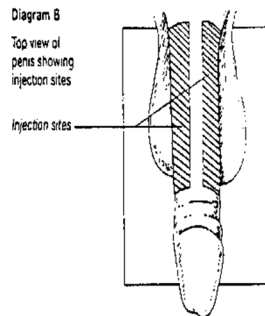


Diagram B. Top view of penis showing injection sites (shaded areas).



Self-injecting the medication:

The medication must be injected into either of the two areas of the corpora cavernosa (spongy tissue of penis). As you can see from **Diagram A** and **Diagram B** above, the corpora cavernosa run down both sides of the penis.

1. Perform the self-injection while sitting in an upright or slightly reclining position and under good lighting.
2. Only use the injection areas shown in **Diagram A** and **Diagram B**. DO NOT inject the very top or underside of your penis. Change the injection site each time you use CAVERJECT STERILE INJECTION (i.e. choose the right side for this injection, use the left side next time, and so on).
3. Grasp the head of your penis with your thumb and forefinger. Stretch your penis tautly and hold it firmly against your thigh so that it does not slip. In uncircumcised men, the foreskin must be pulled back to assure proper placement of the injection.
4. Clean the injection area thoroughly with a new alcohol swab. Put the swab to one side; you will need to use it again.
5. Hold the syringe between your thumb and index finger. Do not put your thumb on the plunger. With the syringe at a right angle (90°) to your penis, insert the needle to penetrate the skin at the injection site (see **Diagram 7**). This is a sensitive area, so expect a little discomfort. Avoid any area where veins are clearly visible.
6. Once the needle pierces the skin and resistance is felt, push the needle firmly forward until a distinct "give" is felt and insert the needle all the way in with a steady, continuous motion.

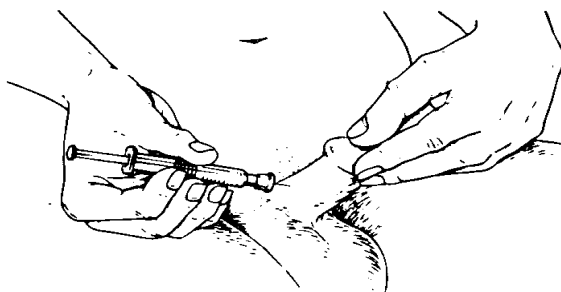


Diagram 7: Inserting the needle into the injection site.

7. Move your thumb or forefinger to the top of the plunger and press down. Inject the entire contents of the syringe using a slow, steady motion (see **Diagram 8**).

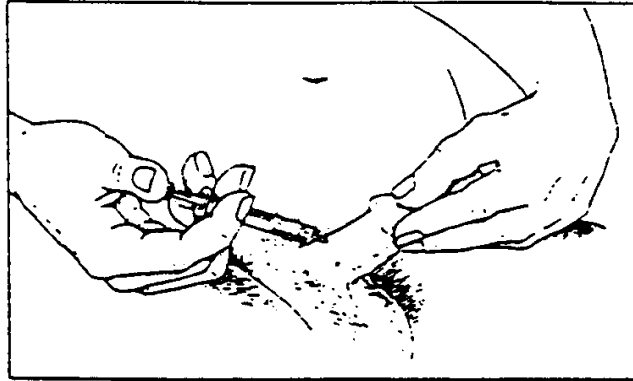


Diagram 8: Injecting the contents of the syringe.

8. Withdraw the needle from your penis and replace the needle cover. Squeeze both sides of your penis immediately, and apply pressure with the alcohol swab to the injection site for about 3 minutes. If bleeding occurs, maintain pressure until the bleeding stops.

As long as you use your healthcare professional's recommended dose, expect an erection to occur within 5 to 20 minutes after an injection.

A standard treatment goal is to produce an erection lasting up to an hour. If an erection is extremely painful (or persists after 3 hours) or if you have other side effects that concern you, talk to your healthcare professional immediately.

Disposal of used materials:

Always safely dispose of the used syringe (needle), vial and swabs. To help you, the CAVERJECT STERILE POWDER case is designed as a safe and convenient disposal unit that should be locked. As another option, your pharmacist may supply a disposal box especially for syringes.

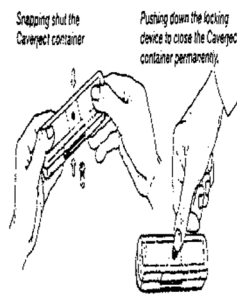


Diagram 9: Snapping shut the CAVERJECT STERILE POWDER case. Pushing down the locking device to close the CAVERJECT STERILE POWDER case permanently.

1. Remove the red plastic lock from its holder inside the case. Put this to the side.
2. Place the used syringe, needle, vial and used swabs in the plastic case. Close firmly so the case snaps shut.

3. Remove the center part of CAVERJECT STERILE POWDER label (perforated area) to show the keyhole.
4. To lock the case, push the red lock through the hole in the case top. The case is now locked.

NOTE: ONCE LOCKED, THE CAVERJECT STERILE POWDER CONTAINER WILL BE PERMANENTLY CLOSED.

You can now safely dispose of the case. Due to the contents, this is not a recyclable product; DO NOT place in a recycle bin.

Overdose:

If you think you, or a person you are caring for, have used too much CAVERJECT STERILE POWDER, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

An erection lasting longer than 3 hours means you have probably used too much CAVERJECT STERILE POWDER. If this happens get immediate medical help.

What are possible side effects from using CAVERJECT STERILE POWDER?

These are not all the possible side effects you may have when using CAVERJECT STERILE POWDER. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- mild to moderate pain in the penis after injection or during an erection
- burning sensation, discomfort or tension in the penis
- irritation, sensitivity, tenderness, numbness
- penile rash, redness
- headache
- dizziness, faintness
- urgent need to urinate

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Prolonged erection: long-lasting (greater than 3 hours in duration) and painful erection of the penis			√
UNCOMMON			
Fibrosis (formation of scar tissue in the penile tissues): penile lumps, can cause curvature of the penis or		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
curved, painful erections (Peyronie's disease)			
Penile edema: painless, non-tender swelling of the penis		√	
RARE			
Pain in the testicles or at the base of the penis		√	
Abnormal ejaculation	√		
Balanitis: inflammation of the tip of the penis, itching	√		
Injection site problems (injuries resulting from poor injection technique): swelling, inflammation, bruising or bleeding at the injection site, bleeding from the urethra, blood blisters, itching			√
Changes in blood pressure: Low: dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up) High: shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		√	
Heart problems: fast or irregular heartbeat		√	
Broken needle: needle that cannot be removed from penis			√
Phimosis (inability to retract the foreskin covering the head of the penis): tight ring or band of foreskin around the tip of the penis preventing retraction		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

1. Store unused vials of CAVERJECT STERILE POWDER between 2°C to 30°C. Do not freeze.
2. Do not use the vials after the expiry date listed on the label.
3. Once dissolved, the solution must be used immediately. Do not freeze the solution.
4. Use the contents of each vial only once. Throw out any unused solution (See **Disposal of used materials** under **How to use CAVERJECT STERILE POWDER**).
5. Keep out of reach and sight of children.

If you want more information about CAVERJECT STERILE POWDER:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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