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Caverject

Caverject (Intracavernosal)

Generic name: alprostadil [al-PROS-ta-dil]

Brand names: Caverject, Edex

Drug classes: Impotence agents, Vasodilators

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Uses Before taking Dosage Warnings Side effects Brand names

Uses for Caverject

Alprostadil injection is used to treat men who have erectile dysfunction (also called sexual impotence). It belongs to a group of medicines called vasodilators that can increase blood flow by expanding blood vessels. This medicine causes an erection because it increases the blood flow to the penis.

Alprostadil should not be used as a sexual aid by men who do not have erectile dysfunction. If the medicine is not used properly, permanent damage to the penis and loss of the ability to have erections could result.

Alprostadil is used alone or with medical tests to help diagnose erectile dysfunction that may be caused by nerve or blood vessel problems in the penis.

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

Before using Caverject

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Alprostadil injection is not indicated for use in newborns and should not be used in children.

Geriatric

Although appropriate studies on the relationship of age to the effects of alprostadil injection have not been performed in the geriatric population, no geriatric-specific problems have been documented to date. However, elderly patients are more likely to have age-related kidney problems, which may require caution and an adjustment in the dose for patients receiving this medicine.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

• Heparin

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Abnormal penis, including curved penis and birth defects of the penis or
- · Heart or blood vessel disease or
- · Leukemia (blood related cancer) or
- Multiple myeloma (blood related cancer) or
- Priapism (prolonged erection) or
- Sickle cell anemia (blood disorder) or
- Sickle cell trait—Chance of problems occurring may be increased and this medicine should be used with caution in these patients.
- Bleeding problems—Chance of bleeding at the injection site may be increased.
- Kidney disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.
- Priapism, history of—Patients with these conditions have an increased risk of priapism (erection lasting longer than 6 hours) while using alprostadil.

Proper use of Caverject

This medicine is given as a shot into your penis. You will receive the first dose of this medicine in your doctor's office to find out the best dose for you. You will need to stay in the doctor's office until your erection is gone.

This medicine comes with a patient information leaflet and patient instructions. Read and follow these instructions carefully. Ask your doctor if you have any questions.

If you will be using alprostadil at home, your doctor will teach you how the injections will be given. Be sure you understand exactly how the medicine is to be injected.

For the injections—There are several alprostadil products that can be injected. Although the injection method is the same, the mixing procedures are different. Be sure you know which of these products you will be using and the proper way to mix the injection.

One product called Alprostadil for Injection (brand names Caverject® and Edex®) is available as a powder in a vial.
 Caverject® must be mixed with a solution called Bacteriostatic Water for Injection USP. Edex® must be mixed with a solution called Sodium Chloride Injection USP. The solution for mixing comes with your product and may be already loaded into a syringe or contained in a vial.

It is important to follow several steps to prepare your alprostadil injection correctly. Before drawing up the medicine into the syringe:

- Wash your hands with soap and water.
- Set the bottles on a clean surface. Wipe the top of the injection bottles with an alcohol swab. Do not wipe the needle.
 Throw away the alcohol swab.
- You may need to attach the needle to the syringe. Do not take the cap off yet.

How to mix Caverject®:

- If the syringe already contains the Bacteriostatic Water for Injection USP, then you need only add the plunger to the syringe. To do this:
 - Pick up the rod-like plunger and place it within the barrel of the syringe until it touches the rubber piece. Gently screw the plunger into the rubber piece until it seems secure. Do not use a lot of force.
 - Hold the syringe by the barrel (not the plunger) and take the cap off the needle.
 - You are now ready to mix the water and the powder. Skip to the directions under the title, "To mix the water and powder."
- If the syringe does not already contain the Bacteriostatic Water for Injection USP, you must withdraw 1 milliliter (mL) of it from the bottle provided. To do this:
 - Pick up the syringe and take the cap off the needle. Pull the plunger back to the 1-mL mark on the syringe. This
 pulls air into the syringe. Insert the needle into rubber top of the bottle while it is upright and inject the 1 mL of air
 into the bottle.
 - Turn the bottle upside down using one hand. Be sure the tip of the needle is covered by solution.
 - With your other hand, pull the plunger back slowly to withdraw 1 mL of solution into the syringe. Remove the needle and skip to the directions under the title, "To mix the water and powder."

- To mix the water and powder:
 - Insert the needle into the bottle of alprostadil and inject 1 milliliter (mL) of Bacteriostatic Water for Injection USP from your syringe into the bottle of alprostadil.
 - Remove the needle from the bottle, holding the barrel of the syringe.
 - Gently swirl the bottle to mix the powder into the solution, turning it upside down to wet all the powder in the bottle.
 - Follow the directions below, "How to draw your dose into the syringe."

How to mix Edex®:

- The syringe already contains the Sodium Chloride Injection USP. You need only attach the needle to the syringe and add the plunger. To do this:
 - Remove the needle from its package. Do not remove the needle cap. Gently screw the needle into place on the syringe tip.
 - Pick up the rod-like plunger and place it within the barrel of the syringe until it touches the rubber piece. Gently screw the plunger into the rubber piece until it seems secure. Do not use a lot of force.
 - Hold the syringe by the barrel (not the plunger) and take the cap off the needle.
 - You are now ready to mix the Sodium Chloride Injection USP and the powder.
 - Insert the needle into the bottle of alprostadil and inject 1.2 milliliters of the Sodium Chloride Injection USP from your syringe into the bottle of alprostadil.
 - Remove the needle from the bottle, holding the barrel of the syringe.
 - Gently swirl the bottle to mix the powder into the solution, turning it upside down to wet all the powder in the bottle.
 - · Use the mixture within 24 hours of mixing it.
 - Follow the directions below, "How to draw your dose into the syringe."

How to draw your dose into the syringe (for all injection products):

- Check the solution to make sure it is clear. Do not use the mixture if it is cloudy, colored, or has particles.
- After the alprostadil solution is mixed and the needle is inserted into the alprostadil bottle, turn the bottle with the syringe as a unit upside down in one hand. Be sure the tip of the needle is covered by the solution. With your other hand, pull the plunger back slowly to draw the correct dose of the medicine into the syringe.
- Hold the syringe upright, push the syringe to the correct mark and check for air bubbles. To remove air bubbles, tap gently on the measuring scale of the syringe to move any bubbles to the top of the syringe near the needle.
- If your dose measures too low in the syringe, withdraw more solution from the bottle. If there is too much medicine in the syringe, put some back into the bottle. Then check your dose again.
- Remove the needle from the bottle, holding the barrel of the syringe, not the plunger.
- Place the cover back on the needle. You are now ready to inject your dose. Follow the directions below, "How to give the alprostadil injection."

How to give the alprostadil injection:

Choose a spot on your penis as directed by your doctor where you will give the injection.

- Clean the injection site with alcohol. Sitting upright or slightly reclined, hold your penis against the side of your thigh so that it cannot move. If your penis is not circumcised, pull the foreskin back. Take hold of the tip of your penis with your thumb and forefinger.
- Remove the cover from the needle and hold the needle at a 90-degree angle to the place of injection.
- Insert the needle until almost all of the metal part of the needle is inserted into the penis.
- Do not inject the medicine just under the surface of the skin, at the top or head of the penis, or at the base of the penis near the scrotum or testes. Avoid injecting the medicine into blood vessels that you can see.
- Press the plunger down slowly, taking 5 to 10 seconds to release the dose into the penis.
- The injection is usually not painful. If the injection is very painful or if you notice bruising or swelling at the place of
 injection, that means you are injecting the medicine under the skin. Stop, withdraw the needle, and reposition it
 properly before continuing with the injection.
- · Remove the needle and recap it.
- After you have completed the injection, put pressure on the place of injection for about 5 minutes or until any
 bleeding stops. This will prevent bruising. Then massage your penis as instructed by your doctor. This helps the
 medicine spread to all parts of the penis, so that the medicine will work better.

Choose a different place of injection each time you use the medicine to prevent skin problems. This includes switching the place of injection from the right side of the penis for one injection to the left side for the next injection.

After a single-use injection is mixed, the medicine must be used immediately. Throw away any unused mixture in the syringe. It cannot be stored for a later injection.

Do not reuse or share your needles or cartridges.

Never use a bent needle and never try to straighten a bent needle prior to injecting.

How to throw away the syringes and bottles safely:

Dispose of your materials properly. Caverject® comes in a plastic case that can be permanently locked with the red locking device that is included with the packaging. When the case label is removed, you can see a hole in the center of the case. The red locking device can be inserted and, by firmly pressing it down with your thumb, you will permanently lock the case. The locked case is safe to be thrown away.

This medicine usually begins to work in about 5 to 10 minutes. You should attempt intercourse within 10 to 30 minutes after using the medicine. An erection may continue after ejaculation.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

• For the treatment of erectile dysfunction:

- For injection dosage form:
 - Adults—1.25 to 60 micrograms (mcg) as a single dose once a day. Your exact dose will be determined by your doctor. Inject this medicine very slowly into your penis as shown to you by your doctor 10 to 30 minutes before intercourse. Allow 5 to 10 seconds to completely inject the dose. Do not inject more than one dose within 24 hours. Also, do not use this medicine for more than 2 days in a row or more than 3 times a week.

Storage

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store in the refrigerator. Do not freeze.

Alprostadil for Injection while in the powder form can be stored at room temperature (between 15 and 25 °C or 59 and 77 °F) for 3 months. After it is mixed, the solution must be used immediately or within 24 hours and not refrigerated or frozen.

Detailed Caverject dosage information

Precautions while using Caverject

Do not use alprostadil if you have a penile implant unless advised by doctor.

If too much of this medicine is used, the erection lasts too long and does not reverse when it should. This condition is called priapism. If the erection is not reversed, the blood supply to the penis may be cut off and permanent damage may occur.

Contact your doctor immediately if the erection lasts longer than 4 hours or if it becomes painful. This may be a sign of priapism and must be treated right away to prevent permanent damage.

If you notice bleeding at the place where you injected the medicine, put pressure on the spot until the bleeding stops. If it doesn't stop within 5 minutes, check with your doctor. If you have an infection that is spread through blood, this could increase the risk of giving the infection to your sexual partner.

This medicine does not prevent pregnancy. Use birth control if you do not want pregnancy to occur.

This medicine will not protect you or your partner from sexually transmitted diseases.

This medicine contains benzyl alcohol, which may cause serious reactions (eg, gasping syndrome) to newborn or premature babies. Discuss this with your doctor if you are concerned.

Side Effects of Caverject

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Rare

- · Curving of penis with pain during erection
- erection continuing for 4 to 6 hours
- erection continuing longer than 6 hours with severe and continuing pain of the penis
- · swelling in or pain of the testes

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Bleeding and pain at the injection site (short-term)
- · painful erection

Rare

• Bruising or clotted blood in the penis at the injection site, usually caused by an incorrect injection

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

<u>Caverject side effects</u> (more detail)

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Commonly used brand name(s)

In the U.S.

- Caverject
- Edex

Available Dosage Forms:

Powder for Solution

Therapeutic Class: Erectile Dysfunction Agent

Pharmacologic Class: Prostaglandin

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Patient resources

Other brands

Edex, Muse, Prostin VR Pediatric

Professional resources

- CaverJect prescribing information
- Alprostadil (Systemic, Local) (AHFS Monograph)

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Other formulations

• CaverJect Impulse

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Further information

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Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

& Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

The Drug history at FDA

User Reviews & Ratings

6.8 / 10

28 Reviews

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