

CAVERJECT(R) Impulse

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 Impulse.

This leaflet answers some common questions about CAVERJECT Impulse.

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 Impulse against the expected benefits it will have for you.

Use CAVERJECT Impulse 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 Impulse is used for

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

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

CAVERJECT Impulse 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 Impulse works by increasing the blood flow to your 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 Impulse 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 Impulse is available only with a doctor's prescription.

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

Before you use CAVERJECT Impulse

When you must not use CAVERJECT Impulse

Do not use CAVERJECT Impulse if you:

- * have an allergy to alprostadil, the active ingredient in CAVERJECT Impulse, 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 causes your erection to last for a long time (priapism)
- * have abnormal thickening of the tissues of your penis.

CAVERJECT Impulse is not for use in women, children or newborns.

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

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

Do not use CAVERJECT Impulse 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 Impulse

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 Impulse 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 Impulse 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 Impulse

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

How much to use

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

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

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 CAVERJECT Impulse

You must be properly instructed and trained in the injection technique by your doctor before using CAVERJECT Impulse. 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 Impulse injection please contact your doctor; this leaflet is only intended to remind you about the instructions that your doctor has already given you.

Note: Follow these instructions exactly to prepare and inject a sterile dose of CAVERJECT Impulse. If the needle is bent at any time, do not use it for injecting CAVERJECT Impulse and do not attempt to straighten it prior to injecting CAVERJECT Impulse. A bent and straightened 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 1 syringe, 1 needle and 2 alcohol swabs from your CAVERJECT Impulse pack.

3. Open one of the alcohol swab packets and use the swab to clean the rubber membrane at the tip of the syringe.
4. Remove the needle from its sterile packaging.
5. Attach the needle to the device by pressing the needle on to the tip of the device and turning clockwise until it is firmly in place. Pull off the outer protective cap of the needle.
6. Hold the device with the needle pointing upwards. The white plunger rod is now in the extended position.
7. Turn the plunger clockwise until it stops. This automatically mixes the alprostadil powder with the diluent. The solution may be cloudy at first and then it should be clear. Do not use if it remains cloudy or contains particles.
8. Hold the device with the needle uppermost. Carefully remove the inner protective cap from the needle. Do not touch the exposed needle.
9. Keeping the device upright, press the plunger rod as far as it will go. A few drops will appear at the needle point and the solution will be free from bubbles. There may be small microbubbles at the side of the glass cartridge.
10. Turn the end of the plunger rod slowly clockwise to choose the right dose. Your doctor or specialist will tell you what this should be. The number appearing in the window indicates the dose of the injection. If you make a mistake, continue to turn the plunger rod clockwise until you reach the correct dose.

If you do not wish to use CAVERJECT Impulse immediately, you can keep the reconstituted solution for up to 24 hours if refrigerated.

How to inject

CAVERJECT Impulse 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 Impulse injection.

DO NOT USE THE NEEDLE IF IT IS BENT

(refer to notes under the subheading "How to prepare CAVERJECT Impulse").

1. Perform the self-injection procedure whilst sitting in an upright, slightly reclining or standing position.
2. Inject only in the side of the penis (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 Impulse; 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 the second alcohol swab and let it dry.

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 Impulse 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 device 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 Impulse (overdose)

Remember to only use the amount of CAVERJECT Impulse that your doctor told you to use. If you use more CAVERJECT Impulse 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 Poison Information Centre (telephone 13 11 26) 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 Impulse.

While you are using CAVERJECT Impulse

Things you must do

Tell your doctor and pharmacist who are treating you that you are using CAVERJECT Impulse.

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

If your partner becomes pregnant while you are using CAVERJECT Impulse, 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) there is an increased chance of bleeding after injection.

An injection with CAVERJECT Impulse 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 your penis and may need to change your dose of CAVERJECT Impulse.

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

Things you must not do

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

Do not use CAVERJECT Impulse 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 for a second injection.

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

Side effects

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

Like many medicines, CAVERJECT Impulse 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 Impulse. 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 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 Impulse 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 Impulse is not causing abnormal thickening of the tissues of the penis. If this happens, your treatment with CAVERJECT Impulse 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 Impulse

Storage

Unused packs of CAVERJECT Impulse should be stored below 25 degrees C. Do not freeze or refrigerate.

After dissolving the CAVERJECT Impulse powder, the solution of CAVERJECT Impulse should be used as soon as possible. If storage is necessary, then store in the refrigerator at 2-8 degrees 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 degrees C. Therefore, do not store in checked luggage during air travel.

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

Do not store CAVERJECT Impulse in the bathroom or near a sink.

Do not keep outdated CAVERJECT Impulse.

Be sure that any discarded CAVERJECT Impulse is out of reach of children.

Keep CAVERJECT Impulse 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 Impulse, dispose of all injection material safely. Your doctor or pharmacist will advise you on how to dispose of the used syringes and needles.

Product description

(R) Registered trademark

(C) Pfizer Australia Pty Ltd 2003

What it looks like

CAVERJECT Impulse contains a dual chamber glass cartridge in a disposable syringe device. The front chamber of the glass cartridge contains a white to off-white powder and the rear chamber contains a clear liquid.

The disposable syringe device consists of a front sleeve and a finger grip/plunger assembly. The syringe device is designed to deliver a single dose only.

Ingredients

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

The other ingredients are:

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

The diluent in CAVERJECT Impulse contains water for injections and benzyl alcohol.

Supplier

CAVERJECT Impulse 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

CAVERJECT Impulse can be identified by the Australian Register number:

10 microgram AUST R 90196

20 microgram AUST R 90197

This leaflet was revised in October 2005.