CAVERJECT® IMPULSE

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CAVERJECT IMPULSE?

CAVERJECT IMPULSE contains the active ingredient alprostadil, also known as prostaglandin E1 (PGE1). CAVERJECT IMPULSE is used to treat erectile dysfunction. It may also be used to help in the diagnosis of erectile dysfunction.
For more information, see Section 1. Why am I using CAVERJECT IMPULSE? in the full CMI.

2. What should I know before I use CAVERJECT IMPULSE?

Do not use CAVERJECT IMPULSE if you have ever had an allergic reaction to alprostadil or any of the ingredients listed at the end of the CMI. Do not use CAVERJECT IMPULSE if you have a penis that is scarred or not straight, painful erections, a penile implant, certain illnesses, or abnormal thickening of the tissues of your penis.

Talk to your doctor if you have any other medical conditions, take any other medicines, or if your partner intends to become pregnant.

For more information, see Section 2. What should I know before I use CAVERJECT IMPULSE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAVERJECT IMPULSE and affect how it works.
For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use CAVERJECT IMPULSE?

- Your doctor will tell you how much CAVERJECT IMPULSE to use.
- You should use CAVERJECT IMPULSE no more than once in a 24-hour period and not more than 3 times a week.
- You must be properly instructed and trained in the injection technique by your doctor before using CAVERJECT IMPULSE.

More instructions can be found in Section 4. How do I use CAVERJECT IMPULSE? in the full CMI.

5. What should I know while using CAVERJECT IMPULSE?

Things you should do	• Tell any doctor or pharmacist you visit 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. • Tell your doctor if your erection lasts for more than one hour. • Visit your doctor regularly.
Things you should not do	• Do not use CAVERJECT IMPULSE to treat any other complaints unless your doctor or pharmacist tells you to. • Do not change the dose without first checking with your doctor. • Do not use any mixture left in the syringe for a second injection. • Do not use the needle if it is bent.
Driving or using machines	• Do not drive or use any machines or tools until you know how CAVERJECT IMPULSE affects you.
Looking after your medicine	• Store CAVERJECT IMPULSE in a cool dry place below 25°C. Do not freeze or refrigerate. • Use the solution of CAVERJECT IMPULSE as soon as possible after dissolving the powder. If the solution is not used right away, store it in the refrigerator at 2°C to 8°C for not more than 24 hours.

For more information see Section 5. What should I know while using CAVERJECT IMPULSE? in the full CMI.

6. Are there any side effects?

Like many medicines CAVERJECT IMPULSE may have side effects. Any side effects are likely to be minor and temporary. However, some may be serious and need medical attention. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CAVERJECT® IMPULSE

Active ingredient(s): *alprostadil*

Consumer Medicine Information (CMI)

This leaflet provides important information about CAVERJECT IMPULSE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CAVERJECT IMPULSE.**

Where to find information in this leaflet:

1. Why am I using CAVERJECT IMPULSE?
2. What should I know before I use CAVERJECT IMPULSE?
3. What if I am taking other medicines?
4. How do I use CAVERJECT IMPULSE?
5. What should I know while using CAVERJECT IMPULSE?
6. Are there any side effects?
7. Product details

1. Why am I using CAVERJECT IMPULSE?

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

CAVERJECT IMPULSE may be prescribed by your doctor to treat 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 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.

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

2. What should I know before I use CAVERJECT IMPULSE?

Warnings

Do not use CAVERJECT IMPULSE if you:

- are allergic to alprostadil, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if:

- you have any other medical conditions
- you take any medicines for any other conditions
- your partner intends to become pregnant.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor or your partner's obstetrician if your partner becomes pregnant while you are using CAVERJECT IMPULSE.

3. What if I am taking other medicines?

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

Tell your doctor if you are taking any medicines used to stop blood clotting (anticoagulants) such as heparin or warfarin.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CAVERJECT IMPULSE.

4. How do I use CAVERJECT IMPULSE?

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 the dose without first talking to your doctor.

How to prepare CAVERJECT IMPULSE

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

You must be properly instructed and trained in the injection technique by your doctor before using CAVERJECT IMPULSE.

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.

Follow these instructions carefully to prepare and inject a dose of CAVERJECT IMPULSE.

If the needle is bent at any time, DO NOT use it for injecting CAVERJECT IMPULSE. 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, remove it from the syringe, discard and attach a new, unused sterile needle to the syringe as described in point 4.

Before you start to prepare and inject CAVERJECT IMPULSE, wash your hands thoroughly with soap and water.

If your partner wishes to be included in preparing or giving the injection, they should also wash and dry their hands.

1. **Connecting the needle to the device.**

- Unpack 1 syringe, 1 needle and 2 alcohol swabs from your CAVERJECT IMPULSE pack.
- Open one of the alcohol swab packets and use the swab to clean the rubber membrane at the tip of the syringe.
- Remove the needle from its sterile packaging.
- Hold the syringe with the needle-end pointing upwards.
- 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.

2. **Removing the outer needle cap**

- Pull off the outer protective cap of the needle.
- Hold the device with the needle pointing upwards.
- The plunger rod is now in the extended position.

3. **Mixing the powder and the liquid in the device**

- Hold the device with the needle pointing upwards, gripping the blue chamber with one hand.
- Turn the plunger clockwise until it will not turn any further (fully wound). This automatically mixes the alprostadil powder with the diluent.
- The reconstituted solution will now appear in the clear chamber.
- The solution may be cloudy at first. Gently shake to make sure the solution is evenly mixed and the powder has dissolved. The solution should be clear. Do not use if it remains cloudy or contains particles.

4. **Removing the inner needle cap**

- Hold the device with the needle pointing upwards.
- Carefully remove the inner protective cap from the needle.

Do not touch the exposed needle.

The needle is very fine. Take care not to bump it.

Do not use if the needle is bent.

5. **Removing air from the device**

- Remove any large bubbles by gently tapping the clear chamber with your finger.
- Ensure the plunger rod is fully wound.
- Hold the device in one hand with the needle pointing upwards.
- Remove air from the clear chamber by pressing 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.

6. **Dialling your dose**

- Hold the device in one hand.
- Grip the blue chamber with the dose window facing you (needle tip to the left).
- Turn the plunger rod slowly clockwise to choose the right dose. Your doctor 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.

7. **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.

- Perform the self-injection procedure whilst sitting in an upright, slightly reclining or standing position.

- 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.

- 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.

8. **Preparing the injection site**

- Open the second alcohol swab packet.
- 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.
- Clean the injection area with the second alcohol swab and let it dry.

9. **Inserting the needle**

- Keeping a firm grip on your penis, take the syringe in your free hand. The needle should be inserted at a 90 degree angle. With a steady, continuous motion, insert the entire length of the needle straight into the injection site.
- Push the plunger firmly with your thumb. This may require some pressure.
- 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.
- **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.
- 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 (overdose)

If you think that you have used too much CAVERJECT IMPULSE you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Always take the outer carton of the medicine with you.

5. What should I know while using CAVERJECT IMPULSE?

Things you should do

Remember to use only 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.

Contact your doctor straight away if your erection lasts for more than four (4) hours. This can be painful and may require medical treatment.

Remind any doctor, dentist or pharmacist you visit that you are using CAVERJECT IMPULSE.

An injection with CAVERJECT IMPULSE should produce an erection that lasts for 30 minutes to 1 hour and enables you to have sex.

Tell your doctor as soon as possible if your erection lasts for more than 1 hour. Your dose may need to be reduced.

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

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 or stop your treatment with CAVERJECT IMPULSE.

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

Things to be mindful of

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.

Things you should 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 the dose without first checking with your doctor.
- 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")

Driving or using machines

Do not drive or use any machines or tools until you know how CAVERJECT IMPULSE affects you.

Looking after your medicine

Store your CAVERJECT IMPULSE in a cool dry place where the temperature stays below 25℃. Do not freeze or refrigerate; do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep CAVERJECT IMPULSE where children cannot reach it.

During travel, care should be taken to avoid allowing the product to be stored at temperatures above 25℃ or below 2-8℃. Do not store CAVERJECT IMPULSE in checked luggage during air travel.

After dissolving the CAVERJECT IMPULSE powder, use the solution of CAVERJECT IMPULSE as soon as possible. If storage is necessary, then store in the refrigerator at 2-8℃ for not more than 24 hours. Do not freeze the dissolved solution.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

When to discard your medicine

Do not keep unused solution of CAVERJECT IMPULSE.

After injecting CAVERJECT IMPULSE, immediately throw away the used medicine in a special 'sharps' container as instructed by your doctor, nurse or pharmacist.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date or damaged, take it to any pharmacy for safe 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Eye disorders: • dilated pupils **Gastrointestinal disorders:** • nausea • dry mouth **General disorders and administration site conditions:** • bruising, redness, swelling, bleeding or itching at the site of injection • localized pain (buttocks, leg, genital, back or pelvis) **Infections:** • yeast infection **Muscle or bone related issues:** • leg cramps **Renal and urinary related issues:** • 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). **Nervous system disorders:** • numbness • dizziness • headache • fainting • increased sweating **Reproductive system related issues:** • pain in the penis during erection • 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 • abnormal ejaculation or painful erection • swelling, redness, pain of the scrotum • disorder of the testis (pain, warmth, swelling, thickening) **Skin related issues:** • skin rash, redness, irritation, itchiness • increased feeling of pain or sensitivity	**Speak to your doctor if you have any of these side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• changes in your heartbeat or palpitations • changes in blood pressure • prolonged erection (lasting 4 to 6 hours).	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you**

Serious side effects	What to do
	notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

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

What CAVERJECT IMPULSE contains

Active ingredient (main ingredient)	alprostadil
Other ingredients (inactive ingredients)	alfadex, lactose monohydrate, sodium citrate dihydrate, hydrochloric acid and sodium hydroxide. The diluent contains water for injections and benzyl alcohol.

Do not use this medicine if you are allergic to any of these ingredients.

What CAVERJECT IMPULSE looks like

CAVERJECT IMPULSE is supplied in a disposable syringe device containing a dual chamber glass cartridge. 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 has a front sleeve and a finger grip/plunger assembly. It is designed to deliver a single dose only.

CAVERJECT IMPULSE 10 microgram - AUST R 90196

CAVERJECT IMPULSE 20 microgram - AUST R 90197

Who distributes CAVERJECT IMPULSE

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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