Package leaflet: Information for the patient

Alprostadil 10 or 20 micrograms powder for solution for injection
alprostadil

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor, pharmacist or nurse.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet
1. What Alprostadil is and what it is used for
2. What you need to know before you use Alprostadil
3. How to use Alprostadil
4. Possible side effects
5. How to store Alprostadil
6. Contents of the pack and other information

1. What Alprostadil is and what it is used for

This medicine contains alprostadil which is similar to the natural substance in your body called prostaglandin E1. It widens blood vessels so that blood can flow in your penis more easily. This makes it easier for you to have an erection.

Alprostadil is used for "erectile dysfunction" including weak erections or impotence. Your doctor may also use it to help find the exact cause of your erectile dysfunction along with other tests.

Alprostadil is not licenced for use in children and **must not be given to children**.

2. What you need to know before you use Alprostadil

Do not use Alprostadil:
- If you are allergic to alprostadil or any of the other ingredients of this medicine (listed in section 6).
- If you have sickle cell anaemia (a blood disease), leukaemia (cancer of the blood), multiple myeloma (bone cancer) or any other problem which increases the risk of getting "priapism". This is a painful condition when your penis continues to remain erect.
- If you have an implant in your penis.
- If you have a condition (such as severe heart disease) in which sexual activity should be avoided.
- If you have a penis which is scarred or not straight.
- If you have a tight foreskin.

Alprostadil must not be given to children (see section 2 Alprostadil contains benzyl alcohol and sodium).

Do not use any Alprostadil until your doctor says that it is right for you.

Warnings and precautions
Talk to your doctor, pharmacist or nurse **before** using Alprostadil if you:

- have a lung, chest or heart disorder (in these cases you also should engage in sexual activity with caution)
- have a history of mental illness or addiction
- have had a mini-stroke (transient ischaemic attack)
- have one or more cardiovascular risk factors (these might include high blood pressure, tobacco use, raised blood glucose, raised blood cholesterol, overweight and obesity)
- have one or more risk factors for stroke (these might include high blood pressure, raised blood cholesterol, coronary artery disease, heart arrhythmia, diabetes)

Sexually transmitted diseases
Alprostadil will not protect you or your partner from sexually transmitted diseases like AIDS, herpes and gonorrhoea. Injection of Alprostadil can start a small amount of bleeding where the needle enters. This could increase the risk of transmission of such diseases. Condoms can protect against sexually transmitted diseases. If you need advice about contraception or 'safe sex' speak to your doctor or contact your local Family Planning Clinic.

Other medicines and Alprostadil
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, and any of the following medicines **before** you start using Alprostadil:
- medicines used for treating high blood pressure (antihypertensives)
- medicines used for respiratory and heart disease (sympathomimetics)
- medicines that widen blood vessels (vasodilative agents)
- other medicines for erectile dysfunction such as sildenafil or papaverine
- medicines to thin your blood such as warfarin or heparin, as you might bleed more when you do the injection.

Pregnancy and breast-feeding
Alprostadil can be used by couples wishing to conceive and with a partner who is pregnant or breast-feeding. It will not protect your partner from pregnancy, so you should use a reliable contraceptive if appropriate.

Driving and using machines
Alprostadil should not affect your ability to drive or use machines.

Alprostadil contains benzyl alcohol and sodium
This medicine contains benzyl alcohol 8.4 mg/ml. Benzyl alcohol may cause allergic reactions.

Using large amounts of Alprostadil may cause a build-up of benzyl alcohol in your body resulting in an increased amount of acid in your blood (called metabolic acidosis). Patients with liver or kidney disease need to be especially cautious and discuss with their doctor.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Alprostadil is not for use in children.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Alprostadil

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
A doctor or nurse will show you how to do the injection for **at least** the first time. Do not try to do it yourself until you have learnt the correct way or if you can't remember what to do, see your trainer again. These instructions are a reminder only. Keep the antiseptic swab away from the eyes.

How much Alprostadil should you inject?
Different people need different amounts of Alprostadil to treat erectile dysfunction. Your doctor will advise on the right dose for you and monitor you regularly to check how it is working. The starting dose is 1.25 - 2.5 micrograms.

Most men find that a dose of 5 - 20 micrograms is right for them, however, some men may require a higher dose. To minimise the risk of prolonged painful erection, your doctor will select the lowest effective dose. **You should never use more than 60 micrograms.** If Alprostadil is being used to find the reason for your erectile dysfunction, the dose will be 5 - 20 micrograms.

If the dose that has been prescribed for you does not work well enough, tell your doctor. Do not change your dose unless your doctor tells you to. If you forget how much to use, read the label on the pack or speak to your doctor.

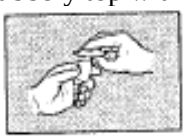
You and your partner
You may like your partner to be involved in preparing and/or giving the injection. If so, you should speak to your doctor about training for your partner. Wash your hands. Dry them on a clean towel. If your partner wishes to be involved in preparing or giving the injection, they should wash their hands too.

1. Check your pack
Make sure that the vial is the correct strength and the expiry date is still valid. The vial, syringe and needles all have protective covers. The flip-off cap on the vial can rotate; this is normal. Check that all the covers are on firmly and if they are not on properly, do not use them – take the whole pack back to your pharmacist. There are two needles in the pack:

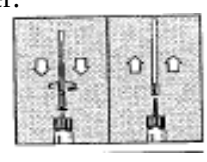
- The larger 22 gauge needle with the grey end is used to mix the solution and Alprostadil Powder.
- The smaller and finer 30 gauge needle with the yellow end is used to inject the mixture into your penis.

If a needle is bent do not use it.

2. To prepare the vial
Flip the plastic cap off the vial. Wipe the rubbery top with one of the wet antiseptic pads.



3. Fitting the needle to the syringe
Hold the syringe and twist the white tamper evident cap to break the seal. Take the foil off the larger needle, (22 gauge) with the grey end, keeping the cover on. Join the needle to the syringe by turning the needle clockwise tightly onto the syringe, then remove the needle cover by pushing it away from the syringe with your thumb and forefinger.



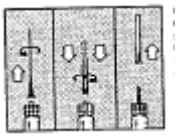
4. Mixing the solution with the powder
Push the needle through the rubbery middle of the vial top. Press the plunger down firmly to squirt all the solution onto the powder. Gently swirl the vial until all the powder has dissolved. If the mixture is cloudy or does not dissolve completely, do not use it. Never use tap water or any liquid other than the one supplied in the syringe.

5. Filling the syringe

With the needle still inserted, turn the vial upside down. The needle should support the vial unaided. Make sure the needle tip is underneath the level of the liquid. Gently pull the plunger to draw all the mixture into the syringe. Pull the needle out of the vial.

6. Changing to the injecting needle

Gently twist the larger needle anticlockwise off the syringe. Remove the smaller injecting needle, (30 gauge) with the yellow end 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.

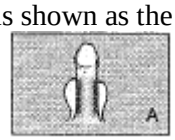


7. Setting the dose

Tap the syringe gently to send any air bubbles to the top, then push the plunger to squeeze the air bubbles out, ensuring that at least one drop of solution comes out of the needle. Continue pushing until the plunger is exactly at the right mark for your dose. Your doctor will have shown you where this is.

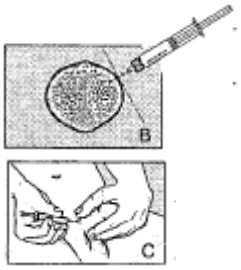
How do you do the injection?

- Get undressed and make yourself comfortable. Take some time to relax yourself and your partner. If your prescriber has recommended use of the second antiseptic pad, open it now.
- Make sure that the injection needle is **not** bent. A bent and re-straightened needle is 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, **do not** use it and throw it away. **Do not** attempt to straighten it out. Attach a new, unused sterile needle to the syringe.
- Take hold of the penis from the front, with the first two fingers underneath close to the testicles and the thumb on top. Gently squeeze the penis between your thumb and finger so that the injection site bulges out. If there is a foreskin on the penis, make sure it is stretched. The injection will go into the part of the penis shown as the shaded area in diagram A.



- If recommended by your prescriber wipe the skin over this area with the second pad and let it dry.
- Keeping a firm grip on the penis and taking the syringe in your free hand, push the needle straight through the skin all the way into the bulgy part avoiding veins or other obvious blood vessels. The angle is shown in diagrams B and C. Push the plunger firmly and if the

Alprostadil does not come out fairly easily, move the needle slightly and try again. **Do not** force the Alprostadil liquid from the syringe.



- Pull the needle out. On the needle mark, press gently with the pad or your thumb, as recommended by your prescriber. Massage the penis to help the Alprostadil spread through it.
- Do not keep any mixture in the syringe to use for a second injection.

How to throw away the syringe and needle safely
Ensure that the syringe, vial and needles are disposed of in a closed, puncture-resistant container such as a sharps bin. Ask your doctor or pharmacist for instructions on how to properly dispose of the container after use if you are at all unsure.

How often can you use Alprostadil?
Do not use Alprostadil more than once in 24 hours or more than three times in a week. Change the exact place and side of the penis that you inject Alprostadil each time you use it.

Your erection after injecting Alprostadil
It will take a little while for your erection to come on after the injection. With the right dose of Alprostadil, your erection should be strong enough for you and your partner to enjoy lovemaking. Usually, your erection should not last longer than an hour. If you would like it to last longer, talk to your doctor**. If your erection lasts longer than four hours you should seek medical advice** (see section 4 **Possible side effects** below).

What if you use too much Alprostadil
Tell your doctor straight away as you may need treatment, particularly if you experience an erection that lasts for longer than four hours.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if your erection goes on for longer than 4 hours. If you cannot contact your doctor, go to a hospital casualty department **immediately** as treatment should be started within 6 hours.

Very common: may affect more than 1 in 10 people

- Pain in the penis

Common: may affect up to 1 in 10 people

- Penis can become bruised, scarred, bent or kinked, particularly after long term use. **Tell your doctor** if this happens as you may need to stop Alprostadil.
- Prolonged erections
- Other problems with your penis

- Swelling and skin discolouration or bruising at site of injection. You may find this happening the first time you use Alprostadil but should occur less often with practice
- Muscle spasms.

Uncommon: may affect up to 1 in 100 people

- The area injected becomes irritated, inflamed or swollen and may itch or bleed, or feel numb, warm, tender or painful
- The testes or scrotum could become red, swollen or painful, or develop lumps called spermatocele, which are cysts containing sperm. The penis could feel numb
- You may get uncomfortable, painful or prolonged erections or none at all, your ejaculation may change or your foreskin could feel tight or swollen, as well as the head of your penis
- The desire to pass urine more urgently or frequently than normal or you may have pain or difficulty in urinating. Some blood may appear in the urine or at the end of the penis especially if Alprostadil is injected by mistake into the tube which carries urine out through the penis (urethra)
- Pelvic pain, weakness, sweating, feeling sick or swollen legs or arms, having a common cold or dry mouth. You may get a yeast infection (thrush)
- Changes in blood pressure and heart rhythm, faintness, shallow breathing and collapse could occur because of the injection itself
- Skin itching, redness of the skin at site of injection, rash or skin growth, increased sweating, eye sensitivity to bright light or excessive dilation of the pupil (blown pupil), impaired or enhanced sense of touch, leg cramps, cold hands and feet, venous problems including bleeding (bleeding from vein(s))
- If you have a blood test you may have raised levels of creatinine (a substance found in your muscles).

Not known
(frequency cannot be estimated from available data)

- Insufficient blood flow to the heart muscle via the coronary arteries
- Stroke.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alprostadil

- Keep the syringe and needles out of the sight and reach of children.
- Store below 25°C.
- When you have mixed the Alprostadil Powder with the solution, use it straight away. Do not keep it to use later on.
- For single use only. Any unused Alprostadil should be discarded.
- Do not use Alprostadil if the injection is cloudy or contains particles.
- Do not use this medicine after the expiry date on the pack after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alprostadil contains
The active ingredient in this medicine is alprostadil. Each vial contains 10 or 20 micrograms of alprostadil.

The other ingredients are lactose monohydrate, sodium citrate, α-cyclodextrine, hydrochloric acid and sodium hydroxide.

The syringe contains benzyl alcohol (8.4 mg/ml) and water for injections. See section 2 **Alprostadil contains benzyl alcohol and sodium**. The antiseptic pads are soaked in isopropyl alcohol.

What Alprostadil looks like and contents of the pack

In the Alprostadil box you will find 5 items:

1 One glass vial containing Alprostadil 10 or 20 micrograms as a white to off-white powder
2 One glass syringe containing 1mL of a clear solution
3 One larger 22 gauge needle - 1½ inches long with a grey plastic end
4 One small 30 gauge needle - 0.5 inch long with a yellow plastic end
5 Two antiseptic pads

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