

Package leaflet: Information for the patient
viridal duo® 10/20/40 micrograms/ml powder and solvent 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Viridal Duo is and what it is used for

Viridal Duo contains the active substance alprostadil which belongs to a group of drugs used to treat erectile dysfunction. This medicine works by widening blood vessels and increasing blood flow to your penis.

Viridal Duo is used in adult males:

- to help you get and maintain an erection
- by your doctor to test whether you suffer from impotence.

Viridal Duo comes in a glass cartridge with two chambers.

One chamber contains alprostadil, the other contains sodium chloride solution. These are mixed together to make a solution that is injected into the penis.

2. What you need to know before you use Viridal Duo

Do not use Viridal Duo:

- if you are allergic to alprostadil or any of the other ingredients of this medicine (listed in section 6).
- if you have a deformity or disease of your penis
- if you have sickle-cell disease (abnormal red blood cells)
- if you have leukaemia (cancer of blood cells)
- if you have multiple myeloma (tumour of the bone marrow)
- if you have an implant in your penis
- if you have been told not to have sex for health reasons such as heart problems or a recent stroke
- if you have Peyronie's disease or any scarring or deformity of the penis or foreskin.

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Viridal Duo

- if you have one or more cardiovascular risk factors (these might include high blood pressure, tobacco use, raised blood glucose, raised blood cholesterol, overweight and obesity)
- if you have or have ever had any heart problems
- if you have or have ever experienced fainting and blackouts
- if you have had short-term changes to your speech, hearing or vision
- if you suffer from lung problems
- if you have one or more risk factors for stroke (these might include high blood pressure, raised blood cholesterol, coronary artery disease, heart arrhythmia, diabetes)
- if you suffer from blood clotting disease
- if you have or have ever had stomach bleeding or bleeding from the intestines.

You may need to have further tests before your doctor can give you this treatment (for example, a stress resistance test and tests to check for other treatable underlying causes of impotence).

Erection lasting over four hours can be dangerous therefore you should report immediately to your doctor, or, if unavailable, seek immediate medical assistance for any erection that persists for longer than four hours.

Viridal Duo will not protect you or your partner from sexually transmitted diseases like chlamydia, gonorrhoea, herpes simplex virus, viral hepatitis, HIV, genital warts or syphilis.

As you may get a small amount of bleeding at the injection site, it is especially important that you use a condom to avoid sexually transmitted diseases.

Viridal Duo should not be used by patients with drug addiction, mental illness or intellectual disability.

You may need to have regular follow up examinations by your doctor to check for the formation of scar tissue on the penis.

Other medicines and Viridal Duo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines:

- Drugs to treat depression known as MAOIs such as phenelzine. When taken with Viridal Duo, these can cause very high blood pressure
- Other drugs injected into the penis for the treatment of erection difficulties such as papaverine or phentolamine. Taking Viridal Duo as well could cause a dangerously prolonged erection
- Any other medicines used to treat erection difficulties including sildenafil. When used in combination with Viridal Duo, they could induce prolonged erection
- Medicines to thin your blood such as warfarin. These can cause bleeding at the site of injection of Viridal Duo

- Drugs to lower your blood pressure and change the diameter of your blood vessels. Viridal Duo may increase their effects and cause very low blood pressure.
- Any other medicine, including medicines obtained without a prescription.
- Other medicines to treat blood clotting as you may need special attention.

Pregnancy, breast-feeding and fertility

You should wear a condom if your partner is, may be or could become pregnant. This is to avoid causing irritation of her vagina or possibly damaging the unborn baby.

If you have any questions on this or if your partner is breast-feeding, please ask your doctor or pharmacist for advice.

Viridal Duo does not interfere with ejaculation and fertility.

Driving and using machines

If you feel dizzy or faint after using Viridal Duo you should not drive or use machinery or tools.

3. How to use Viridal Duo

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Important:

Before you use Viridal Duo at home, you must be taught how to prepare and inject it by your doctor. **You should never start treatment without talking to your doctor first.**

Remember: If you find it difficult to use your hands properly or if you cannot see very well your partner can be taught how to give you the injection.

Discuss this with your doctor if necessary.

How much Viridal Duo to use

To test for impotence and to find out the dose of Viridal Duo you need:

For erectile dysfunction of primary neurological origin

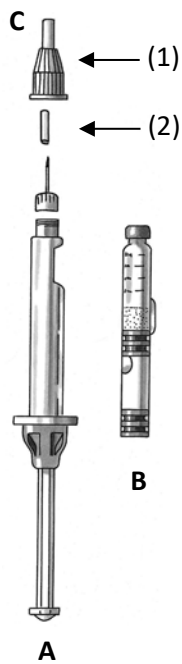
- Your doctor will give you a starting dose of 2.5 or 5 micrograms. However, if your impotence is due to neurological problems, your doctor will give you a starting dose of 1.25 micrograms.
- Your doctor will then increase your dose by 2.5 or 5 micrograms at a time
- Your correct dose is the one which produces an erection which lasts for no longer than 1 hour.

For an erection:

- Most men need between 10 and 20 micrograms for each injection
- Do not use more than 40 micrograms in one injection.
- Do not use more than 2 or 3 times a week with at least 24 hours between the injections.

How to inject Viridal Duo

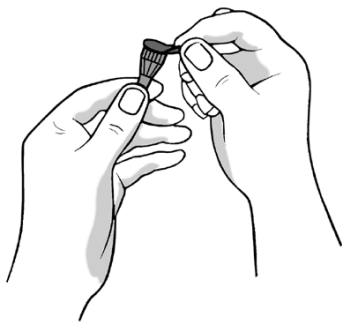
Fig 1:



For each injection you will need:

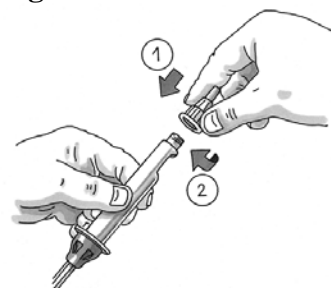
- a) Easy-Duo[®] reusable. If you have used Viridal Duo before you should already have an injector. You may also obtain one by calling the free phone number given at the end of the leaflet
- b) One cartridge, which is made up of two chambers.
There will be 10, 20 or 40 micrograms of alprostadil (white powder) in the top chamber, and 1 ml of sterile saline (colourless liquid) in the bottom chamber
- c) One injection needle with outer protective cap (1) and inner protective cap (2)

Fig 2:



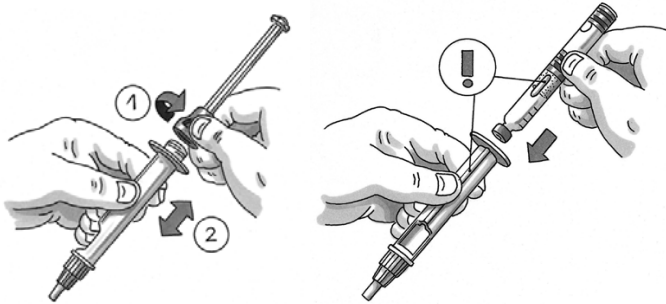
Check that the **seal** on the injection needle is **not broken**. Tear off the seal.

Fig 3:



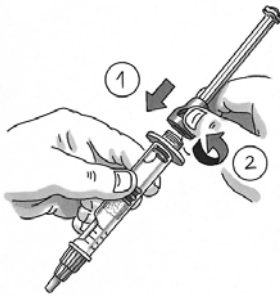
Put the needle on the end of the injector by screwing it clockwise until it is **tight**. **Always** screw on the injection needle **before** inserting the cartridge.

Fig 4:



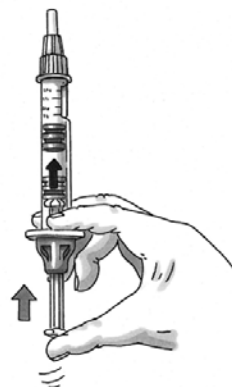
Unscrew the plunger from the injector. Take the cartridge and clean the tip with alcohol swab. Insert the cartridge into the transparent body of the injector. Take care to advance the bulge into the groove of the injector

Fig 5:



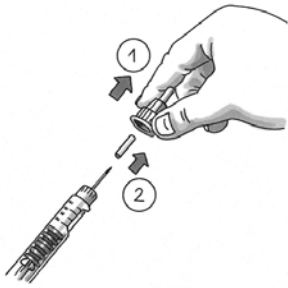
Screw the plunger onto the back thread of the injector body.

Fig 6:



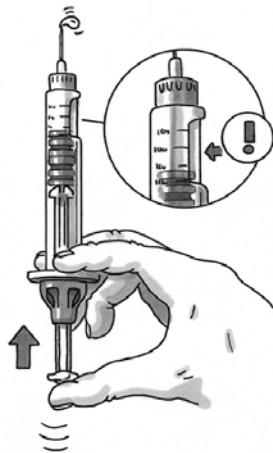
Hold the injector with the needle pointing up. Push the plunger forward until the two grey stoppers of the cartridge meet. You will see that the liquid passes into the front chamber and the powder dissolves within a few seconds. Shake the injector gently until no bits can be seen. At first the solution may appear slightly cloudy because of the bubbles, but this will clear after a short time.

Fig 7:



Remove the outer and inner protective caps of the needle. **Warning: do not touch anything with the tip of the needle** so that it stays clean and sterile (free from germs).

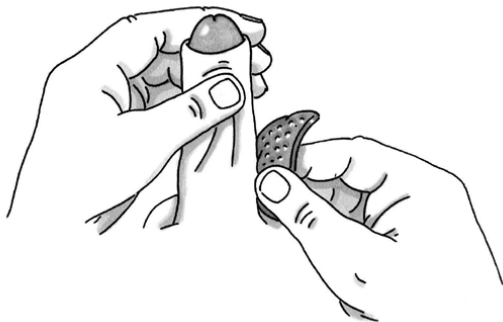
Fig 8:



While you hold the injector with the needle pointing up, tap against the injector vigorously until all bubbles have moved upward. Cautiously advance the plunger until one drop of the solution leaves the needle. Make sure that all air was removed from the cartridge.

Set the dose your doctor prescribed you. To do so, move the plunger of the injector slowly upward until the upper edge of the front grey stopper has reached the prescribed dose.

Fig 9:

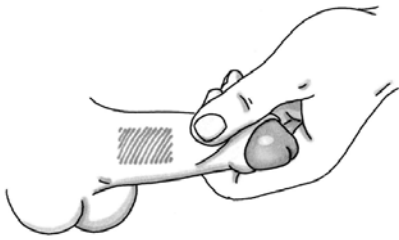


Make sure that your penis has been cleaned thoroughly.

Clean the injection site with an alcohol swab. Draw the penis slightly away from your body until the intended injection site has dried.

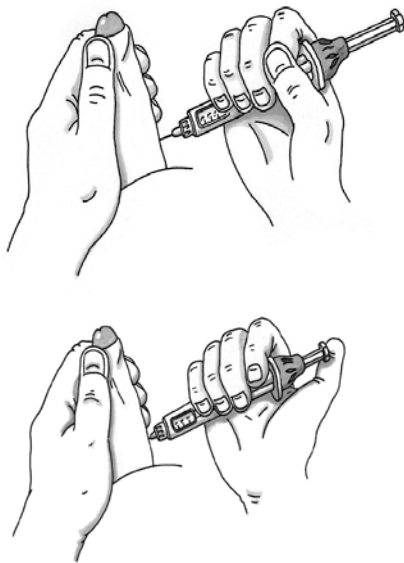
Take the injector and make sure that the grey stopper is at the prescribed dose and that no air bubbles are in the cartridge.

Fig 10:



The injection site must be within the area shown in figure 10.

Fig 11:



Hold the injector in your fingers as shown. Always **hold it level** with the penis and insert the needle **almost completely straight**, into the penis. The place where you inject should be within the area shown on the picture. Use a **different side** of the penis than you used the last time.

Pushing your thumb gently on the plunger, **inject** the solution slowly over a period of **5 to 10 seconds**.

Fig 12:



After injection, remove the injector and needle from your penis and put it down. If **bleeding**

occurs, **apply pressure** to the injection site with a clean pad for 3 minutes to stop the bleeding. If it continues to occur, carry on **applying pressure until it stops**.

It will take between 5–15 minutes for your erection to develop. Your erection should last for about one hour. If it lasts for between 2-4 hours, discuss this with your doctor. If it lasts for **longer than 4 hours, contact your doctor immediately**.

Disposing of the used pack:

- Cut the needle with a needle cutter (available from your doctor, pharmacist or the Marketing Authorisation holder)
- Unscrew the needle base and put it into a container for needles (called a sharps bin) (also available from your doctor or pharmacist)
- Remove the cartridge by unscrewing the plunger from the injector body and sliding out the cartridge.
- Wash the Easy-Duo® injector with warm water and a mild detergent. Once dry, store it in original carton for your next injection.
- **Do not throw the injector away.** Not all packs contain injectors so you will need to use this again for your next injection. However, do not use a damaged injector. Replacements are available from the company.
- Place the cartridge in a plastic bag and tie it carefully. This can be thrown away with normal household rubbish.
- **It is important to discard any unused medicine.** The mixture of Viridal Duo you have made is intended for single use only and any unused contents should be disposed of with the cartridge

Medical check-ups

After the first time you use this medicine and then again every 3 months or so, your doctor will ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

If you use more Viridal Duo than you should

Immediately contact the nearest hospital casualty department or your doctor. Using too much Viridal Duo can increase your risk of scarring to the penis and can cause your erection to last too long which may require treatment by a specialist doctor to reverse the effects.

4. Possible side effects

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

Seek immediate medical help if you have any of the following symptoms:

- **An erection that lasts for more than 4 hours**
- **Serious allergic reactions which causes difficulty in breathing or dizziness**
- **Skin reactions such as rashes and blistering.**

Very common: may affect more than 1 in 10 people

- Pain in the penis

Common: may affect up to 1 in 10 people

- Burning sensation during injection which quickly gets better

- Pain at the site of injection
- Lumps at the site of injection or in your penis after long-term use.
- Spot-like bruising (blood spots under the skin) at the site of injection
- Fluttering or vibrating feeling sensation due to uncontrollable muscle movement
- Erections might occur more often and longer in duration
- Bend or kink in the penis, especially after long-term use

Uncommon: may affect up to 1 in 100 people

- Reddening, itching, swelling, blistering, numbness, tenderness or a feeling of warmth at the site of injection
- Bleeding at the site of injection
- Headache
- Priapism (prolonged erection of more than 4 hours)
- Fungal infection
- Common cold
- Reduced sense of touch or sensation
- Heightened sense of touch or sensation
- Dilation of the pupils
- Changes to heart rhythm or increased heart rate
- Low blood pressure
- Raised creatinine
- Decreased or altered blood flow to the arms or legs
- Feeling sick
- Dry mouth
- Skin rash
- Excessive sweating
- Pain when urinating, urinating more frequently or a sudden need to urinate
- Bleeding in the urethra, which can cause there to be blood in your urine
- A general increase in iron stores in the body
- Problems attaining or maintaining an erection
- Problems with ejaculation
- Painful or swollen testicles
- Lumps on the testicles
- Pain in the pelvis
- Pain, swelling or reddening of the scrotum
- Pain, swelling or reddening at the tip of the penis

Rare: may affect up to 1 in 1,000 people

- Serious allergic reactions which causes difficulty in breathing or dizziness
- Skin reactions such as rashes and blistering
- Drop in blood pressure, which may cause dizziness or fainting
- Scarring of the inside of the penis after long-term use.
- Rare nervous system disorders like vertigo (disorientation with spinning sensation), dizziness

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Very rare: may affect up to 1 in 10,000 people

- Isolated cases of thrombocytopenia (abnormal drop in the number of platelets)

Not known: frequency cannot be estimated from the available data

- Loss of memory
- Stroke
- Insufficient blood flow to the heart muscle via the coronary arteries, often resulting in chest pain (angina pectoris); heart attack
- Bleeding of the stomach and intestines

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: 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 Viridal Duo

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package in order to protect from light.
- Do not use this medicine if you notice some moisture in the powder.
- When you have mixed the powder with the liquid in the injector, use immediately. This cannot be stored.
- 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 Viridal Duo contains

The active substance is alprostadil. There are three strengths of Viridal Duo that contain the active substance alprostadil 10, 20 or 40 micrograms.

The other ingredients of the powder are lactose monohydrate and alfadex.

The liquid contains sodium chloride and water for injection.

What Viridal Duo looks like and contents of the pack

Viridal Duo is a powder and solvent for solution for injection. Viridal Duo comes in a glass cartridge with two chambers. One chamber contains a white powder with the active ingredient alprostadil. The other contains a clear, colourless solution of sodium chloride solution. This is used to dissolve the powder.

There are various packs containing:

- 1 cartridge, 1 needle with and without injector
- 2 cartridges, 2 needles with and without injector
- 6 cartridges and 6 needles without injector.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

UCB Pharma Limited
208 Bath Road
Slough, Berkshire
SL1 3WE
United Kingdom

Manufacturer

Aesica Pharmaceuticals GmbH
Alfred-Nobel-Strasse 10
D-40789 Monheim
Germany

This leaflet was last revised in May 2019.

If this leaflet is difficult to see or read or you would like it in a different format, please contact:

UCB Pharma Limited
208 Bath Road
Slough, Berkshire
SL1 3WE, UK

Telephone Advice Line

Further information is available by telephone from:

- **Viridal Duo Patent Helpline freephone 0800 731 698 (UK only)**

This is a fully automated, free service for ordering replacement injectors and needles cutters. Advice and replacement injectors can also be ordered by writing to:

- **FREEPOST RLSG-HARX-BGGA**
UCB Pharma Limited
208 Bath Road
Slough
Berkshire
SL1 3WE
UK