

Package leaflet: Information for users

viridal® 20 µg

powder and solvent for preparation of an injection solution

For use in adults

Active ingredient: Alprostadil

Read the the entire package leaflet carefully through, before you with the use this medicinal product start, because it contains important information.

Keep You the package leaflet on. Perhaps you would like you this later again read.

If you further questions have, contact you yourself to your doctor or pharmacist.

This medication was prescribed to you personally. Do not give it to others .It can other people harm, even if they have the same symptoms as you ..

you notice side effects, contact your doctor . to your doctor or pharmacist. This also applies to side effects that are not listed inthis package leaflet indicated are .. section 4. 4.

this package leaflet Package leaflet stands

1. What is viridal and what for is it used?
2. What should you before the application of viridal consider?
3. How is viridal to use?
4. What side effects are possible?
5. How is viridal to store?
6. Contents of the package and further Information

1. What is viridal and what is it usedfor?

viridal is a medicationthat contains the active ingredient Alprostadil contains. Alprostadil is a endogenous substance, which occurs in high concentrations in the human semen fluid.

viridal is used for:

treatment of erectile dysfunction ((erectile dysfunction), also commonly impotence or. lack of penile rigidity called, in adults due to various (neurogenic, vascular, psychogenic or mixed) causes.

as aid in the diagnostics for clarification of an erectile dysfunction.

Furthermore serves the medication Medication for inducing of erections, which are prerequisites for further diagnostic procedures , e.g. Doppler-ultrasound(duplex sonography),corporal measurement (dynamic cavernosometry),), if these not on natural way achieved can be.

2. What should you before the use of viridal consider?

viridal must not be used if

you are allergic to Alprostadil or any of the ingredients listed in 6. 6. other components of this medication are.

in patients with penile implant.

in patients, in whom sexual activity inadvisable or contraindicated is (e.g. patients, who suffer from severe heart diseases suffer).

in patients with anatomical deformations of the penis, such as penile curvature (angulation), scarring of the corpora cavernosa (fibrosis), induratio penis plastica (Peyronie's disease, IPP) or a narrowing of the foreskin (phimosis).

if you suffer from a disease that is associated with prolonged erection or painful persistent erection accompany, such as multiple myeloma, sickle cell anemia or those genetic predisposition, thalassemia, leukemia.

There are no clinical experiences in patients under 18 or over 80 years of age.

Warnings and precautions

Please consult your with your doctor or pharmacist, before you viridal use.

Underlying treatable medical causes of erectile dysfunction should before the Treatment with viridal diagnosed and treated will be. viridal is not for the simultaneous application with other medications for treatment of the erectile dysfunction intended.

If in you a cardiovascular disease, such as coronary heart disease, heart defect, heart failure, or short-term severe Circulatory disorders of the brain (transient ischemic attacks) or lung diseases detected were, can sexual stimulation and sexual intercourse cardiovascular system- or breathing difficulties trigger. In these cases it is before starting treatment a thorough examination by an internist to recommend.

viridal is in patients with transient ischemic attacks in the history, with unstable cardiovascular-disease and in patients with risk factors for a stroke like hypertension with utmost caution and only under careful benefit-risk assessment to be used.

Please adhere to exactly to the the by the doctor recommended dosage or frequency of application (see section Dosage Instructions: for treatment at home), as otherwise the risk of a Corporal fibrosis increased his can.

Prolonged erections and/or painful persistent erections (erections, that last six hours or more) can after an intracavernous administration of viridal occur. Your doctor should give you the lowest effective dose administer , the Risk to minimize. In every Erection, that over 4 Hours beyond goes, inform your immediately treating Doctor or or – if this not reachable is – contact you yourself to a clinic with urological department. Prolonged erections can, if they not treated are, the erectile tissue of the penis damage and lead to an irreversible erectile dysfunction.

Painful erections occur more likely in patients with anatomical deformities of the penis such as penile curvature ,narrowing of the foreskin ,scarring of the corpora cavernosa ,Peyronie's disease Peyronie's disease or Skin changes. A

Penile fibrosis including a penile curvature, fibrotic nodules and Peyronie's disease (IPP) may as a result of the intracavernous use of viridal occur. The risk of a fibrosis may with longer treatment duration be increased. Monitoring of the patient, which includes a careful examination of the penis, is strongly recommended, to signs of penile fibrosis or of Peyronie's disease to detect. If you a penile curvature, corporal fibrosis or a Peyronie's disease develop, should you the treatment with viridal end.

In patients with bleeding disorders or patients, who medications for inhibition of blood coagulation (Anticoagulants) such as Warfarin or Heparin use, can the use of viridal the tendency to bleeding after an intracavernous injection increase. Should you belong to these patients, then your doctor should closely monitor the coagulation values of the blood closely monitor. should you the injection site at the penis sufficiently long with a swab compress.

The intracavernous injection of viridal can a Bleeding at the injection site cause. In diseases that through blood transmitted are can thereby the risk of transmission to the partner increased be. Please use you a condom.

In patients with mental illnesses or addiction disorders in the history should the potential risk of dependency from viridal be considered.

Application of viridal together with other medicines

Inform your doctor or pharmacist if you are other medicines take/use, recently other medicines taken/used have or intend other medicines to take/to use.

Sympathomimetics (Medicines, that stimulate the the sympathetic nervous system act) can the effect of viridal reduce. The effect of the combination of viridal with Phosphodiesterase-5 inhibitors, Apomorphine or into the urethra (intraurethral) applied Alprostadil is currently not known ..

can can the effect blood pressure-lowering (antihypertensives) and vasodilating (vasodilators) medications as well as of anticoagulants (anticoagulants) and medications, which the clumping the platelets prevent (antiplatelet agents), enhance.

Since viridal the platelet aggregation inhibits and thus the bleeding tendency increases, can the effect of simultaneously administered anticoagulants enhanced can be.

The effects of Alprostadil in combination with other treatment forms of erectile dysfunction (e.g. Sildenafil) or other erection-inducing drugs (e.g. Papaverine) were not specifically studied. These substances should not in combination with viridal used as possibly a prolonged duration of erection triggered can be.

Please note you please, that these information also for before recently applied medicinal product apply can.

pregnancy, lactation and fertility-fertility

If your partner is pregnant or breastfeeding, or if your partner suspects, pregnant or intends to become pregnant, ask your doctor or pharmacist before you use this medication or your doctor or pharmacist for advice.

The natural content of prostaglandin (PGE₁, tissue hormone with vasodilating Properties) in semen can through the content of PGE₁ in viridal increased be. In case of pregnancy of the partner should during the sexual intercourse a condom used be, to irritations of the vagina, the risk of a preterm birth or a risk to the fetus to avoid.

Driving ability and Ability to Operate machinery Machines

No studies have been conducted on the effect on driving ability and the Ability to operate of machines performed.

In individual cases are effects on the circulatory system, such as short-term blood pressure reduction and/or Dizziness after intracavernous injection of viridal to observe. The ability to drive and operate machinery can thereby up to 30 minutes after after Application impaired be.

viridal contains sodium, but less than 1 mmol (23 mg) sodium per double-chamber cartridge, i.e. it is almost "sodium-free".

3. How is viridal to use?

Apply this medicine always exactly according to the agreement with your doctor or pharmacist .. your pharmacist at your doctor or pharmacist about, if you are not sure ..

you start, viridal yourself to to inject, must you by the treating doctor thoroughly in the preparation of the injection solution and in the injection technique instructed be. Also the to Home to be used Dosage is by doctor to be determined (see section Dosage instructions). Precise instructions your doctor are prerequisite for the therapy to home.

If you have difficulties having, safely self-injections performing, e.g. due to reduced manual ability, in severe visual impairment or pronounced obesity (obesity), can your partner instructed to perform the injections to perform.

Avoid you misinjections, i.e. inject you not directly under the skin but only at the site that you your doctor shown has, as viridal otherwise not properly work can.

The injection should under hygienic conditions be performed, as it otherwise to infections of penis or corpora cavernosa may occur.

An erection will itself approximately 5 to 15 minutes after the injection develop. How to injection to perform is, read please in the following sections.

The following information apply, as far as you your doctor viridal not otherwise prescribed has. Please adhere you to the application instructions , as viridal otherwise otherwise not correctly act can.

Treatment of erectile dysfunction

Dosage at start of treatment

Diagnostic injections and injections for dose finding are by treating doctor performed. He selects a individual dosage, which a diagnostic examination of the erectile dysfunction enables.

If you viridal for treatment of erectile dysfunction prescribed received have, will your doctor also your individual dose in practice test. As starting dose is recommended to in patientswhose erectile dysfunction neurogenic origin is, a dose of 1.25 µg Alprostadil to inject. In all other patients should with 2.5 µg Alprostadil be started. During the dose adjustment are steps between 2.5 and 5 µg Alprostadil to recommend. The most patients require between 10 and 20 µg Alprostadil, i.e. 0.5 ml viridal 20 µg (= 10 µg Alprostadil) and 1 ml viridal 20 µg (= 20 µg Alprostadil).

In the case of dosages above 20 µg Alprostadil is available to you viridal 40 µg available. At the maximum dosage of 40 µg Alprostadil is 1 ml viridal 40 µg to inject. This maximum dose must not be exceeded be.

Dosage for treatment at home

You should only inject the dose injectthat from your treating doctor through a series of injections according to the above-mentioned scheme for you determined was. This dosage should to home to a not longer than 1 hour lasting erection lead. In case of prolonged erection between 2 and 4 hours must You your doctor point out that, that he a new dose adjustment must perform ..

you viridal 20 µg only until to to 3 injections per week at, whereby between 2 injections at least a period of 24 hours must elapse.

Diagnosis of erectile dysfunction (is only performed by a doctor)

In case of suspicion of a non- vascular dysfunction, e.g., in neurogenic or psychogenic cause, the recommended starting dose for the diagnostic procedure is 2.5 µg alprostadil. This initial dose is increased until a full erection is achieved .. Otherwise can in general with a injection of 10 µg Alprostadil (= 0.5 ml viridal 20 µg) be started. Between the individual injections should at least 24 hours lie, whereby the number of injections to 3 per week limited is.

Clinical experiences in diagnostics are up to 40 µg Alprostadil available; this maximum dose may not exceeded be. For dosages up to 10 µg is available to viridal 10 µg at your disposal, and for dosages between 20 µg and 40 µg Alprostadil is viridal 40 µg to use.

Patient instructions for injection into the corpus cavernosum

Preparations

Before you start the preparation , should you your Hands and your penis thoroughly with water and soap wash.

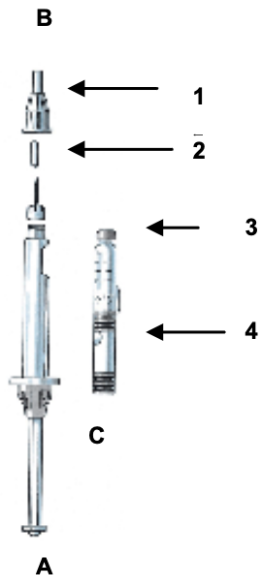
Prepare you please the injection solution immediately before the injection to and use you them immediately. Do not used injection solution is to discard.

Tear-off instructions

Tear you the white film laterally from Protective container from and remove you the dual-chamber cartridge and the injection needle.

Place you the components of the injection set in front of you on a clean surface and make sure you yourself that the injector has no obvious damage . Easy-Duo-.

Abbildung 1



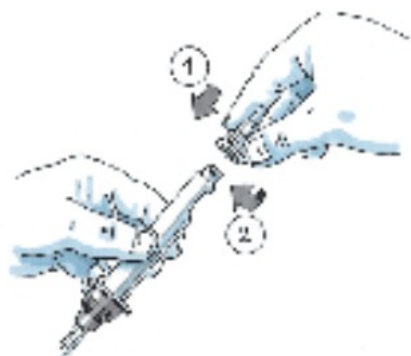
- A. injection needle with
- B. Injection needle with outer protective cap (1) and inner protective cap (2)
- C. dual-chamber cartridge with dry substance in the front chamber and solvent in the rear chamber, cartridge tip (3) and front gray Rubber stopper (4)

Note

Please ensure you before each use ,that the Easy-Duo- Injector has no visible damage . The Injector may exclusively with viridal double-chamber cartridges and the supplied injection needles (B-D Microfine+ 0.33x12.7 mm) used be.



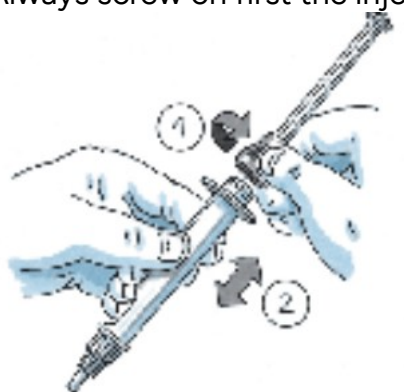
Check first whether theseal of the injection needle is intact . is. Remove the then the seal of the injection needle.



Screw the the injection needle clockwise onto the front thread Thread of the injector, until it is secure.

Note

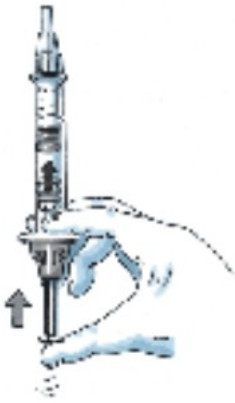
Always screw on first the injection needle on, before you the cartridge insert.



Screws You the plunger from injector off. Take You the cartridge and clean You the tip with a disinfecting swab. Insert the the cartridge into the transparent body of the injector a. Ensure that thereonthe curvature of the cartridge into the groove of the injector to insert.



Screw the plunger back onto the rear threaded part of the injector body.



Hold the the injector with the Needle after up.
Push You the plunger forward , untilboth gray stoppers of the cartridge touch . During.
During this Process runs the sodium chloride solution from the rear chamber of the cartridge into the front chamber.
Shake now the injector carefully ,to to the dissolution of the dry substance to accelerate. The solution may appear milky cloudy initially due to air bubbles. Within a short time arises a clear solution.



Remove the outer outer and inner protective cap of the needle.

Note

From now on may the Needle with no other Object anymore in Contact come, to keep sterile to maintain.

Injection



Tap You, while You the injector with the needle upwards hold, firmly against the injector , until allair bubbles upwards have moved . migrated are.
Push the plunger carefully forward , untila drop of the solution emerges from the needle . Makesure to ensure that, that all air from the cartridge removed was.

Make sure the by your doctor specified dosage set. Press You for this the plunger of the injector carefully upwards , until the upper edge of the front gray stopper your prescribed dose is reached (see window of the the Figure). Place the injector on a clean surface and make sure that the needle does not come into contact other Object more in Contact comes.

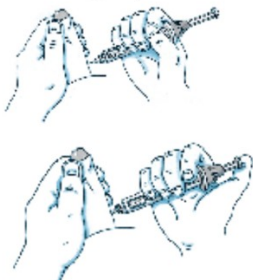


Make sure ,that your penis is well washed . Clean. the You the Injection site with a disinfectant (e.g. some gauze, which with diluted alcohol for medical purposes soaked is), and hold you thereby the penis under light tension from the body away, until the designated injection site dry is. Take you now the injector and ensure You again ensure, that the gray stopper is on the set dose and that no air bubbles are in the cartridge present contained are.



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

Abbildung 11



Hold the the injector as in the figure 11 shown. Guide the injection needle ,without pressing on the plunger of the injector , horizontally and almost completely into the penis insert , as it is done You your doctor shown has. Place you now the thumb on the plunger and inject you the solution over a period from 5 to 10 seconds.

Notes

The injection site should at each injection be changed . If you into the right side inject, take You the injector in the right hand. Inject you in the left side, take you it in the left hand. During the injection may a slight pain occur.

If you experience resistance or a severe, burning pain, carefully change the position of the position of the Injection needle. Insert the needle slightly further or withdraw it slightly, until the solution is easily injected. Light injections can be successful. Should the injection nevertheless not be simple and painless, pull the needle out of the injection site. Sit down please in this case before the next injection with your treating doctor in contact.

After the injection

Abbildung 12



Pull the injection needle from the penis, and place the injector aside. Press for at least 3 minutes on the injection site (e.g. with some gauze), to prevent bleeding. Note

If bleeding occurs, press further on the injection site, until the bleeding stops.

After you have performed the injection, place the outer protective cap on the needle, and unscrew this from the injector.

Remove the cartridge, by pulling the plunger from the injector body and unscrewing the cartridge.

Dispose of the injection needle and the cartridge safely and properly.

After you have used the Easy-Duo-Injector, clean it please with warm water and a mild detergent.

Put it in the injector after cleaning dry back into its case.

Since the viridal refill packs no injector contain, store the EasyDuo injector for your next injections.

A obviously damaged or not functional injector should not be used. Ensure you are before each further injection, that the injector fully operational is.

Note

It is recommended, after completion of the injection and during of sexual intercourse for safety reasons a condom to use.

Duration of the application

It should regularly check-ups by the attending physician performed will be. In this case it is then to decide, whether a adjustment of the dosage necessary is and how long the treatment continued will be should.

Please talk to your doctor or pharmacist, if you have the impression that the effect of viridal is viridal to strong or too weak is.

If you a larger amount viridal applied have, than you should

In clinical studies with Alprostadil were no overdoses observed. In case of an overdose a prolonged, sometimes painful erection may occur. Until all systemic effects subsided are and/or to a penile detumescence occurred is, should you under medical supervision observed

be. Therefore should you contact immediately your treating physician or a clinic with a urological department as a prolonged erection the erectile tissue of the penis damage can. The treatment of a priapism (prolonged erection) should not later than after 6 Hours initiated will be.

4. What side effects are possible?

Like all medicines can also this medicine have side effects , which however not in not in each occur must.

In the frequency indications for side effects the following frequency indications are based on:

Very common: more than 1 treated of 10
Common: 1 to 10 treated of 100
Occasionally: 1 to 10 treated of 1000
Rare: 1 to 10 treated of 10000
Very rarely: less than 1 treated out of 10000
Not known: Frequency based on the available data not estimable

The on most common reported side effect after an intracavernous injection was pain at the penis. Thirty percent of the patients reported at least once of pain. Pain was in 11% with the injection associated. In the majority of cases was the pain as mild to moderate assessed. 3% of the Patients discontinued the treatment due to pain.

Penile fibrosis including penile curvature, fibrotic nodules and Peyronie's disease was in 3% of all patients who participated in clinical Studies participations, reported. In a study on self-injection, which over 18 months lasted, the occurrence of a penile fibrosis higher and was at approximately 8%.

Bruise (Hematoma) and Skin bleeding (Ecchymosis) at the injection site, are more likely in connection with the injection technique than the effect of Alprostadil and were in 3% and 2% of the patients reported.

Prolonged erections (an erection over 4-6 hours) developed 4% of the patients. priapism (a painful erection for more than 6 hours) occurred in 0.4% on. In the most cases resolved themselves these spontaneously back.

Examinations

Occasionally:

- Lowered blood pressure
- Increased heart rate
- Increased blood creatinine levels

Heart diseases

Occasionally:

- Increased occurring heartbeats outside the heart rhythm, which originate in one of the atria (supraventricular extrasystoles) Not

known Circulatory disorder

- of the of the Heart (Myocardial ischemia)
- Heart attack

Diseases of the Nervous system

Occasionally:

- Reduced Touch- and Pressure sensitivity of the skin (Hypoesthesia)
- Hypersensitivity to Touch stimuli (Hyperesthesia)
- Dizziness
- Headaches
- Short, persistent Unconsciousness (Syncope)
- Symptoms of incipient fainting such as Drowsiness, Visual-/Hearing disorders, Pallor, Sweating, Nausea without subsequent loss of consciousness (so-called.)Not

known Memory impairment

- Stroke
- Eye diseases

Eye diseases

Occasionally:

- Dilation of the pupils (mydriasis)

Disorders of the ear and labyrinth

Rare

- Vertigo

Disorders of the gastrointestinaltract

Occasionally:

- Nausea
- Dry mouth

Diseases of the kidneys and urinary tract

Occasionally:

- Difficult possibly. painful bladder emptying (dysuria)
- Frequent urination of small amounts of urine (Pollakiuria)
- Urge to urinate
- Bleeding the urethra (Urethral bleeding)
- Increased occurrence of red blood cells in urine (Hematuria)

Diseases of Skin and of the subcutaneous tissue

Occasionally:

- Rash
- Itching (Pruritus)
- Redness of the skin of the scrotum (Erythema of the scrotum)
- Redness of the skin
- Increased sweating (Hyperhidrosis)

Skeletal muscle-, Connective tissue- and bone disorders

Common

- Muscle cramps

Occasionally:

- Back pain

Infections and parasitic diseases

Occasionally:

- Fungal infections
- Infections of the upper respiratory tract
- Common Cold

Vascular diseases

Frequent:

- Symptomatic Blood pressure drop (Hypotension)
- Blue bruises (Hematomas)

Occasionally:

- Blood pressure drop (Hypotension)
- Bleeding (Hemorrhage)
- Dilation of the Blood Vessels (Vasodilation)
- Peripheral Vascular Disease
- Venous Bleeding
- Circulatory Disorders
- Venous Diseases

General Disorders and Complaints in the Site of administration

Common:

- Small-scale bleeding of the skin (ecchymoses) at the injection site Bruises (hematomas) at the injection site Fibrosis at the Injection site
- Fibrosis of the Injection site (e.g., plaques at the injection site, fibrotic nodules)
- Pain at the injection site

Occasionally:

- Bleeding (hemorrhage) at the injection site, Irritations at the injection site, numbness at the injection site, feeling of warmth at the injection site, itching at the injection site, Erythema at the injection site, volume increase at the injection site, swelling at the injection site, edema at the injection site, Inflammations at the injection site
- Inflammations
- Irritations
- Swelling
- Tissue swelling due to fluid retention (edema)
- Peripheral edema
- Weakness (asthenia)

Disorders the genital organs and the mammary gland

Very common:

- Penile pain

Common:

- Prolonged erections
- Localized hardening of the penis, which a deformity of the erect Penis causes (Peyronie's disease, IPP)
- Proliferation of connective tissue of the penis (penile fibrosis) - Penile diseases (penile curvature, penile deviation)

Occasionally:

- balanitis (Balanitis)
- Painful Persistent erection (Priapism)
- Phimosis (Phimosis)

- Painful Erections
- Ejaculation disorders
- Erectile dysfunction
- Testicular, Scrotal- and Pelvic pain
- Testicular and Scrotal edema
- Diseases of the scrotum
- Formation of fluid-filled cysts in the area of the epididymis or less commonly in the area of the spermatic cords (spermatocele)
- Testicular dysfunction
- Feeling of warmth on the testicles
- Testicular swelling
- Testicular enlargement

Diseases of the immune system

Rare

- Hypersensitivity with allergic skin inflammation/skin reaction (dermatitis), hives (urticaria) to to anaphylactic /anaphylactoid reactions Diseases

of the blood and the lymphatic system Very

rare Lack of

- platelets in blood (thrombocytopenia) Report

Report from side effects

If you side effects notice, contact your doctor or pharmacist . This applies also to side effects , which are not listed in this package leaflet this Package leaflet specified are. You can side effects also directly via national reporting system of the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, D53175 Bonn, Website: <http://www.bfarm.de> display . By you side effects report, can you contribute to that more information about the safety of this medication Medicinal product to disposal provided will be.

5. How is viridal to be stored?

Keep this medicine out of the reach of children . You.

not may this medication after the on the carton after "Use by date indicated expiry date no longer use. The expiry date refers to the the last day of the month.

Storage conditions

Do not store above 25°C store.

Dual-chamber cartridges in the outer carton store, to protect the contents from Light to protect.

You must not use this medicine if you notice the following

In case of damage to the dual-chamber cartridge can the normally dry content of the anterior chamber moist and sticky become and significantly in volume lose. viridal may in this case not used be.

Note on shelf life after opening or preparation

The ready-to-use injection solution must immediately before the application freshly prepared be. Not used injection solution must be discarded be.

The powder dissolves itself after addition of the sodium chloride solution immediately on. Initially can the solution milky cloudy appear. This is due to air bubbles attributable and without significance. Within a short time a clear solution forms.

6. Contents of the package and further information

What viridal 20 µg contains

The active ingredient is Alprostadil.

1 dual-chamber cartridge with 48.2 mg powder and 1 ml Solvent contains 20 µg Alprostadil in powder.

The other ingredients are:

Powder: Lactose, Alfadex

Solvent: Sodium chloride, Water for injection purposes (= Sodium chloride solution 0.9%)

How viridal looks and Contents of the package

The contents of the front chamber of the dual-chamber cartridge consists of a white and dry powder that a compact cake with a height of approximately 8 mm forms. This cake can show cracks and slightly crumble, which the Efficacy not affected. The posterior chamber contains the clear, colorless sodium chloride solution (solvent).

viridal 20 µg is as starter set with 2 Dual-chamber cartridges as well as as refill pack with 2 or 6 dual-chamber cartridges available.

A starter set contains:

2 dual-chamber cartridges with each 48.2 mg powder and 1 ml sterile sodium chloride solution 0.9%

2 injection needles 29 G x ½ (0.33 mm x 12.7 mm)

reusable injector (Easy-Duo)

The refill packs contain:

or. 6 dual-chamber cartridges with each 48.2 mg powder and 1 ml sterile sodium chloride solution 0.9%

2 or. 6 injection needles 29 G x ½ (0.33 mm x 12.7 mm)

It is possible not all package sizes are marketed .

Pharmaceutical entrepreneur

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This package leaflet was last in July 2013 revised.

Information about the medical devices

Please note the instructions for use for the following medical devices , which are in the viridal package Package contained are, in the section "Patient Guide for injection into the corpus cavernosum".

Sterile injection needles

B-D Micro-Fine+ 29 G x ½ (0.33 mm x 12.7 mm) from Becton Dickinson Europe CE 0050

Easy-Duo®

reusable Injector for viridal dual-chamber cartridges (only in Starter Set included) by the company Androsystems Srl
CE