SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Viridal Duo 40 microgram/ml, Powder and Solvent for Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Alprostadil 40 micrograms (used as a 1:1 clathrate complex with alfadex).

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

Double chamber glass cartridge containing lyophilised powder and solvent for reconstitution (0.9% w/v sodium chloride solution).

The powder is white and the isotonic sodium chloride solution is clear colourless liquid without a special odour. The powder is freely soluble within 60 seconds when dissolved in isotonic sodium chloride solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Viridal Duo is indicated in adult males:

- as an adjunct to the diagnostic evaluation of erectile dysfunction.
- for treatment of erectile dysfunction.

4.2. Posology and method of administration

Posology

Adults:

Dosage for diagnosis of erectile dysfunction

Injections for diagnostic evaluation and dose titration must be performed by the treating physician. He will determine an individual dose suitable to produce an erectile response for diagnostic purposes.

For erectile dysfunction of neurological origin, the starting dose is 1.25 mcg Viridal Duo In all other patients with erectile dysfunction the recommended starting dose is 2.5 mcg. Dose adjustments may be performed in increments of about 2.5 mcg to 5 mcg Viridal Duo. Most of the patients require between 10 and 20 mcg per injection. Some patients may need to be titrated to higher doses. Doses exceeding 20 mcg should be prescribed with particular care in patients with cardiovascular risk factors. The dose per injection should never exceed 40 mcg.

Dosage for the treatment of erectile dysfunction

Treatment initiation and dose titration

Injections for treatment initiation and dose titration must be performed by the treating physician. The recommended starting dose is 1.25 mcg Viridal Duo in patients with erectile dysfunction of primary neurological origin. In all other patients with erectile dysfunction 2.5 mcg is the recommended starting dose. Dose adjustments may be performed in increments of about 2.5 mcg to 5 mcg. Most patients require between 10 and 20 mcg per injection. Some patients may need to be titrated to higher doses.

The dose per injection should never exceed 40 mcg.

Dosage for self-injection therapy

Before starting treatment at home, each patient or the patient's partner has to be taught by a physician how to prepare the drug and perform the injection. In no cases should the injection therapy be started without precise instructions by the physician. The patient should only use his optimum individual dosage which has been pre-determined by his physician using the above-mentioned procedure. This dose should allow the patient to have an erection at home, which should not last longer than one hour. If he experiences prolonged erections beyond 2 hours but less than 4 hours, the patient is recommended to contact his physician to re-establish the dose of the drug. The maximum injection frequency recommended is 3 times a week with an interval of at least 24 hours between the injections.

Follow-up

After the first injections and at regular intervals, e.g. every three months, the physician should re-evaluate the patient. Any local adverse reaction, e.g. haematoma, fibrosis or nodules should be noted and controlled. Following discussion with the patient, an adjustment of dosage may be necessary.

Paediatric population

The safety and efficacy of Viridal Duo in children under 18 years of age has not yet been established. No data are available.

Elderly
The safety and efficacy of Viridal Duo in patients over 80 years of age has not yet been established. No data are available.

Method of preparation and administration
Intracavernosal use
The drug solution should be prepared shortly before the injection.
Prior to injection the needle should be screwed onto the tip of the injector. After disinfecting the tip of the cartridge with one of the alcohol swabs, the cartridge should then be inserted into the injector. The tip should face towards the front of the applicator.

Put the cartridge into the Easy Duo device. Screw the syringe and plunger together. Hold the device in the vertical position and push the plunger upwards. The solvent will by-pass the upper stopper into the front chamber and dissolve the dry substance within a few seconds.

As soon as the dry substance is reconstituted, the larger external and the smaller inner protective cap have to be removed from the needle. The device is still held in the vertical position and the air should then be expelled out of the cartridge by tapping against the cartridge and by carefully pushing the plunger until the air is pushed out. The plunger is pushed up until the grey stopper reaches the prescribed dose.

Viridal Duo is injected into either the right or the left cavernous body of the penile shaft. Once the needle is in the cavernous body, the injection should be done within 5 to 10 seconds and is very easy without much resistance if the needle is in the correct position.

The development of an erection will start approximately 5 – 15 minutes after the injection.

Notes
Injections for treatment initiation, diagnostic evaluation and dose titration must be performed by the treating physician. For patients who require a starting dose of 1.25 mcg, the dose of the reconstituted injection solution can be extracted from the carpoule using a syringe with a needle size 29 G x1/2 (0.33 mm x 12.7 mm) and appropriately graduated to extract and administer 0.125 ml injection volume from the carpoule containing 10 mcg Viridal Duo. Under aseptic conditions the solution can be extracted from the carpoule through the rubber seal.
Unused solution must be discarded immediately.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Patients with diseases causing priapism e.g. sickle-cell anaemia or trait, multiple myeloma or leukaemia or patients with anatomical deformation of the penis such as angulation, cavernosal fibrosis or Peyronie's disease. Patients with penis implants should not use Viridal Duo**.**

Viridal Duo should not be used in men for whom sexual activity is contraindicated (e.g. patients suffering from severe heart disease).

4.4 Special warnings and precautions for use

The physician should carefully select patients suitable for self-injection therapy. Underlying treatable medical causes of erectile dysfunction should be diagnosed and treated prior to initiation of therapy with Viridal Duo.

Sexual stimulation and intercourse can lead to cardiac and/or pulmonary events in patients with coronary heart disease, congestive heart failure or pulmonary disease. These patients when using Viridal Duo should engage in sexual activity with caution and patients should be examined and cleared for stress resistance by a cardiologist before treatment.

Viridal Duo should be used with caution in patients with cardiovascular and cerebrovascular risk factors.

Viridal Duo should be used cautiously in patients with a history of gastrointestinal disease, including erosive gastritis; gastrointestinal bleeding and gastric and/or duodenal ulcer.
Caution should be advised in patients receiving concomitant medications, which could increase the risk of bleeding, such as anticoagulants or platelet aggregation inhibitors (see Section 4.5).
Those patients should be closely monitored for signs and symptoms of bleeding.

Priapism (erection lasting over six hours) may occur following intracavernosal administration of alprostadil. Prolonged erections of more than four hours can be dangerous. Treatment of priapism should not be delayed more than six hours (see

section 4.9). Therefore it is recommended that the patient has an emergency telephone number of his attending physician or of a clinic experienced in therapy of erectile dysfunction. Prolonged erection may damage penile erectile tissue and lead to irreversible erectile dysfunction.

To minimise the risk, select the lowest effective dose and instruct the patient to immediately report to his prescribing physician, or, if unavailable, seek immediate medical assistance for any erection that persist longer than four hours. Treatment of priapism should be according to established medical practice.

Painful erection is more likely to occur in patients with anatomical deformations of the penis, such as angulation, phimosis, cavernosal fibrosis, Peyronie's disease or plaques. Penile fibrosis, including angulation, cavernosal fibrosis, fibrotic nodules and Peyronie's disease may occur following the intracavernosal administration of Viridal Duo. The occurrence of fibrosis may increase with increased duration of use. Regular follow-up of patients, with careful examination of the penis, is strongly recommended to detect signs of penile fibrosis or Peyronie's disease. Treatment with Viridal Duo should be discontinued in patients who develop penile angulation, cavernosal fibrosis, or Peyronie's disease.

Patients who have to be treated with alpha-adrenergic drugs due to prolonged erections (see: overdose) may in the case of concomitant therapy with monoamino-oxidase-inhibitors, develop a hypertensive crisis.

Other intracavernous drugs e.g. smooth muscle relaxing agents or alpha-adrenergic blocking agents may lead to prolonged erection and must not be used concomitantly.

Viridal Duo is not intended for co-administration with any other agent for the treatment of erectile dysfunction (see section 4.5).

Patients with blood clotting disorders or patients on therapy influencing blood clotting parameters should be carefully selected for treatment by the treating physician and treated with special care, e.g. monitoring of the clotting parameters. Patients should be thoroughly educated by their physician about the risks and the patients should be advised to compress the site of injection with a swab for a sufficiently long period after the intracavernous injection (see section 4.5). Patients on anticoagulants such as warfarin or heparin may have increased propensity for bleeding after the intracavernous injection.

To prevent abuse, self-injection therapy with Viridal Duo should not be used by patients with drug addiction and/or disturbances of psychological or intellectual development.

In cases of excessive use, e.g. higher frequencies than recommended, an increased risk of penile scarring cannot be excluded.

Use of intracavernous alprostadil offers no protection from the transmission of sexually transmitted diseases. Individuals who use alprostadil should be counselled about the protective measures that are necessary to guard against the spread of sexually transmitted diseases, including the human immunodeficiency virus (HIV). In some patients, injection of Viridal Duo can induce a small amount of bleeding at the injection site. In patients infected with blood borne diseases, this could increase the transmission of such diseases to the partner. For this reason we recommend that a condom is used for intercourse after injecting Viridal Duo.

Viridal Duo is for intracavernous injection. Subcutaneous injection or injections at areas of the penis other than the cavernous body should be avoided.

The injection should be performed under hygienic conditions to avoid infections. In any condition that precludes safe self-injection like poor manual dexterity, poor visual acuity or morbid obesity, the partner should be trained in the injection technique and should perform the injection.

Up to now, there is no clinical experience in patients under 18 and over 80 years of age.

Reconstituted solutions of Viridal Duo are intended for single use only. The injection delivery system / Syringe and remaining solution should be properly discarded.

Human semen contains PGE1, but additional amounts may be present due to administration of Viridal Duo. This way an appropriate contraception is recommended if the partner is a woman of child-bearing age (see section 4.6). Viridal Duo must not be used for sexual intercourse with a pregnant woman without a condom.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of combinations of alprostadil with other treatments for erectile dysfunction (e.g. sildenafil) or other drugs inducing erection (e.g. papaverine) have not been formally studied. Such agents should not be used in combination with Viridal Duo due to the potential for inducing prolonged erections.

Risks exist when using alpha-adrenergic drugs to terminate prolonged erections in patients with cardiovascular disorders or receiving MAO inhibitors.

Sympathomimetics may reduce the effect of alprostadil. Alprostadil may enhance the effects of antihypertensives, vasodilative agents, anticoagulants and platelet aggregation inhibitors.

Patients with impaired coagulation, thrombocytic function-disorder or those being treated with anticoagulative therapy, anti-platelet therapy or with thrombolytic agents are at higher risk of bleeding. These patients should be carefully selected by the treating physician. Clotting parameters should be monitored closely. Patients should be thoroughly educated by their physician about the risks and should be advised to compress the site of injection with a swab for a sufficiently long period after the intracavernous injection (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
The natural amount of PGE1 present in the sperm may be increased by the PGE1 present in Viridal Duo. In case the partner is pregnant, a condom should be used in order to avoid irritation of the vagina and a risk for either pre-term delivery or for the foetus.

Fertility
Alprostadil does not interfere with ejaculation and fertility.

4.7 Effects on ability to drive and use machines

Viridal Duo would not be expected to have an influence on the ability to drive and use machines.

4.8. Undesirable effects

Summary of the safety profile:
The most frequent adverse effect following an intracavernous injection was pain in the penis. Thirty percent of patients reported pain at least once. Pain was associated with 11% of the injections administered. In most cases pain was assessed as mild or moderate. Three per cent of patients discontinued treatment because of pain.

Penile fibrosis, including angulation, fibrotic nodules, and Peyronie's disease, was reported in 3% of clinical trial patients overall. In one self-injection study in which the duration of use was up to 18 months, the incidence of penile fibrosis was higher, approximately 8%.

Haematoma and ecchymosis at the injection site, which is related with the injection technique rather than the effect of alprostadil, was reported by 3% and 2% of patients, respectively.

Prolonged erection (an erection for 4 - 6 h) developed in 4% of patients. Priapism (a painful erection for more than 6 hours) occurred in 0.4%. In most cases it disappeared spontaneously.

Adverse drug reactions reported during clinical trials and post marketing experience are presented in the table below.

Tabulated list of adverse reactions:
Frequencies are defined as:
Very common (≥1/10);
Common (≥1/100 to <1/10);
Uncommon (≥1/1,000 to <1/100);
Rare (>1/10,000, < 1/1,000);
Very rare (<1/10,000);
Not known (cannot be estimated from the available data).

During administration of Viridal Duo the following undesirable effects may be observed:

System Organ Class	**Frequency**	**Undesirable effects**
Infections and infestations	Uncommon	Fungal infection, nasopharyngitis
Blood and lymphatic system disorders	Very rare	Isolated cases of thrombocytopenia
Immune system disorders	Rare	Hypersensitivity ranging from dermatitis allergic urticaria to anaphylactic / anaphylactoid reactions

Nervous system disorders	Uncommon	Headache, hypoaesthesia, hyperaesthesia, presyncope
	Rare	Vertigo, dizziness
	Not known	Amnesia, cerebro-vascular accident
Eye disorders	Uncommon	Mydriasis
Cardiac disorders	Uncommon	Supraventricular extrasystoles
	Rare	Circulatory effects such as short periods of hypotension
	Not known	Myocardial ischemia, myocardial infarction
Vascular disorders	Common	Haematoma
	Uncommon	Vein disorder, hypotension, vasodilation, peripheral vascular disorder
Gastrointestinal disorders	Uncommon	Nausea, dry mouth
	Not known	Gastrointestinal haemorrhage
Skin and subcutaneous tissue disorders	Uncommon	Rash, pruritis, erythema, hyperhidrosis
	Rare	Urticaria
Muskuloskeletal and connective tissue disorders	Common	Muscle spasms
Renal and urinary disorders	Uncommon	Dysuria, haematuria, pollakiuria, micturition urgency, urethral heamorrhage
Reproductive system and breast disorders	Very common	Penile pain
	Common	Erection increased, Peyronie's disease, penis disorder, fibrotic alterations (e.g. fibrotic nodules, plaques at the site of injection or in the corpus cavernosum) can occur during long term treatment
	Uncommon	Fibrotic alterations associated with slight penile axis deviations, erectile dysfunction, balanoposthitis, priapism (mainly seen during dose titration), phimosis, painful erection, ejaculation disorder, testicular pain, scrotal

		disorder, scrotal erythema, scrotal pain, pelvic pain, testicular swelling, testicular oedema, scrotal oedema, spermatocele, testicular disorder, testicular mass
	Rare	Fibrotic changes of the cavernous body during a long term treatment lasting up to 4 years.
General disorders and administrative site conditions	Common	Ecchymosis, injection site haematoma, burning sensation during injection and after the injection, pain of mostly mild intensity at the site of injection.
	Uncommon	Spot-like haemorrhage / spot-like bruises at the site of puncture, haemosiderin deposits, inflammation, oedema peripheral, oedema, injection site haemorrhage, injection site mass, injection site inflammation, injection site pruritis, injection site swelling and reddening, injection site oedema, injection site irritation, injection site anaesthesia, injections site pain, injection site warmth, asthenia, haemorrhage
	Not known	Penile oedema
Investigations	Uncommon	Blood pressure decreased, heart rate increased, blood creatinine increased

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed below.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

Symptoms

Full rigid erections lasting more than four hours.
Overdosage was not observed in clinical trials with alprostadil.

Management

If intracavernous overdose of Viridal Duo occurs, the patient should be placed under medical supervision until any systemic effects have resolved and/or until penile detumescence has occurred.

- Observation of the erection, since spontaneous dtumescence is frequent but the treatment of priapism (prolonged erection) should not be delayed more than six hours.
- Symptomatic treatment of any systemic symptoms would be appropriate.
- Initial therapy should be by penile aspiration. Using aseptic technique, insert a 19-21 gauge butterfly needle into the corpus cavernosum and aspirate 20-50 ml of blood. This may detumesce the penis. If necessary, the procedure may be repeated on the opposite side of the penis until a total of up to 100 ml blood has been aspirated.
- If still unsuccessful, intracavernous injection of alpha-adrenergic medication is recommended. Although the usual contra-indication to intrapenile administration of a vasoconstrictor does not apply in the treatment of priapism, caution is advised when this option is exercised. Blood pressure and pulse should be continuously monitored during the procedure. Extreme caution is required in patients with coronary heart disease, uncontrolled hypertension, cerebral ischaemia, and in subjects taking monoamine oxidase inhibitors. In the latter case, facilities should be available to manage a hypertensive crisis.
  A 200 microgram/ml solution of phenylephrine should be prepared, and 0.5 to 1.0 ml of the solution injected every 5 to 10 minutes. Alternatively, a 20 microgram/ml solution of epinephrine should be used.
- If necessary, this may be followed by further aspiration of blood through the same butterfly needle. The maximum dose of phenylephrine should be 1 mg, or epinephrine 100 micrograms (5 ml of the solution). As an alternative metaraminol may be used, but it should be noted that fatal hypertensive crises have been reported. If this still fails to resolve the priapism, urgent surgical referral for further management, which may include a shunt procedure is required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in erectile dysfunction,

ATC Code: Other urologicals G04BX 05

Mechanism of Action

Alprostadil [Prostaglandin E_1 (PGE_1)], the active ingredient of Viridal Duo, is an endogenous compound derived from the essential fatty acid dihomogammalinolenic acid. Alprostadil is a potent smooth muscle relaxant that produces vasodilation and occurs in high concentrations in the human seminal fluid. Pre-contracted isolated preparations of the human corpus cavernosum, corpus spongiosum and cavernous artery were relaxed by alprostadil, while other prostanoids were less effective. Alprostadil has been shown to bind to specific receptors in the cavernous tissue of human and non-human primates.

The binding of alprostadil to its receptors is accompanied by an increase in intracellular cAMP levels. Human cavernosal smooth muscle cells respond to alprostadil by releasing intracellular calcium. Since relaxation of smooth muscle is associated with a reduction of the cytoplasmic free calcium concentration, this effect may contribute to the relaxing activity of this prostanoid.

Pharmacodynamic effects

Intracavernous injection of alprostadil in healthy monkeys resulted in penile elongation and tumescence without rigidity. The cavernous arterial blood flow was increased for a mean duration of 20 min. In contrast, intracavernous application of alprostadil to rabbits and dogs caused no erectile response.

Systemic intravascular administration of alprostadil leads to a vasodilation and reduction of systemic peripheral vascular resistance. A decrease in blood pressure can be observed after administration of high doses. Alprostadil has also been shown in animal and *in vitro* tests to reduce platelet reactivity and neutrophil activation. Additional alprostadil activity has been reported: increase in fibrinolytic activity of fibroblasts, improvement of erythrocyte deformability and inhibition of erythrocyte aggregation; inhibition of the proliferative and mitotic activity of non-striated myocytes; inhibition of cholesterol synthesis and LDL-receptor activity; and an increase in the supply of oxygen and glucose to ischaemic tissue along with improved tissue utilisation of these substrates.

5.2 Pharmacokinetic properties

Absorption

After reconstitution, alprostadil (PGE_1) dissociates from the α-cyclodextrin clathrate, and the two components have independent fates.

In symptomatic volunteers, systemic mean endogenous PGE_1 venous plasma concentrations measured before intracavernous injection are approximately 1pg/ml. After injection of 20 mcg of alprostadil, the PGE_1 venous plasma concentrations increase rapidly to concentrations of about 10-20 pg/ml. The PGE_1 plasma concentrations return to concentrations close to the baseline within 2 hours.

Distribution

Approximately 90% of PGE_1 found in plasma is protein-bound.

Biotransformation

Enzymatic oxidation of the C15-hydroxy group and reduction of the C13,14 double bond produce the primary metabolites, 15-keto-PGE_1, PGE_0 (13,14-dihydro-PGE_1) and 15-keto-PGE_o. Only PGE_0 and 15-keto-PGE_o have been detected in human plasma. Unlike the 15-keto metabolites, which are less pharmacologically active than the parent compound, PGE_0 has a potency similar to that of PGE_1 in most respects.

In symptomatic volunteers, the mean endogenous PGE_0 venous plasma concentrations measured before an intracavernous injection are approximately 1 pg/ml. After the injection of 20 mcg of alprostadil, the PGE_0 plasma concentrations increase to concentrations of about 5 pg/ml within 20 minutes followed by a return to concentrations close to baseline. The terminal half-life of PGE_0 is about 30 minutes.

Elimination

After further degradation of the primary metabolites by beta and omega oxidation, the resulting, more polar metabolites are excreted primarily with the urine (88%) and the faeces (12%) and there is no evidence of tissue retention of PGE_1 or its metabolites.

5.3 Preclinical safety data

Studies on local tolerance following single and repeated intracavernous injections of alprostadil or alprostadil alfadex in rabbits and/or monkeys, in monkeys up to 6 months with daily injection revealed in general good local tolerance. Possible adverse effects like haematomas and inflammations are more likely related to the injection procedure.

Within the 6 months study in male monkeys, there were no adverse effects of alprostadil alfadex on male reproductive organs.

Alprostadil did not cause any adverse effects on fertility or general reproductive performance in male and female rats treated with 40-200 mcg/kg/day. The high dose of 200 mcg/kg/day is about 300 times the maximum recommended human dose on a body weight basis (MHRD < 1 mcg/kg).

Alprostadil was not fetotoxic or teratogenic at doses up to 5000 mcg/kg/day (7500 times the MHRD) in rats, 200 mcg/kg/day (300 times the MHRD) in rabbits and doses up to 20 mcg/kg/day (30 times the MHRD) in guinea pigs or monkeys.

Mutagenicity studies with alprostadil alfadex revealed no risk of mutagenicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder for injection: lactose, alfadex
Diluent: sodium chloride, water for injection.

6.2 Incompatibilities

It is not intended that this medicinal product be mixed with other medicinal products. Therefore in the absence of compatibility studies this medicinal product must not be mixed with other medicinal products

6.3 Shelf life

Shelf life for the product as packaged for sale: 3 years.
Shelf life after reconstitution: for immediate use only.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from light.

6.5 Nature and contents of container

1. Cartons containing one colourless glass double-chamber cartridge, one injection needle 29 G x ½ (0.33 mm x 12.7 mm) and one reusable injector (starter kit).
2. Cartons containing two colourless glass double-chamber cartridges, two injection needles 29 G x ½ (0.33 mm x 12.7 mm) and one reusable injector (starter kit).
3. Cartons containing one, two or six colourless glass double-chamber cartridges and corresponding number of injection needles 29 G x ½ (0.33 mm x 12.7 mm) without reusable injector.

Not all packs may be marketed.

Administration devices

1 reusable injector (starter kit)
1 double chamber cartridge with dry substance and 1 ml 0.9% sterile sodium chloride solution
1 injection needle 29G x ½ (0.33 mm x 12.7 mm)

1 alcohol swab to be obtained for each injection

6.6 Special precautions for disposal

Preparation and handling of the product:
Fix the injection needle onto the front part of the injector.

Disinfect the tip of the cartridge with one of the alcohol swabs. Insert the cartridge into the reusable injector and fix it by screwing the thread part. Dissolve the drug substance in the front chamber of the cartridge by completely screwing the thread-part into the injector thus moving both rubber stoppers to the top of the cartridge and allowing the solvent in to the bottom chamber to reach the dry substance via the bypass of the cartridge. Shake slightly until a clear solution is produced.

Expel the air and adjust the prescribed dosage precisely prior to intracavernous injection.

After preparation of the solution, the injection must be performed using aseptic procedures into either the left or right cavernous body of the penile shaft. Care should be taken not to inject into penile vessels or nerves on the upper side of the penis and into the urethra on the under side. The injection should be completed within 5 to 10 seconds and manual pressure should be applied to the injection site for 2 to 3 minutes.

Unused solution must be discarded immediately.

Advice

The content of the front chamber of the cartridge consists of a white, dry powder, which forms a compact layer, approximately 8 mm in height. The layer may show cracks and crumble slightly.

In case of damage to the cartridge, the usually dry content of the front chamber becomes moist and sticky and extensively loses volume. Viridal Duo must not be used in this case.

The bottom chamber contains the clear, colourless sodium chloride solvent solution.

The dry substance dissolves immediately after addition of the sodium chloride solution. Initially after reconstitution the solution may appear slightly opaque due to the presence of bubbles. This is of no relevance and disappears within a short time to give a clear solution.

Disposal
Disposal of needle: disable needle then dispose of in a sharps container.
Disposal of cartridge: no special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0647

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

21/09/2023