

Essential Information for the Supply of Viaredin

50 mg film-coated tablets (sildenafil)

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Introduction

This booklet is part of an information package that was put in place to support the marketing of Viaredin as an OTC treatment for Erectile Dysfunction. This document contains essential information you need to know and consider when assessing men as suitable candidates for use of Viaredin.

The sections in this booklet contain the following information:

SECTION 1

General information about erectile dysfunction and Viaredin

Provides a basic understanding of Viaredin and how it works.

SECTION 2

Who can be supplied Viaredin?

Details the types of men who can safely use Viaredin taking into account comorbidities and concomitant drug use.

SECTION 3

What is the Viaredin Pharmacy Consultation Guide?

The Viaredin Pharmacy Consultation Guide is provided as an optional tool to help accurately assess patients and their suitability for treatment.

SECTION 4

Providing advice about Viaredin

Information on the advice you can offer patients who are suitable for Viaredin and follow-up advice for those who are found to be not suitable.

SECTION 5

Patient supply scenarios

Test your knowledge with several patient supply scenarios to which you can apply your professional judgement and check against the suggested supply outcomes.

SECTION 6

Case study responses

Section 1

1. General information about erectile dysfunction and Viaredin

Definition of Erectile Dysfunction

Erectile Dysfunction (ED) has been defined as the inability to attain and/or maintain an erection hard enough for satisfactory sexual intercourse.¹ It can occur occasionally or frequently, and men are able to recognize the condition, which can vary in severity from mild (a soft erection) to severe (no erection at all).

Causes of ED

Understanding the causes and conditions associated with ED can help you manage the patients appropriately. In general, ED has 3 main causes:²

- Physical causes
- Psychological causes
- Some types of medication

1. Physical causes

ED usually has an underlying physical cause, that may predispose the patients to ED. These could include diabetes mellitus, hypertension, hypercholesterolaemia and cardiovascular disease (CVD).^{2,3}

CVD and most physical causes of ED are linked to vascular endothelial dysfunction, and many men with ED also have CV risk factors.³

2. Psychological causes

Psychological causes inhibit normal stimuli to and from the brain and can interfere with the ability to achieve a normal erection. Although there can be a perception that ED is a psychological issue, the reality is, purely psychological causes account for only 1 in 10 cases.⁴

Psychological causes can include:⁵

- Performance anxiety in relation to ED and the fear that it will re-occur.
- Depression - the link with ED appears to be bidirectional. In depressed men, ED may be a symptom of depression, and in men with ED, the emotional stress commonly associated with loss of sexual function may lead to depression.
- Antidepressant drugs (e.g. the tricyclics and selective serotonin reuptake inhibitors) can also cause ED.⁶
- Lack of arousal and/or inhibition between partners Other sexual dysfunction (e.g. premature ejaculation)
- Major life stress such as: money worries, bereavement, etc
- Low self-esteem can be due to prior episodes of ED or can be caused by other issues unrelated to sexual performance.

Indifference may arise as a result of age and a subsequent loss of interest in sex, or stem from problems in a couple's relationship.

3. Medication-induced

Some drugs (including recreational drugs and alcohol) can directly cause erection problems (iatrogenic cause). Many of the drugs shown in Table 1 are used to treat diseases that are themselves associated with ED.

Table 1: Medications that can cause ED⁶⁻¹²

Therapy area	Drug class or drug	Impact on ED
Cardiovascular	Diuretics (e.g. hydrochlorothiazide)	Not determined, but believed to interfere with smooth muscle relaxation
	ACE inhibitors (e.g. captopril, enalapril) and ARBs (e.g. candesartan, valsartan)	Interferes with smooth muscle relaxation
	Aldosterone antagonists (e.g. spironolactone)	An anti-adrenergic action
	Beta-blockers (e.g. metoprolol, atenolol)	Affects sex hormones, impairs vasodilation of the corpora cavernosa
	Clonidine	Depresses adrenergic output
Psychotropic	Anti-depressants: selective serotonin reuptake inhibitors (e.g. fluoxetine); tricyclics (e.g. amitriptyline); monoamine oxidase inhibitors (e.g. tranylcypromine); lithium	Decreases arousal and desire
	Anti-psychotics: phenothiazines (e.g. chlorpromazine); Butyrophenones (e.g. haloperidol)	Increases prolactin levels
Anti-epileptics	Carbamazepine Phenytoin Barbiturates	Affects sex hormone levels

Table 1 continued

Therapy area	Drug class or drug	Impact on ED
Endocrine drugs	Testosterone antagonists/ oestrogen agonists (e.g. flutamide); Anabolic steroids (e.g. testosterone enanthate/ cypionate, methyltestosterone); Luteinising hormone-releasing hormone analogues (e.g. goserelin)	Affects androgen receptors, reducing sexual desire
Recreational drugs	Alcohol, heroin, cocaine, marijuana, Methadone	Causes vasoconstriction and/or impacts on neurotransmitters in the erectile pathway
Other	H2 antagonists, ranitidine and Cimetidine	Increases prolactin levels, reducing sexual desire
	Cytotoxics, e.g. cyclophosphamide, Methotrexate	The effect of nausea and general malaise associated with such drugs often diminish libido

What is Viaredin and what is it indicated for?

Viaredin contains sildenafil 50 mg and is a pharmacy-only medicine to treat erectile dysfunction (ED) in men aged 18 years and over. It is a well-established and well-tolerated treatment which provides men with access without prescription to a legal ED medication and professional health advice from the pharmacy.

Successful treatment with sildenafil can also have emotional benefits for many men with ED, helping them to regain their self-confidence, self-esteem and relationship satisfaction. It can improve their quality of life and thus positively impact the wider social implications of erection problems, such as depression.¹³

How does Viaredin function?

When a man is sexually stimulated, impulses from the brain reach the cavernous nerve which releases nitric oxide (NO) at nerve endings in the penis. The NO diffuses across the endothelial cells into smooth muscle and stimulates the enzyme, guanylate cyclase, to convert GTP into cyclic GMP (cGMP). Cyclic GMP starts a further cascade of biochemical reactions which results in smooth muscle relaxation and the cavernous bodies fill with blood and become rigid. Cyclic GMP is normally broken down by the enzyme PDE5 to GMP, which terminates the pathway and produces detumescence. Viaredin inhibits the action of this enzyme thus increasing cGMP levels and maintaining these levels for longer. Hence Viaredin helps a man attain and maintain an erection in response to sexual stimulation.¹⁴

To make Viaredin effective, sexual stimulation is required.

Section 2

2. Who can be supplied Viaredin?

Viaredin efficacy and indication

Viaredin is an efficacious treatment for ED at the recommended 50 mg OTC dose. In fixed dose studies, the proportions of patients reporting that treatment improved their erections were 62 % (25 mg), 74 % (50 mg) and 82 % (100 mg) compared to 25 % on placebo.¹⁵ These data show that sildenafil is effective in men with ED and a wide range of concomitant diseases.

In some patients, 50 mg may not be efficacious and a referral to the GP is required as the dose may need to be increased to 100 mg. Patients with renal or hepatic impairment, with concomitant medication such as CYP3A4 inhibitors or alpha blockers or with tolerability issues should also seek medical advice as a 25 mg dose may be appropriate. The 25 mg and 100 mg doses are only available on prescription.

Only adult men aged 18 years or older with erectile dysfunction (ED) can use the product.

The active ingredient sildenafil is a part of the class of medicines known as Phosphodiesterase 5 Inhibitors (PDE5i) that are recommended as a first line treatment for ED by The European Association of Urology Guidelines.¹⁶

There are a number of contraindications or special warnings which mean that in certain circumstances the product cannot be used by men with ED.

Viaredin is contraindicated in:

- Men aged under 18 years, as it is not indicated for this age group.
- Women, as it is only indicated for men. Women interested in the product for their male partner should encourage their partner to visit the pharmacy or their doctor for additional advice.
- Men without ED. In this case, Viaredin will not enhance men's erections or sexual performance and it will not help problems such as premature ejaculation. Men in the latter group should be directed to their GP for further advice.
- Men allergic to sildenafil or any other ingredient
- Men using a different dose of sildenafil or another ED treatment

Viaredin is contraindicated in men with the following health problems:

- Men with hypotension (<90/50 mm Hg) must not use Viaredin because the safety of sildenafil has not been studied in these sub-groups of patients, and its use is, therefore, contraindicated.
- Men with previously diagnosed mild, moderate or severe hepatic impairment (e.g. liver cirrhosis), should be advised to talk with their GP about a suitable starting dose or alternative treatment options. Men should be asked the questions included in the Pharmacy Consultation Guide ([see Section 3](#)) relating to those diagnosed with liver problems. If they are under the care of a doctor for liver problems, they will be aware of this and answer 'yes'. Therefore, you must not supply the product.
- Men with previously diagnosed severe renal impairment. In most cases, patients with severe renal impairment will have some signs or symptoms of the underlying issues and will be under the care of a GP or renal specialist. A question regarding severe kidney problems is included in the Pharmacy Consultation Guide. If the answer to this is "yes", the patients should be advised to talk with their doctor about alternative options for the treatment of ED.

- Viaredin must not be used in patients with anatomical deformation of the penis (such as cavernosal fibrosis, angulation or Peyronie's disease), in patients with sickle cell anaemia, multiple myeloma or leukaemia. Due to increased risk of priapism these patients should be directed to their GP for further advice.
- Men with an inherited eye disease such as retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases) must not use Viaredin because the safety of sildenafil has not been studied in these sub-groups of patients, and its use is therefore contraindicated.
- Viaredin is contraindicated in patients with loss of vision in 1 eye because of nonarteritic anterior ischaemic optic neuropathy (NAION), regardless of whether this episode was in connection with previous PDE5 inhibitors exposure or not.
- Men who have any bleeding issues (e.g. haemophilia) or suffer from stomach ulcers must not use Viaredin and should be directed to their GP.
- Patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose galactose malabsorption must not take Viaredin because of the lactose contained within the tablet.
- Men with cardiovascular issues (see section below)

Viaredin is contraindicated in men with the following cardiovascular (CV) issues:

- Men with recent history (in the last 6 months) of stroke or myocardial infarction must not use Viaredin and should follow up with their GP.
- Men who have been advised to avoid sexual activity because of a CV problem. This group of men are potentially at higher risk due to the burden of over-activity on their heart and should be referred to their GP.
- Men who get very breathless or experience chest pains under light or moderate physical activity (i.e. walking briskly for 20 minutes or climbing 2 flights of stairs) should be referred to their GP.¹⁷
- Patients with increased susceptibility to vasodilators, including those with left ventricular outflow obstruction (e.g. aortic stenosis), or those with the rare syndrome of multiple system atrophy manifesting as severely impaired autonomic control of blood pressure must not use the product without consulting a doctor.

Patients previously diagnosed with the following must be advised to consult with their GP before resuming sexual activity:

- uncontrolled hypertension or hypotension
- moderate to severe valvular disease left
- ventricular dysfunction
- unstable angina
- hypertrophic obstructive and other cardiomyopathies
- significant arrhythmias
- severe cardiac failure

Note: Some low-risk cardiovascular patients may be suitable for Viaredin, if their doctor has advised they can resume sexual activity (i.e. patients with asymptomatic controlled hypertension, mild valvular disease or patients which underwent successful coronary artery bypass grafting, stenting or angioplasty).

Viaredin is contraindicated in men taking the following medicines:

- Nitrates (e.g. isosorbide mononitrate/dinitrate and glyceryl trinitrate), nitric oxide donors (e.g. nicorandil), 'poppers' (e.g. amyl nitrate), or sodium nitroprusside. Consistent with its known effects on the NO cGMP pathway, sildenafil has been shown to potentiate the hypotensive effects of nitrates. These men should be directed to their GP for further advice.
- Ritonavir (a potent CYP3A4 inhibitor used in the treatment of HIV). Due to the potential for increased blood levels of sildenafil in these patients they should consult with their doctor for further guidance.
- Guanylate cyclase stimulators, such as riociguat. As it may potentially lead to symptomatic hypotension, these men should consult with a doctor for further advice.
- Another PDE5 inhibitors, or a higher or lower dose of sildenafil. Men taking 50 mg of sildenafil can use the product providing they meet the criteria for pharmacy supply and do not exceed 50 mg as a daily dose.
- CYP3A4 inhibitors or alpha-blockers (see Table 2 for examples). These patients should be advised to speak with their GP about a lower suitable starting dose which is available on prescription.

Table 2: Examples of CYP3A4 inhibitors and alpha-blockers

Drug class	Drug name
Antibiotics	Erythromycin, clarithromycin
Antifungals	Itraconazole, ketoconazole
Calcium channel blockers	Diltiazem, verapamil
H2-antagonists	Cimetidine
HIV-protease inhibitors	Amprenavir, fosamprenavir, atazanavir, darunavir, indinavir, lopinavir, ritonavir, saquinavir, tipranavir
Alpha blockers	Phenoxybenzamine, phentolamine, tolazoline, trazodone, alfuzosin, doxazosin, tamsulosin, prazosin, terazosin

Case studies

Case study 1:

Mr. B is a 70-year-old man who wants to talk to you about sildenafil. After questioning, you discover he is a smoker with a history of cardiovascular issues including angina, despite undergoing bypass surgery 3 years ago. He is taking a range of cardiac medications including glyceryl trinitrate spray for his chest pains. He also has a number of other issues including type 2 diabetes and benign prostatic hypertrophy treated with tamsulosin.

How would you talk to him? Would you supply Viaredin in this situation?

See page 25 for case study responses.

Section 3

3. What is the Viaredin Pharmacy Consultation Guide?

The Viaredin Pharmacy Consultation Guide (see pages 13-14) has been created as an optional assessment tool. It helps you evaluate whether your patient is suitable for Viaredin. It also provides information which enables you to offer valuable health advice for men.

Primarily you should rely on your professional judgement to decide when and how to use the Guide. The recommendation, however, is to use the supplied questions as a framework to assess suitability. You may also wish to check the patient's medication record and their concomitant conditions.

The Pharmacy Consultation Guide includes an assessment of the man's overall fitness for sex. In particular, the focus is on cardiovascular problems, such as a recent heart attack or stroke which would be revealed through questioning. The following should be considered:

- There is a degree of cardiac risk associated with sexual activity, although the risk is small in those with stable CVD.
- Checking the man's fitness for sex helps identify his CV risk. Patients with a low risk can be initiated on Viaredin and reminded to follow up with their GP as soon as possible within 6 months.
- It also helps identify men at higher risk of CV problems who would benefit from further investigation by their doctor, preferably as soon as possible.

The patients who do not receive the product should be provided with the reason for non-supply and advised to go to the doctor. A tear off piece is included at the bottom of the Pharmacy Consultation Guide for this purpose which contains an applicable section. The patient can then show the slip to the doctor to help start the conversation.

Pharmacy Consultation Guide

The following Guide has been created as a useful tool to help determine whether your patient is suitable for Viaredin, or whether he should visit a doctor for further advice. Use of the Pharmacy Consultation Guide is optional. Primarily you should rely on your professional judgement to decide when and how to use it. The Essential Information for the Supply of Viaredin provides additional background information.

Repeat supply

If the patient has previously taken Viaredin, he should be asked if anything has changed with respect to his health status or use of concomitant medication. There is no need to repeat the questions below prior to resupply in that case. Please remind the patient to make an appointment with his doctor as soon as possible within the first 6 months after starting to use Viaredin, to ensure that his erection problems are not caused by any serious health condition. If any factors have changed, Sections 2–4 should be reviewed again. The repeat supply tear-off slip (see below) can also be given to the patient.

1. Who is Viaredin for?

Viaredin is only indicated for men aged 18 years and older with erectile dysfunction (ED) (i.e. difficulty in getting and/or maintaining an erection satisfactory for sexual performance). This product must not be supplied to men without ED. It is not essential whether a patient has a previous diagnosis of ED.

It is important to detect if a patient is already receiving treatment for this condition.

Patients currently prescribed sildenafil 50 mg can be supplied with this product if they meet the criteria for pharmacy supply, provided they do not take more than 50 mg daily. If a patient is using a different dose of sildenafil or another ED treatment, he should be referred to his doctor.

2. Check patient's cardiovascular (CV) status

If the patient answers **YES** to any of the following: **do not supply the product** and refer to the doctor. If you have any reason to suspect, based on physical status, the patient should not use this product, refer to the doctor too.

- Y** **N** Has your doctor advised that you are not fit enough for any physical and/or sexual activity?
- Y** **N** Do you feel very breathless or experience chest pain with light or moderate physical activity, such as walking briskly for 20 minutes or climbing two flights of stairs?
- Y** **N** Have you had a heart attack or a stroke within the last 6 months?
- Y** **N** Do you have any other heart problems or do you receive any treatment for any of the following:
- Unstable angina (chest pain), irregular heartbeat or palpitations (arrhythmia)
 - Low blood pressure or uncontrolled high blood pressure
 - A problem with one of the valves in your heart (valvular heart disease)
 - A problem where the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy)
 - Heart problems causing blood flow issues (e.g. left ventricular outflow obstruction, aortic narrowing) or severe cardiac failure

3. Check concomitant conditions

If the patient answers **YES** to any of the following: **do not supply the product** and refer to the doctor.

- Y** **N** Do you have Peyronie's disease or any other deformation of the penis?
- Y** **N** Have you ever had loss of vision because of damage to the optic nerve (such as non-arteritic anterior ischaemic optic neuropathy [NAION]) or an inherited eye disease (such as retinitis pigmentosa)?
- Y** **N** Do you have any bleeding issues (e.g. haemophilia) or active stomach ulcer?
- Y** **N** Do you have previously diagnosed hepatic (liver) disease (including cirrhosis of the liver) or severe renal (kidney) impairment?
- Y** **N** Do you have any of the following: sickle cell anaemia, multiple myeloma or leukaemia?
- Y** **N** Do you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption?

4. Check concomitant medication use

If the patient answers **YES** to any of the following or if there is uncertainty around the patient's current medications: **do not supply the product** and refer to the doctor.

- Y** **N** Are you taking nitrates (nicorandil or other nitric oxide donors e.g. glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?
- Y** **N** Are you using riociguat or other guanylate cyclase stimulators for lung problems?
- Y** **N** Are you taking drugs called 'poppers' for recreational purposes (e.g. amyl nitrite)?
- Y** **N** Are you taking ritonavir (for HIV infection)?
- Y** **N** Are you taking any CYP3A4 inhibitors, e.g. saquinavir (to treat HIV infection), cimetidine (a heartburn treatment), itraconazole or ketoconazole (to treat fungal infections), erythromycin (antibiotics) or diltiazem (for high blood pressure)?
- Y** **N** Are you taking any alpha-blockers, such as alfuzosin, doxazosin or tamsulosin (to treat urinary problems) due to enlarged prostate (benign prostatic hyperplasia) or occasionally to treat high blood pressure?

Additional advice

1. As well as the physical causes of ED (e.g. diabetes mellitus cardiovascular disease) you should also consider psychological causes, such as undiagnosed anxiety, depression, or excessive alcohol use.
2. The following medications can cause ED: diuretics, anti-hypertensives, corticosteroids, anticonvulsants and recreational drugs.
3. Besides, you should provide lifestyle advice and recommend a follow-up with a doctor.

Points for counselling and additional information

Please follow these points to ensure that your patient is counselled appropriately whether he is supplied the product or not.

Advice for men who have not been supplied Viaredin

Men who have not been supplied Viaredin due to their cardiovascular health or another concern must be told to see their GP as soon as they can within 6 months. The tear-off slip (below) can be filled in and given to the man to facilitate his discussion with the doctor.

Advice for men who have been supplied Viaredin

Men should be advised:

- They should schedule a health check-up with their GP as soon as possible within the first 6 months of starting to use Viaredin to ensure that their erection problems are not caused by any serious health condition.
- Viaredin is only indicated for men aged 18 years and older who have erectile dysfunction (ED). Men who without ED will not benefit from using this product.
- The maximum recommended dosing frequency is one 50 mg tablet per day.
- Take one tablet approximately 1 hour prior to a sexual intercourse. Viaredin starts to work within 30 minutes.
- Take with or without food. Please consider that Viaredin may take longer to work after a high-fat meal.
- They may need to take Viaredin a number of times on different occasions (a maximum of one 50 mg tablet per day), before they can achieve a penile erection satisfactory for sexual activity. If, after several attempts, patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult a doctor.
- Medicines containing any nitrates (e.g. glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, amyl nitrite also known as 'poppers'), or nitric oxide donors (e.g. sodium nitroprusside or nicorandil), must NOT be used at the same time as Viaredin as this combination may lead to a dangerous fall in blood pressure.
- Do not take Viaredin with grapefruit or grapefruit juice, as it may modestly increase plasma levels of sildenafil.
- Men should tell their doctor that they have started taking Viaredin, especially if they receive any new medicines.
- Remind patients about common side effects. These include: headache, dizziness, flushing, dyspepsia, nasal congestion, nausea, visual disturbance, cyanopsia (blue-tinted vision) and blurred vision.

Note: If any of these become a concern, advise the patient to consult a pharmacist or a doctor.

Men should be advised to STOP TAKING Viaredin and seek medical advice IMMEDIATELY if they experience the following SERIOUS SIDE EFFECTS (Side effects can be reported by patients or pharmacists via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine):

- Chest pains: If this occurs before, during or after intercourse, they should get into a semi-sitting position and try to relax. Nitrates must NOT be used to treat chest pains.
- An allergic reaction. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat.
- A sudden decrease or loss of vision.
- A persistent and sometimes painful erection lasting longer than 4 hours.
- Serious skin reactions such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Syndrome (TEN). Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals and around the eyes, fever.
- Seizures or fits.

Follow up advice for all men

- ED can be associated with a number of contributing conditions, e.g. diabetes mellitus, hypertension, hypercholesterolaemia or cardiovascular disease. As a result, all men with ED should be advised to consult their doctor within 6 months for a clinical review of potential risk factors associated with ED.
- You may also want to check if the man is buying products from unregulated sources. It is important to explain that these products are not tested for their safety or effectiveness, may not contain the ingredients listed within them and are therefore potentially dangerous, unlike products sourced from a pharmacy and medicines obtained via prescription from the doctor.
- Provide appropriate advice on lifestyle factors and general healthy living, including:
 - Losing weight
 - Cutting back on alcohol/recreational drugs
 - Giving up smoking
 - Exercising regularly
 - Reducing stress
- You can also offer the man a health check, if available.

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Section 4

4. Advice for men who are suitable for the treatment with Viaredin

Advise patients:

- The product is only for men with ED aged 18 years and over. Men who do not have ED will not benefit from this product.
- While visiting the doctor men should tell the doctor that they have started taking Viaredin, especially if they are started on any new medicines.
- To avoid taking nitrates (e.g. glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate), nitric oxide donors (e.g. sodium nitroprusside or nicorandil) or amyl nitrite (“poppers”) as these can cause a dangerous drop in blood pressure when used concomitantly.
- Excessive alcohol consumption can impact sexual function, as it can impair motor and cognitive function. In this case, Viaredin may be less effective.
- How to take Viaredin:
 - Take 1 tablet approximately 1 hour prior to sexual intercourse or to masturbation.
 - Do not take more than 1 tablet per day.
 - Swallow the tablet whole, with water.
 - Viaredin can start to work within 30 minutes, but men are still able to obtain an erection in response to sexual stimulation for up to 4 hours post-dose.
 - Viaredin can be taken with or without food but it may take longer to work after a high-fat meal.
 - Avoid grapefruit juice as this may increase sildenafil levels in the blood.
- One Viaredin tablet can be taken daily, men should be advised to visit their doctor as soon as possible within 6 months of starting the product for a general health check-up. Once reviewed by their doctor, they can continue using the product, providing there is no change in their circumstances (health or medication).
- For most men, Viaredin will work the first or second time they try it. For men who have not been able to have sexual intercourse for some time, it can take additional attempts to obtain maximum benefit. If after several attempts (up to 8 separate dosing occasions) patients are still not able to achieve a penile erection sufficient for satisfactory sexual activity, they should be advised to consult their doctor.
- If they experience any of the serious side effects (see Side Effect section), they should stop taking Viaredin and seek IMMEDIATE medical advice.

What should be done if a patient takes more than the recommended dose of Viaredin?

In single dose volunteer studies of doses up to 800 mg, adverse reactions were similar to those seen at lower doses, but the incidence rates and severities were increased.¹⁵ If you are concerned a patient has taken an overdose, refer him immediately to the nearest Hospital Emergency Department or their on-call GP.

Are there any side effects associated with Viaredin?

Sildenafil is generally well tolerated and side effects reported in association with its use are usually transient and mild to moderate in intensity.

Patients who experience any of the following after taking Viaredin should be advised to STOP it and seek IMMEDIATE medical advice:

- During or immediately after sex: chest pain, dizziness, feeling of faintness or nausea.
- Nitrates must NOT be used to treat chest pain.
- Sudden decrease in vision or hearing
- A persistent and sometimes painful erection that lasts more than 4 hours
- Allergic reaction including sudden difficulty breathing, wheeziness, dizziness or swelling of eyelids, face, lips and throat
- Serious skin reactions which include severe peeling and swelling of the skin, blistering of mouth, genitals and around the eyes, and fever
- Seizure or fits

A full list of side effects experienced with Viaredin can be found in the SmPC which is available on the HPRA website.¹⁵

The most commonly reported side effects in the use of Viaredin are:

- Headache
- Flushing, hot flush
- Nausea, dyspepsia
- Nasal congestion
- Dizziness
- Visual disturbance, blurred vision
- Visual color distortions

Advice for men who are not suitable for Viaredin

Please see also Section 2.

If unsuitable for Viaredin, it is important to advise the man of the reason (e.g. it may be a contraindication or absence of ED). All men with ED should be referred to their GP to assess other suitable opts as soon as possible within 6 months. Men should be encouraged to seek advice from their doctor for two reasons. First, ED may be a symptom of other conditions that need medical attention. Second, although Viaredin is not suitable for them, the doctor may be able to prescribe medicines which are suitable.

General advice for all men

ED can be associated with psychological conditions and certain medications, as well as a number of underlying conditions, e.g. diabetes mellitus, hypertension, hypercholesterolaemia or cardiovascular disease. As a result, all men with ED should be advised to consult their doctor within 6 months for a clinical review of potential underlying conditions and risk factors associated with ED. A patient leaflet may also help him to learn more about ED.

Lifestyle advice should be provided to all men, as it can help to reduce the risk factors for ED and improve general health:

- Weight management
- Regular exercise
- Healthy food
- Reducing stress
- Quitting smoking
- Moderating alcohol consumption
- Avoiding recreational drugs

Case studies

Case study 3:

Mr. T is a 55-year-old smoker who asks if he can speak to you in private. You take him into the consultation area, where you find out he has ED. Mr. T wants to buy 2 packs of Viaredin but does not want to go into any details about his issue. You ask him how long he has had the problem and he explains that he has been drinking more since he lost his job last year. He tells you his partner asked him to visit the pharmacy amid worries about his sexual and mental health.

How would you talk to him? Would you supply Viaredin in this situation? What other advice could you offer?

Remember: ED may not be the only concern; Mr. T has some signs that could indicate untreated depression.

See page 25 for case study responses

Section 5

5. Patient supply scenarios

The decision to supply Viaredin or not is simple in the majority of cases. But there may be some situations where the decision is less clear.

In this section, you find some less frequent, but more thought-provoking supply scenarios.

Which of the following patients do you think are suitable for Viaredin?

For some suggested actions see pages 23-24.

- S1** Mr. W is a 59-year-old man. He has started a new relationship and reveals that he has been having problems with his erectile function for the last year. At his regular health check-up at his doctor 6 months ago, there was nothing untoward found in his assessment. He is in relatively good health and takes ibuprofen for osteoarthritis; he was a smoker but gave up about 7 years ago.
- S2** Mr. G has had difficulty controlling his hypertension over the last months. After many changes, he has been stabilized for the past 3 months on a thiazide-related diuretic and an angiotensin-II receptor antagonist combination. Currently, he is having problems with his ability to keep an erection and wonders if Viaredin would be suitable for him.
- S3** Mr. T has had a heart attack 7 months ago that resulted in bypass surgery. After cardiac rehabilitation, he is no longer experiencing any chest pain or breathlessness. He explains he is interested in using Sildenafil and his GP has advised him to talk with you about the OTC options available. Mr. T is on a standard regimen of drugs including aspirin, a statin and an ACE inhibitor and he also takes a non-steroidal anti-inflammatory drug.
- S4** Mr. J is a 40-year-old man in good health and follows a good diet and exercise regime. But he tells you his new girlfriend is hard to satisfy. While he has no issues with having sexual intercourse, he is finding it is taking him longer to recover post coitus and he wants something to 'pep him up'.
- S5** Mr. R came to discuss options for the treatment of ED. He said that although he has held a prescription for sublingual glyceryl trinitrate for a number of years, he has not needed to use this. He is on a standard combination of other drugs to control his symptoms. His doctor has removed the nitrate from his drug regimen yesterday. Therefore, he is keen to discuss whether or not Viaredin would be suitable for him as he is experiencing erectile dysfunction. You see from his drug records there are no other contraindicated medicines, and he has no further cardiovascular related symptoms.

S6

Mr. L has been coming to your pharmacy on a regular basis and has been purchasing Viaredin. 7 months passed since his first purchase and although you have repeatedly reminded him he needs to follow up with his doctor, he hasn't done so.

S7

Mr. H came into your pharmacy last week and after asking him questions from Pharmacy Consultation Guide you supplied an 8-tablet pack of Viaredin. He is back this week and has asked for a further supply of 8 tablets.

S8

Mr. S is a regular patient who was started on a course of treatment with an SSRI for depression about 4 weeks ago. Whilst Mr. S is feeling much happier, he has noticed he has had trouble getting and keeping an erection. Mr. S is keen to try Viaredin

S9

Mr. A is a 70-year-old man who has recently started a new relationship. He tells you he is concerned about the quality of his erection. You ask him about his medication history, and he tells you he takes a product for BPH. On further questioning you ascertain the drug is finasteride. Mr. A has not had sex since he lost his wife 3 years ago, and he is keen to try Viaredin.

Scenarios: Suggested actions

- S1** Viaredin can be supplied to Mr. W. He appears to be in good health. He has given up smoking and he regularly visits his doctor. The information he has provided helps with the supply decision. For most men, Viaredin will work the first or second time they try it. For men who have not been able to have sexual intercourse for some time, it can take additional attempts to obtain maximum benefit (up to 8 separate dosing occasions). If he doesn't respond after 8 doses, he should be advised to consult with his GP. He should also inform his GP about taking Viaredin as soon as possible within 6 months.
- S2** Viaredin can be supplied to Mr. G as his hypertension is controlled and he is not taking any contraindicated medicines now. Mr. G is under the care of a doctor as he has been stabilized with respect to his hypertension. Mr. G appears to be fit for sex. Advise him of the likely side effects of Viaredin and say that he should visit the doctor as soon as possible within 6 months. Advise him to come back if he has any problems or if there are any changes to his health or medication.
- S3** Viaredin can be supplied to Mr. T as it has been more than 6 months since his heart attack, and he is not taking any contraindicated medications. Provide Mr. T with the usual follow-up advice. He has obviously followed his specialist's advice and has done well with his cardiac rehabilitation. Therefore, he should be counselled on using the product correctly and to go back to the doctor as soon as possible within 6 months.
- S4** Viaredin cannot be supplied to Mr. J as it can not help with his problem. The drug is only indicated for men who have ED and have described their symptoms in line with the definition of ED. The no supply slip should be completed, and he should be advised to visit his doctor for further advice.
- S5** Viaredin can be supplied to Mr. R. By means of the Pharmacy Consultation Guide, it has been ascertained that he is not taking any contraindicated medications and had no other overt CV issues. Therefore, he looks like a suitable candidate for the product. The Pharmacy Consultation Guide should be used to provide advice to counsel Mr. R in using the product correctly and advise that he return to see his doctor as soon as possible within 6 months.
- S6** As there are no restrictions within the SPC to prevent supply of the product under such circumstances, the product can be supplied. However, the man should again be reminded that he should see his GP and that this may be because there are underlying conditions which may be causing the ED. If you get to the point where you feel that the man has not taken your advice, it is longer than 6 months post supply and the man has continued not to see his GP, you are free to use your professional judgement and state you do not wish to supply until he has been assessed by his GP.

S7

Provided there has been no change since Mr. H completed the Pharmacy Consultation Guide, you can provide a further supply of Viaredin. Remind him the maximum dose is 1 tablet per day. It is also important to check that the drug is working for Mr. H. The message to see his GP as soon as possible within 6 months should be repeated.

S8

Provide Mr. S with positive encouragement that it is good to hear that the anti-depressant is working and that he is feeling happier and reiterate that despite this issue he should not stop taking the anti-depressants. State that ED can be a side effect of anti-depressants but reinforce that Viaredin can be supplied. Make sure to advise Mr. S to tell his GP he has started taking Viaredin and that he has experienced ED. You should also counsel him on what he should do Viaredin makes no difference and that in this case he should not discontinue his SSRI medication but return to the GP immediately for further advice.

S9

Viaredin can be supplied to Mr. A as according to the Pharmacy Consultation Guide, he is fit for sex, he has good cardiovascular health and is not taking any contraindicated medicines. Provide advice on using the product, particularly as he has not had sex for 3 years, it may take several attempts before it works. For most men, Viaredin will work the first or second time they try it. For men who have not been able to have sexual intercourse for some time, it can take additional attempts to obtain maximum benefit (up to 8 separate dosing occasions). If it doesn't work after 8 different dosing occasions (a maximum of one 50 mg tablet per day) he should see his GP. He should also be advised to see the GP as soon as possible within 6 months of taking Viaredin for a health check.

Section 6

6. Case Study Responses

Case study 1

Mr. B falls in the category of patients using nitrates. Therefore, you must not supply Viaredin to him. Taking a nitrate and Viaredin together may lead to a significant drop in blood pressure. You should advise Mr. B of this fact and advise him to speak to his GP about this. Additionally, it is important to provide counselling around his other medical issues.

Case study 2

Given that ED can be an early sign of the development of underlying CVD and coupled with the fact Mr. G is getting out of breath quickly, you should advise him to visit his doctor for a check-up. You can discuss Mr. G's lifestyle and provide him with some information on this. You should not supply the product and advise him to take further advice from his GP. This guide and the Pharmacy Consultation Guide provide more information on these issues.

Case study 3

In case of Mr. T, the Pharmacy Consultation Guide should be applied to establish his symptoms and to look at the underlying issues. As he is a smoker, there is a possibility that he has some health problems. The Pharmacy Consultation Guide is designed to help you explore these issues. It is important to remember ED may not be the only concern. Mr. T has some signs that could indicate untreated depression. Therefore, Mr. T should be advised to see his doctor to get a thorough assessment of his physical and mental health. The decision to supply the product will depend on the answers he gives you.

Case study 4

For some patients Viaredin may not work after the first few doses. This can be for a variety of reasons. The man may have been out of practice for a while or may need a higher dose or an alternative treatment. With Mr. H, it is important to clarify, how he used the product, e.g. did he take it on an empty stomach or after a meal? Did he take it one hour prior to a sexual intercourse?

Once correct use is established and advised on, it will be important to understand what his situation is. For example, is this a new relationship or an existing one? Was he nervous because he hadn't had sex for some time? Experts advise that men may need to take up to 8 doses of a PDE5 inhibitor on different occasions before they are considered a non-responder. In this case, you should advise Mr. H to try the product on his own to get used to the effects before proceeding to sexual intercourse. If after a few attempts the product is still not providing a satisfactory response, Mr. H should be advised to come back to speak to you or to visit his GP for further advice.

Case study 5

There is no need for Mr. W to stop treatment and seek medical advice due to the headache or nausea he has experienced. You should remind him that headache is a very common side effect of Viaredin and may be experienced by approximately 1 in 10 men. Nausea is also common, but both side effects are generally mild and transient. You can also suggest that if Mr. W gets an occasional headache when taking Viaredin. If his headaches continue or worsen in intensity, Mr. W should be advised to come back to speak to you or visit his GP for further advice.

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