

PHARMACIST SUPPLY OF VEDAFIL[®] (sildenafil citrate) WITHOUT A PRESCRIPTION



Brought to you by Viatris New Zealand
in association with Vedafil[®]



INTRODUCTION

The 51st Medicine Classification Committee (MCC) meeting held in April 2014 approved the reclassification of sildenafil to:

*“[prescription medicine] except in medicines for oral use containing 100 milligrams or less per dose unit when sold in the manufacturer’s original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35-70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand”.*¹



TRAINING CONTENTS

- Introduction to erectile dysfunction
- Physiology of erection
- Erectile dysfunction causes and risk factors
- Erectile dysfunction management
- Mechanism of action of Vedafil (sildenafil)
- Vedafil (sildenafil) indication and presentations
- Vedafil (sildenafil) dosage and administration
- Vedafil (sildenafil) precautions and contraindications
- Vedafil (sildenafil) adverse effects
- Erectile dysfunction assessment for pharmacists
- Vedafil (sildenafil) patient assessment tool
- Patient counselling
- Advising the patient's doctor of the supply of Vedafil (sildenafil)
- Resupply of Vedafil (sildenafil)
- Assessment of understanding



ERECTILE DYSFUNCTION (ED)¹

- Persistent inability to **attain and/or maintain penile erection** sufficient for satisfactory sexual performance.
- ED is a common condition affecting approximately one in three NZ men aged between 40 – 70 years.¹ It can be the total inability to achieve an erection, an inconsistent ability to do so, or a tendency to sustain only brief erections.
- ED affects the quality of life for men and their partner.

PHYSIOLOGY OF ERECTION

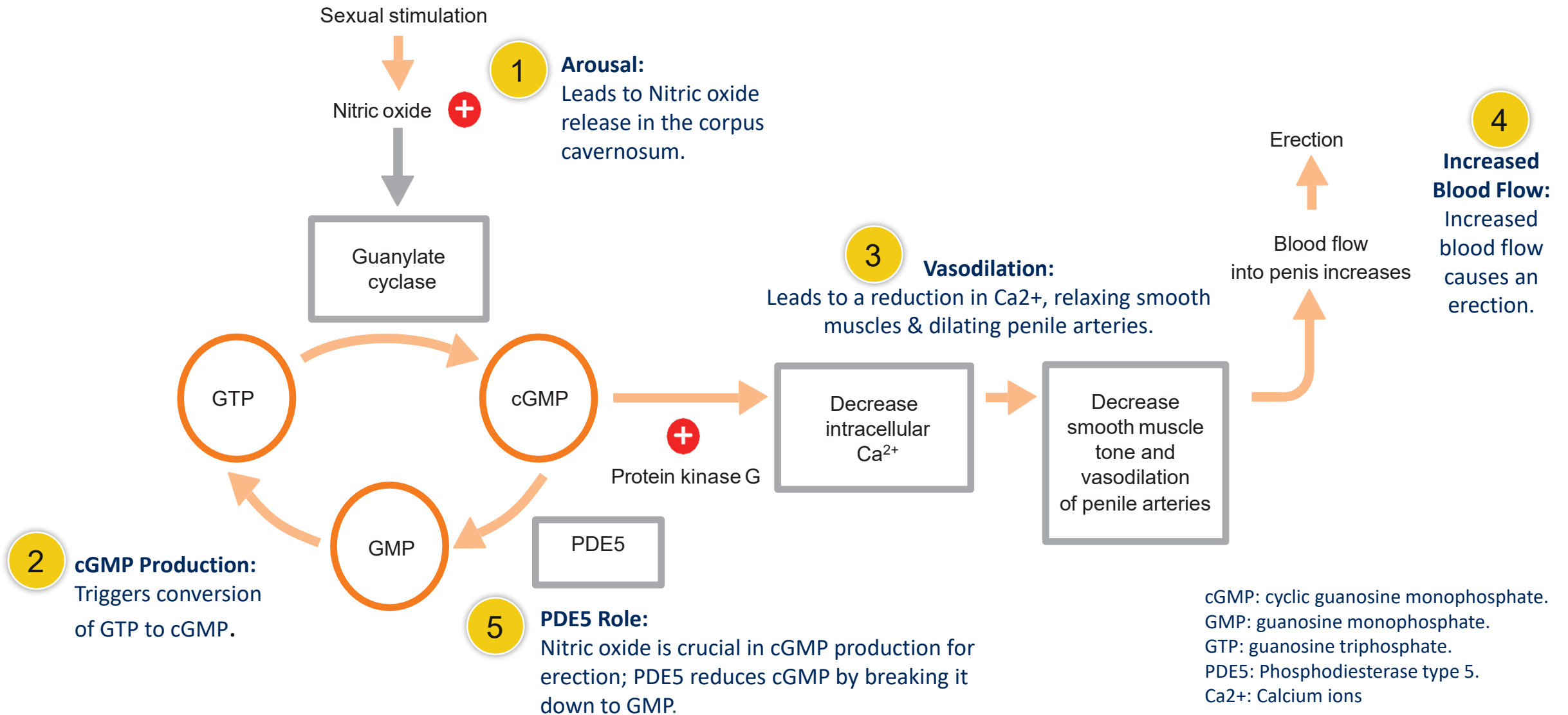


Figure 1: Mechanism of erection (Adapted from Stacey P, Mount N. Male erectile dysfunction: the biochemistry of Viagra. The Biochemist 2002;24(2):16-18.)

ERECTILE DYSFUNCTION CAUSES^{1,2}

Multifactorial aetiology:

ED has multiple underlying causes.

Possible Factors:

- **Organic:** Physical health issues.
- **Psychological:** Psychological factors.
- **Combination:** A mix of both.

Practice Point: During consultations, identify potential ED causes by considering the patient's concerns, symptoms, and treatment history.

Organic and psychological causes of ED	
Organic	Psychological
Vascular disease	Performance anxiety
Diabetes mellitus	Generalised anxiety
Medications <ul style="list-style-type: none"> • Antidepressants • Psychotropics • Antihypertensives 	Major depression
Cigarette smoking	
Alcohol	
Neurological disorders	
Hypogonadism	

References:

1. Arduca P. Erectile dysfunction: A guide to diagnosis and management. Aust Fam Physician 2003; 32(6): 414-420.
2. McMahon CG. Current diagnosis and management of erectile dysfunction. Med J Aus 2019;210(10):469-476.

ERECTILE DYSFUNCTION RISK FACTORS

Risk factors may include¹:

- **Physiological:** increased Age, Metabolic syndrome
- **Medical Condition:**
 - **Cardiovascular disease and its risk factors** e.g. sedentary lifestyle, obesity, diabetes, hypertension, dyslipidemia, smoking.
 - **Endocrine disorders** e.g. diabetes, androgen deficiency, thyroid disorders, hyperprolactinaemia.
 - **Neurological conditions** affecting the brain, spinal cord, or autonomic nervous system.
 - **Prostate cancer therapy.**
 - **Penile disorders** e.g., Peyronie disease
- **Prescription Medication:** e.g., beta blockers, antidepressants, antipsychotics
- **Lifestyle:** recreational drugs, cigarette smoking, alcoholism
- **Psychological:** Performance Anxiety, Depression

Practice Point: During patient consultations, identify and address potential ED risk factors to provide comprehensive care and appropriate treatment options.



ERECTILE DYSFUNCTION MANAGEMENT

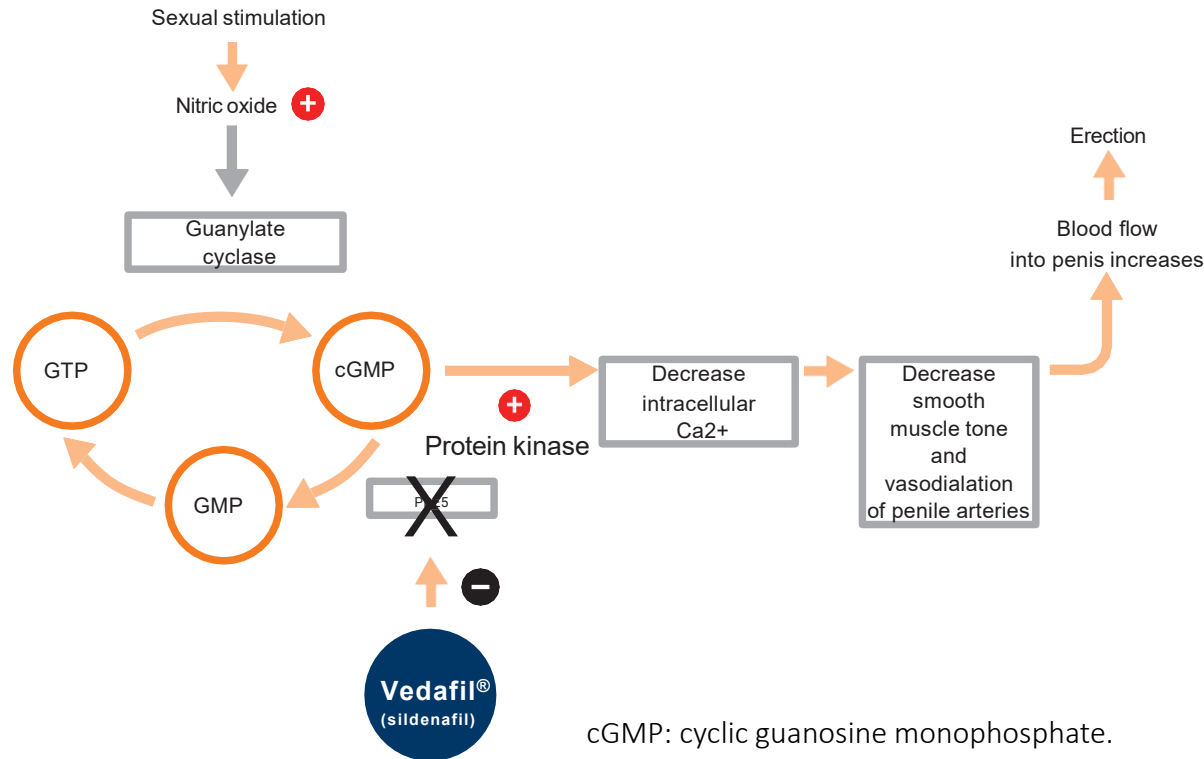
ED Management depends on causes and risk factors and can involve non-pharmacological and pharmacological interventions¹.

- **Consider causes and risk factors:** e.g. discussing anxiety, stress, or performance issues, and exploring ways to enhance your relationship may help couples have a more satisfying sex life.
- **Consider lifestyle changes:** e.g. discuss, where applicable, reducing alcohol consumption, smoking cessation
- **Review medicines:** e.g. review medicines that may contribute to ED, if possible, discuss with prescriber discontinuation or switching to alternatives.
- **Pharmacological options:** can include PDE5 inhibitors (e.g. sildenafil, tadalafil, vardenafil), hormonal therapy and surgical options.
- **Other interventions:** e.g. vacuum devices or intracavernosal injections.

Practice Point: Evaluate risk factors, provide counseling, assess cardiac risk, and tailor treatment to individual needs.



MECHANISM OF ACTION OF VEDAFIL (sildenafil)¹



cGMP: cyclic guanosine monophosphate.
GMP: guanosine monophosphate.
GTP: guanosine triphosphate.
PDE5: Phosphodiesterase type 5.
Ca²⁺: Calcium ions

cGMP Breakdown:

- PDE5 breaks down cGMP to GMP and then to GTP.
- This causes penile arteries to constrict, reducing blood flow and resulting in a flaccid penis.

Vedafil (sildenafil) Action:

- Vedafil (sildenafil), potent selective inhibitor of PDE5.
- Prevents cGMP degradation in the corpus cavernosum.
- Sustains erection by maintaining cGMP levels.

Nitric Oxide/cGMP Pathway:

- Activated by sexual stimulation. PDE5 inhibition increases cGMP, enhancing erection.

Practice Point: Sildenafil requires sexual stimulation to be effective by inhibiting PDE5, thereby sustaining erection.

VEDAFIL (sildenafil) INDICATION AND PRESENTATION

Indication:

- Used for the treatment of ED¹.
- Requires sexual stimulation for effectiveness¹.

Presentation:

- Available in various doses (e.g., 25 mg, 50 mg, 100 mg)¹.

Access:

- Prescription only but can be supplied by a registered pharmacist without a prescription when sold in the original pack containing not more than 12 tablets for the treatment of ED in males aged 35-70 years after undertaking this training programme².



References:

1. Vedafil[®] Data Sheet (20 August 2021). Retrieved from: www.medsafe.govt.nz. Accessed July 2024.
2. Sildenafil. Medsafe Classification Database. Retrieved from: www.medsafe.govt.nz/profs/class/classintro.asp

VEDAFIL (sildenafil) DOSAGE AND ADMINISTRATION¹

Effectiveness:

- Works only with sexual stimulation, taking usually **30 minutes to 1 hour** to work.

Dosage:

- **Recommended starting dose:** 50 mg one hour before sexual activity.
- **Adjust** based on efficacy and tolerance.
- **Maximum dose:** is 100 mg per day.
- **Do not** exceed one dose per day.

Special Considerations:

- **Elderly:** consider lower starting dose of 25 mg due to reduced clearance.
- **Potent CYP3A4 inhibitors** (e.g. ketoconazole, itraconazole, erythromycin): start with 25 mg.
- **Alpha Blockers:** Stabilise alpha blocker therapy before starting sildenafil; consider a lower dose.

Food Interaction:

- Onset **may be delayed** if taken with food. High-fat meals reduce absorption rate. Adjust dosing based on food intake and individual response.

Practice Point: Vedafil (sildenafil) requires sexual stimulation to work and has specific dosage recommendations and considerations for elderly patients and those on certain medications. Adjust based on efficacy, tolerability.

VEDAFIL (sildenafil) PRECAUTIONS AND CONTRAINDICATIONS¹

Identification of any of the following precludes supply of Vedafil (sildenafil) by pharmacists without a prescription and medical referral is required:

Cardiovascular (CV) health

- Advised by doctor to avoid vigorous exercise incl. sexual activity
- Difficulty walking briskly for 5 minutes or uphill without experiencing breathlessness or chest pain
- Previous heart attack/stroke/transient ischaemic attack
- History of angina (chest pain/tightness)
- Arrhythmia (irregular heartbeat or palpitations)
 - If Resting Heart Rate (HR) < 50 or > 100 bpm
- Previous coronary intervention (e.g. angioplasty, bypass, surgery, valve replacement)
- Cardiomyopathy (heart muscle disorder)
- Diabetes
- Low blood pressure or uncontrolled high blood pressure*
 - If Blood Pressure (BP) < 110/70 or > 160/95 mmHg
- High cholesterol (uncontrolled or untreated)
- Current tobacco smoker

Other medical conditions

- Deformity of the penis (e.g. Peyronie's diseases)
- Severe liver dysfunction
- Severe kidney dysfunction
- Blood disorders (sickle cell disease, leukaemia, multiple myeloma)
- Personal or family history of serious eye disorders (e.g. Retinitis pigmentosa), excluding glaucoma and cataracts

Concomitant medication:

- 2 or more antihypertensives
- Nitrates (e.g. glyceryl trinitrate, isosorbide salts) for chest pain
- Poppers (e.g. amyl nitrite) for recreational purposes
- Pulmonary arterial hypertension (PAH) treatments
- Ritonavir and saquinavir to treat HIV infection
- ED medication incl. other PDE5 inhibitors

Refer to the Vedafil® Data Sheet for further details on precautions, contraindications and drug interactions that warrant medical referral.

* Pharmacists conducting the vedafil® assessment must be appropriately trained in the measurement of blood pressure. Where an electronic monitor is used, the monitor must be of an appropriate standard for professional use and be regularly calibrated

Reference: 1. Vedafil® Data Sheet (20 August 2021). Retrieved from: www.medsafe.govt.nz. Accessed July 2024.

VEDAFIL (sildenafil) ADVERSE EFFECTS (AEs)¹

Most Common AEs:

- Headache
- Flushing
- Dyspepsia
- Nasal congestion
- Urinary tract infection
- Diarrhoea
- Rash.
- Dizziness

Serious AEs: (seek medical attention)

- Sudden loss of vision in one or both eyes.
- Sudden decrease or loss of hearing.
- Prolonged erections > 4 hours (or priapism > 6 hours) Conditions such as sickle cell anaemia, multiple myeloma or leukaemia can predisposes those.

Other AEs:

Transient visual disturbances (colour tinge, sensitivity to light, blurred vision) and dizziness have been reported, particularly at 100 mg dose .Driving or operating machinery is cautioned.





ERECTILE DYSFUNCTION ASSESSMENT FOR PHARMACISTS

Key Steps

- Take a thorough medical history.
- Use screening questions to address concerns and identify potential causes.

Health Checks:

- ED can signal vascular disease.
- Encourage all men with ED to see a doctor for heart and diabetes checks.

Patient Assessment Tool (see next slide):

Identify low-risk men for whom Vedafil (Sildenafil) can be supplied without a prescription.

Important: Ensure comprehensive evaluation before dispensing.

VEDAFIL (sildenafil) PATIENT ASSESSMENT TOOL

Use the Vedafil (sildenafil) Patient Assessment Tool to:

- Assess if Vedafil (sildenafil) is safe and appropriate for your patient
- Provide a record of your consultation

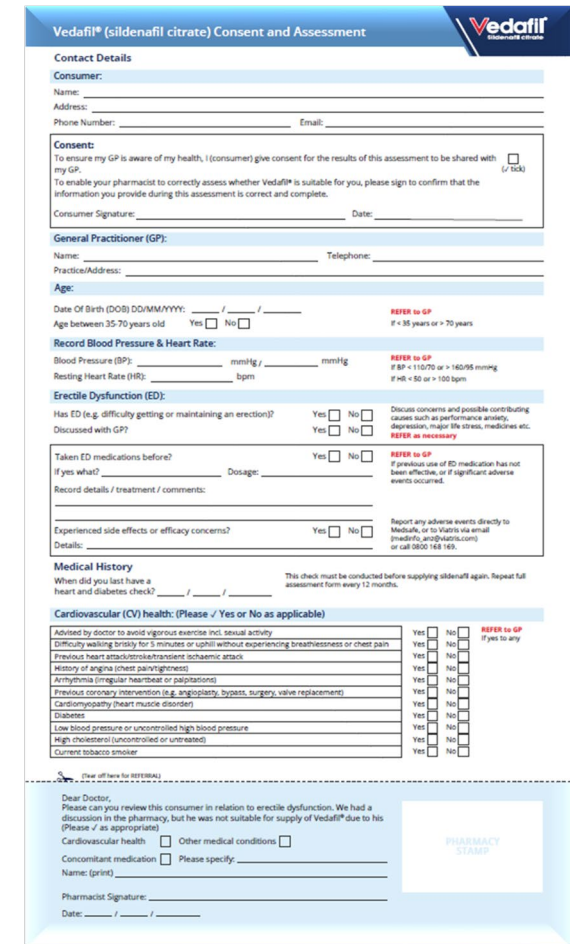
The Vedafil (sildenafil) Patient Assessment Tool includes the following sections:

- Contact Details: Consumer and GP
- Age
- Record Blood Pressure & Heart Rate
- Presentation / History of ED
- Medical History
- Vedafil (sildenafil) Dose Selection
- Counselling Tips

GP Referral:

- Certain responses may immediately indicate that a patient requires referral. The Vedafil (sildenafil) Patient Assessment Tool includes a tear off section where referral notes may be filled out for the patient to share with their GP.

Ensure the patient consultations are conducted in a private consultation room/area.



Vedafil® (sildenafil citrate) Consent and Assessment

Contact Details

Consumer:

Name: _____

Address: _____

Phone Number: _____ Email: _____

Consent:

To ensure my GP is aware of my health, I (consumer) give consent for the results of this assessment to be shared with my GP. (tick)

To enable your pharmacist to correctly assess whether Vedafil® is suitable for you, please sign to confirm that the information you provide during this assessment is correct and complete.

Consumer Signature: _____ Date: _____

General Practitioner (GP):

Name: _____ Telephone: _____

Practice/Address: _____

Age:

Date of Birth (DOB) DD/MM/YYYY: ____ / ____ / ____ **REFER to GP**

Age between 35-70 years old Yes No **if < 35 years or > 70 years**

Record Blood Pressure & Heart Rate:

Blood Pressure (BP): _____ mmHg / _____ mmHg **REFER to GP**

Resting Heart Rate (HR): _____ bpm **if BP < 115/70 or > 140/95 mmHg**

Erectile Dysfunction (ED):

Has ED (e.g. difficulty getting or maintaining an erection)? Yes No Discuss concerns and possible contributing causes such as performance anxiety, depression, major life stress, medicines etc. **REFER as necessary**

Discussed with GP? Yes No

Taken ED medications before? Yes No **REFER to GP**

If yes what? _____ Dosage: _____ **if previous use of ED medication has not been effective, or if significant adverse events occurred.**

Record details / treatment / comments: _____

Experienced side effects or efficacy concerns? Yes No Report any adverse events directly to Medsafe, or to Viatrix via email (medsafe_arp@viatrix.com) or call 0800 148 148.

Medical History

When did you last have a heart and diabetes check? ____ / ____ / ____ This check must be conducted before supplying sildenafil again. Repeat full assessment form every 12 months.

Cardiovascular (CV) health: (Please ✓ Yes or No as applicable)

Advised by doctor to avoid vigorous exercise incl. sexual activity	Yes <input type="checkbox"/>	No <input type="checkbox"/>	REFER to GP
Difficulty walking briskly for 5 minutes or uphill without experiencing breathlessness or chest pain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	if yes to any
Previous heart attack/stroke/transient ischaemic attack	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
History of angina (chest pain/angina)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Arrhythmia (irregular heartbeat or palpitations)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Previous coronary intervention (e.g. angioplasty, bypass, surgery, valve replacement)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Cardiomyopathy (heart muscle disorder)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Diabetes	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Low blood pressure or uncontrolled high blood pressure	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
High cholesterol (uncontrolled or untreated)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Current tobacco smoker	Yes <input type="checkbox"/>	No <input type="checkbox"/>	

Draw off here for REFERRAL

Dear Doctor,
Please can you review this consumer in relation to erectile dysfunction. We had a discussion in the pharmacy, but he was not suitable for supply of Vedafil® due to his (Please ✓ as appropriate)

Cardiovascular health Other medical conditions

Concomitant medication Please specify _____

Name: (print) _____

Pharmacist Signature: _____

Date: ____ / ____ / ____

PHARMACY STAMP

Contact Details

Consumer:

Name: _____
 Address: _____
 Phone Number: _____ Email: _____

Consent:

To ensure my GP is aware of my health, I (consumer) give consent for the results of this assessment to be shared with my GP. (✓ tick)

To enable your pharmacist to correctly assess whether Vedafil® is suitable for you, please sign to confirm that the information you provide during this assessment is correct and complete.

Consumer Signature: _____ Date: _____

General Practitioner (GP):

Name: _____ Telephone: _____
 Practice/Address: _____

Age:

Date Of Birth (DOB) DD/MM/YYYY: ____ / ____ / ____ **REFER to GP**
 Age between 35-70 years old Yes No if < 35 years or > 70 years

Record Blood Pressure & Heart Rate:

Blood Pressure (BP): _____ mmHg / _____ mmHg **REFER to GP**
 Resting Heart Rate (HR): _____ bpm if BP < 110/70 or > 160/95 mmHg
 if HR < 50 or > 100 bpm

Erectile Dysfunction (ED):

Has ED (e.g. difficulty getting or maintaining an erection)? Yes No Discuss concerns and possible contributing causes such as performance anxiety, depression, major life stress, medicines etc.
 Discussed with GP? Yes No **REFER as necessary**

Taken ED medications before? Yes No **REFER to GP**
 If yes what? _____ Dosage: _____ if previous use of ED medication has not been effective, or if significant adverse events occurred.

Record details / treatment / comments: _____

Experienced side effects or efficacy concerns? Yes No Report any adverse events directly to Medsafe, or to Viatris via email (medinfo_ano@viatris.com) or call 0800 168 169.

Medical History

When did you last have a heart and diabetes check? ____ / ____ / ____ This check must be conducted before supplying sildenafil again. Repeat full assessment form every 12 months.

Cardiovascular (CV) health: (Please ✓ Yes or No as applicable)

Advised by doctor to avoid vigorous exercise incl. sexual activity	Yes <input type="checkbox"/> No <input type="checkbox"/>	REFER to GP
Difficulty walking briskly for 5 minutes or uphill without experiencing breathlessness or chest pain	Yes <input type="checkbox"/> No <input type="checkbox"/>	if yes to any
Previous heart attack/stroke/transient ischaemic attack	Yes <input type="checkbox"/> No <input type="checkbox"/>	
History of angina (chest pain/tightness)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Arrhythmia (irregular heartbeat or palpitations)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Previous coronary intervention (e.g. angioplasty, bypass, surgery, valve replacement)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Cardiomyopathy (heart muscle disorder)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Diabetes	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Low blood pressure or uncontrolled high blood pressure	Yes <input type="checkbox"/> No <input type="checkbox"/>	
High cholesterol (uncontrolled or untreated)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Current tobacco smoker	Yes <input type="checkbox"/> No <input type="checkbox"/>	

(Tear off here for REFERRAL)

Dear Doctor,
 Please can you review this consumer in relation to erectile dysfunction. We had a discussion in the pharmacy, but he was not suitable for supply of Vedafil® due to his (Please ✓ as appropriate)

Cardiovascular health Other medical conditions

Concomitant medication Please specify: _____

Name (print) _____

Pharmacist Signature: _____

Date: ____ / ____ / ____

PHARMACY
 STAMP

Other medical conditions: (Please ✓ Yes or No as applicable)

Deformity of the penis (e.g. Peyronie's diseases)	Yes <input type="checkbox"/> No <input type="checkbox"/>	REFER to GP
Severe liver dysfunction	Yes <input type="checkbox"/> No <input type="checkbox"/>	if yes to any
Severe kidney dysfunction	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Blood disorders (sickle cell disease, leukaemia, multiple myeloma)	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Personal or family history of serious eye disorders (e.g. Retinitis pigmentosa, excluding glaucoma and cataracts)	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Concomitant medication: (Please ✓ Yes or No if consumer is taking any of the following):

2 or more antihypertensives	Yes <input type="checkbox"/> No <input type="checkbox"/>	REFER to GP
Nitrates (e.g. glyceryl trinitrate, isosorbide salts) for chest pain	Yes <input type="checkbox"/> No <input type="checkbox"/>	if yes to any
Poppers (e.g. amyl nitrite) for recreational purposes	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Pulmonary arterial hypertension (PAH) treatments	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Zidovudine and zalcitabine to treat HIV infection	Yes <input type="checkbox"/> No <input type="checkbox"/>	
ED medication incl. other PDE5 inhibitors	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Alpha-blockers (e.g. doxazosin, prazosin)	Yes <input type="checkbox"/> No <input type="checkbox"/>	See "Dose Selection" section below and refer to the data sheet for interactions and dose adjustments.
Potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, erythromycin)	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Any other medicines, either prescribed or purchased: _____

Any other health concerns or comments: _____

Dose Selection:

- A starting dose of **25 mg** should be considered for consumers:
 - Over 65 years of age
 - Taking alpha blockers such as doxazosin, prazosin
 - Taking CYP3A4 potent inhibitors such as erythromycin, ketoconazole and itraconazole
 - With hepatic impairment
 - With renal impairment
 And titrate accordingly to response and tolerability. See data sheet for further details.
- For all other eligible consumers, a starting dose of **50 mg** is recommended, and **100 mg** can be offered to established consumers requiring a higher dose.
- A pack size of 4 tablets is recommend for consumers taking Vedafil® for the first time. Larger pack sizes may be recommended for consumers who previously have taken Vedafil® successfully.
- Supply is restricted to a maximum of 12 tablets at any one time.

Vedafil® to be supplied (Please ✓)

25 mg 4 tablets 50 mg 4 tablets 100 mg 4 tablets 100 mg 12 tablets

Counselling Pharmacist:

Name (print) _____

Signature: _____

Date of consultation: ____ / ____ / ____

Date next full assessment due: ____ / ____ / ____

PHARMACY
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Vedafil® (sildenafil citrate) 25 mg, 50 mg & 100 mg tablets. Prescription Medicine except when supplied by a pharmacist who has successfully completed an approved training programme. Indication: For the treatment of erectile dysfunction in adult males. Vedafil® is an unfunded medicine. Special Authority and meeting the eligibility criteria may apply for select indications. Before recommending Vedafil® read the data sheet (available at www.medsafe.govt.nz) for information on dosage, contraindications, precautions, interactions and adverse effects. Vedafil® is a Viatris company trade mark. Viatris Limited, Auckland. Copyright© 2024 Viatris Inc. All rights reserved. NZ-VED-2024-00002. TAPS DA 2303MM-0604

Counselling Tips: (Please ✓)

- | | | | |
|--|--------------------------|--|--------------------------|
| Recommend to visit GP for a heart and diabetes check if not already had one. | <input type="checkbox"/> | Provide appropriate lifestyle advice including losing weight, giving up smoking, cutting back alcohol/recreational drugs, exercising regularly, reducing stress. | <input type="checkbox"/> |
| How to take Vedafil® | <input type="checkbox"/> | Provide, if appropriate: | |
| What to expect with Vedafil® | <input type="checkbox"/> | • Vedafil® CMI | <input type="checkbox"/> |
| When to seek further medical assistance | <input type="checkbox"/> | • Vedafil® Quick Guide | <input type="checkbox"/> |
| • Adverse effects | | • Vedafil® Loyalty card | <input type="checkbox"/> |
| • Warnings and precautions | | | |

PATIENT COUNSELLING

Dose Selection:

- The **Dose Selection** section of the Vedafil (sildenafil) Patient Assessment Tool provides guidance towards determining the appropriate Vedafil (sildenafil) strength and pack size for supply.

Counselling Tips:

- The **Counselling Tips** section of the Vedafil (sildenafil) Patient Assessment Tool provides prompts for you to cover with your patients such as lifestyle changes, how to use Vedafil (sildenafil), what to expect with Vedafil (sildenafil) etc.

GP Referral:

- Recommend to visit GP for a heart and diabetes check if not already had one.

PATIENT COUNSELLING

Once a suitable product has been selected, your patient should be counselled on the correct use of Vedafil (sildenafil) including:

- **How to take Vedafil (sildenafil)**, explaining if a lower dose has been recommended and why it is recommended to be taken an hour before anticipated sexual activity.
- **What to expect with Vedafil (sildenafil)**, sexual stimulation is required for Vedafil (sildenafil) to work.
- **Common adverse effects** and when the patient needs to seek medical assistance.
- **Any warnings and precautions**, including advice when taking other medicines.
- **General advice** on factors that could be contributing to the patients' condition e.g. smoking and alcohol, offer Self-Care cards.
- **Recommend to visit the doctor** for heart health and diabetes check.
- **Vedafil (sildenafil) CMI** for Pharmacist supply (available from Medsafe website) should be handed out.

This is located in the **Counselling Tips** section of the Vedafil (sildenafil) Patient Assessment Tool.



ADVISING THE PATIENT'S DOCTOR OF THE SUPPLY OF VEDAFIL (sildenafil)

The **Consent** section of the Vedafil (sildenafil) Patient Assessment Tool allows to record:

- Patient's permission to contact their doctor to advise them of the supply of Vedafil (sildenafil).
 - If patient consent to contact their doctor has been granted, supply a copy of the completed Vedafil (sildenafil) patient assessment tool to the doctor.
- Some patients may prefer you not to contact their doctor.
- The Vedafil (sildenafil) Patient Assessment Tool also includes a prompt to confirm that the information the patient has provided is complete and correct. If you have any concerns on the accuracy of the information provided, Vedafil (sildenafil) must not be made and the patient must be referred to their doctor.

RESUPPLY OF VEDAFIL (sildenafil)

Use previous Vedafil (sildenafil) Patient Assessment Tool as a record to assess resupply of Vedafil (sildenafil).

If Vedafil (sildenafil) was dispensed with previous successful assessments:

- Pharmacist does not need to repeat the full assessment in the consultation.
- Pharmacist may use the **Vedafil (sildenafil) Patient Resupply Assessment Tool** to determine if there has been any changes to the patient which might affect contraindications or precautions.

A full assessment is required every 12 months or sooner if clinical status of the patient has changed since last assessment.

The image shows a 'Resupply Vedafil Sildenafil citrate' form. At the top, it features the product name and a note: 'A full reassessment is due every 12 months. Please continue on another sheet if needed.' Below this is a 'Patient details' section with fields for Name, Telephone, Date of last full assessment, and Date next full assessment due. The main body of the form is divided into three identical sections, each containing a 'Review before resupply' checklist and a 'Resupply' decision area. The checklist includes: Health/medical condition changes, Changes in concomitant medicines, Vedafil efficacy, and Vedafil Adverse events. The Resupply section has 'Yes' and 'No' radio buttons, followed by fields for Comments, Quantity, Dose, Pharmacist Name, Pharmacist Signature, and Date. At the bottom of the form, there is a QR code and a small 'Vedafil' logo.

THE END

- This concludes the training programme for the **Pharmacist Supply of Vedafil (sildenafil) without a Prescription.**
- You will now be guided through a series of multiple-choice questions to assess your understanding of the training.

[Click here](#) to start the online assessment

On the successful completion of your training:

- A certificate will be emailed to you.
- You may contact your local Viatrix Representative for:
 - Vedafil (sildenafil) Patient Assessment Tool Pad
 - Vedafil (sildenafil) Patient Resupply Assessment Tool Pad
 - Vedafil (sildenafil) Quick Guide
- You may access the Vedafil (sildenafil) CMI at www.medsafe.govt.nz



Vedafil[®] (sildenafil citrate) 25 mg, 50 mg & 100 mg tablets. Prescription Medicine except when supplied by a pharmacist who has successfully completed an approved training programme. Indication: For the treatment of erectile dysfunction in adult males. Contraindications: Hypersensitivity to the active ingredients or any of the excipients; concomitant use with nitric oxide donors, organic nitrates or organic nitrites in any form; concomitant use with guanylate cyclase stimulators such as riociguat; men for whom sexual intercourse is inadvisable due to cardiovascular risk factors; a previous episode of non-arteritic anterior ischaemic optic neuropathy (NAION); known hereditary degenerative retinal disorders such as retinitis pigmentosa; severe hepatic impairment; hypotension (<90/50 mmHg), hypertension (>170/110 mmHg); recent history of stroke or myocardial infarction. Precautions: Use with caution in patients with cardiovascular risks e.g., recent onset angina, left ventricular outflow obstruction and multiple system atrophy manifesting as severely impaired autonomic control of blood pressure; anatomical deformation of the penis; priapism; bleeding disorders; active peptic ulceration and diabetic retinopathy; caution when driving or operating machinery. Interactions: in combination with other PDE5 inhibitors, pulmonary arterial hypertension treatments, alpha-blockers, CYP3A4 or CYP2C9 inhibitors or inducers, ritonavir. Adverse Effects: Headache, flushing, dyspepsia, nasal congestion, diarrhoea, abnormal/decreased vision, cardiovascular events. Dosage & Administration: usual dose is 50 mg approximately one hour before sexual activity; maximum of 100 mg once per day. Vedafil[®] is an unfunded medicine- doctor's fees and pharmacy charges will apply. Special Authority and meeting the eligibility criteria may apply for select indications. Before prescribing, please refer to the full datasheet, available from www.medsafe.govt.nz. Vedafil[®] is a Viatris company trade mark, Viatris Limited, Auckland. Copyright© 2023 Viatris Inc. All rights reserved. NZ-VED-2024-00003. TAPS 2407MM-0719. PSNZ Accreditation number: 2025/01, Expiry: January 2027