




VIAGRA CONNECT[®]

Pharmacy Introduction

November 2020, PP-VCO-IRL-0033

VIAGRA
CONNECT[®]

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Summary

Understanding Erectile Dysfunction (ED)



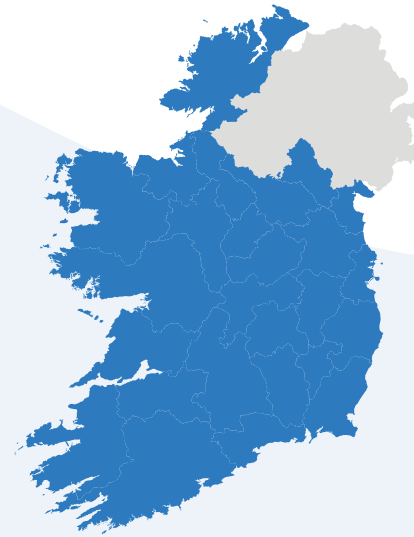
What is erectile dysfunction (ED)?

ED is the inability to achieve or maintain an erection firm enough for satisfactory sexual intercourse.¹

ED:

- Is a self-recognised condition
- May occur occasionally or frequently
- Can vary in severity, from mild (a soft erection) to severe (no erection at all)

Although ED can occur at any age, prevalence increases as men get older.³



**One
in five
Irish men**
experience erectile
dysfunction (ED)
regularly²

ED can be caused by:⁴

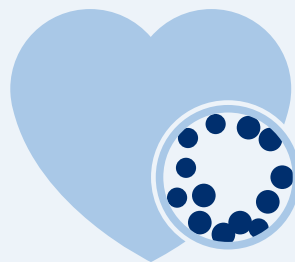
- Physical factors
- Psychological factors
- Medication

ED usually has an underlying physical cause⁴

Certain co-morbidities may predispose men to ED, for example:⁴



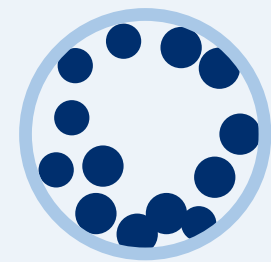
Hypertension



Hypercholesterolemia



Diabetes mellitus

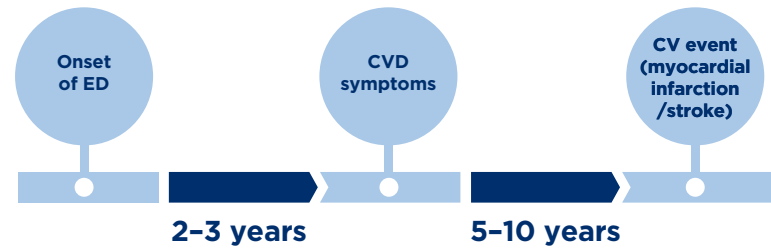


Cardiovascular disease (CVD)

ED can be an early warning sign of cardiovascular disease (CVD)

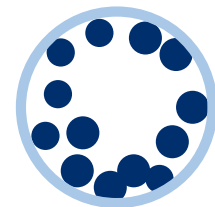
The majority of men with ED have cardiovascular risk factors.⁵

Men presenting with ED may be in the early stages of cardiovascular disease and could go on to experience a major cardiovascular event within 5–10 years.⁶



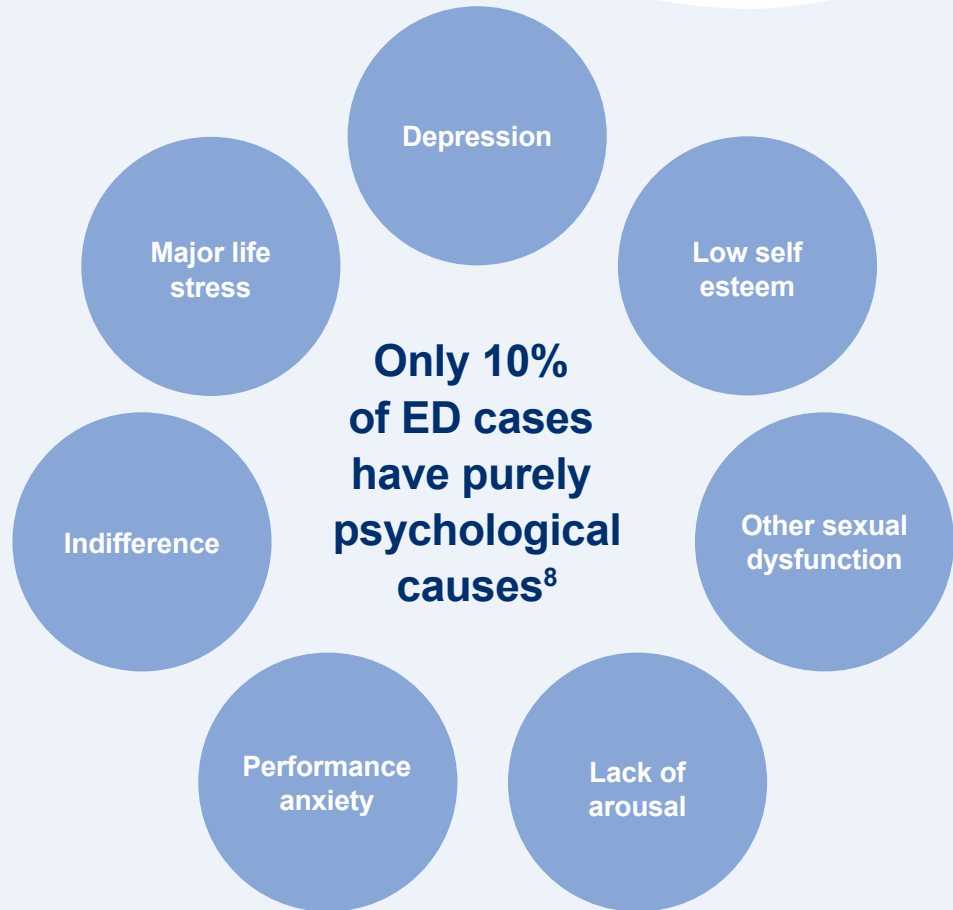
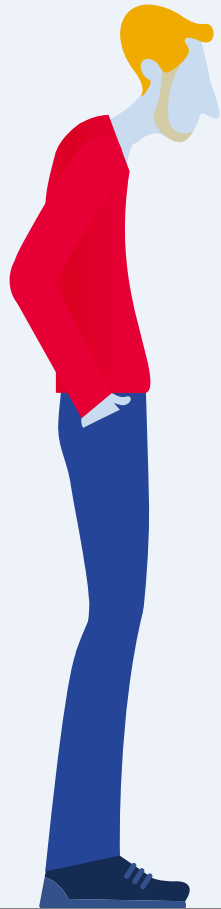
ED as a predictor of CVD^{6,7}

Men with ED should be advised to see their doctor as soon as possible within 6 months for a health check up so that any underlying causes can be identified and treated.



Cardiovascular disease (CVD)

Psychological causes of ED can include:⁸




A number of commonly used medications can cause ED

These include:

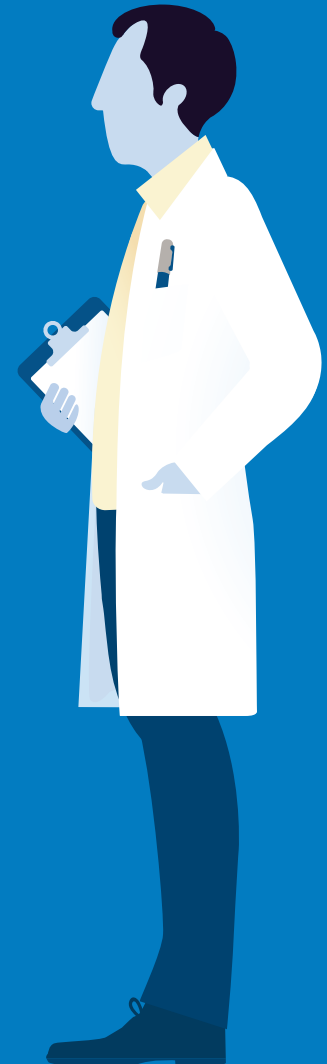
- Diuretics
- ACE and ARB inhibitors
- Beta-blockers
- Anti-depressant medication (e.g. SSRIs)
- Anti-epileptic medication (e.g. Carbamazepine)



 Please refer to page 8 of the Essential Information for Supply for further details and other medication that can cause ED.



Introducing **VIAGRA CONNECT[®]**



What is VIAGRA CONNECT®?

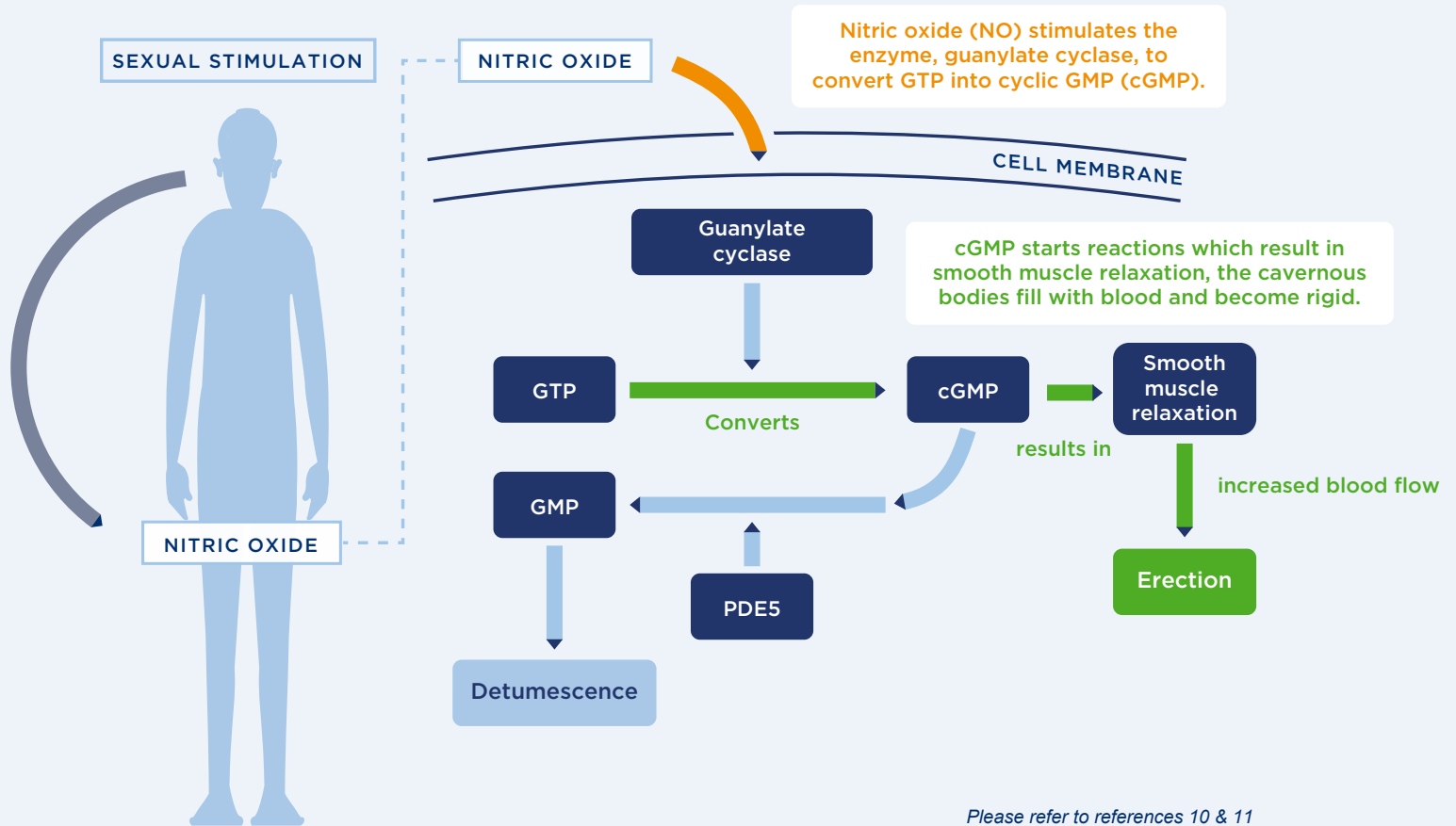
Men
18+

VIAGRA CONNECT contains sildenafil 50 mg and is a pharmacy-only medicine used to treat symptoms of erectile dysfunction (ED) in men aged 18 years and over⁹

50 mg
(sildenafil)

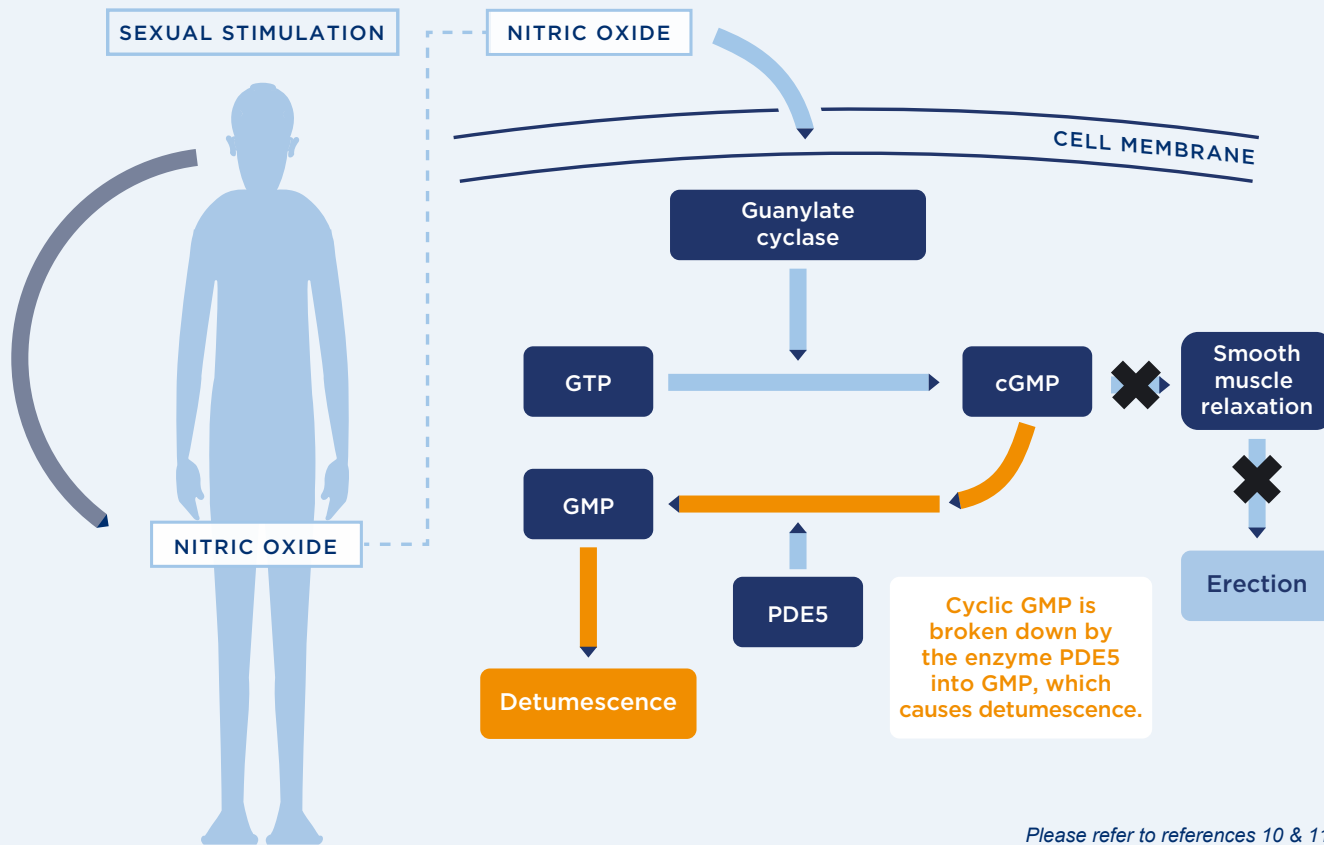
The maximum dosing frequency is one **50 mg tablet per day**.⁹
Available in packs of 4 and 8 tablets

How does VIAGRA CONNECT® work?



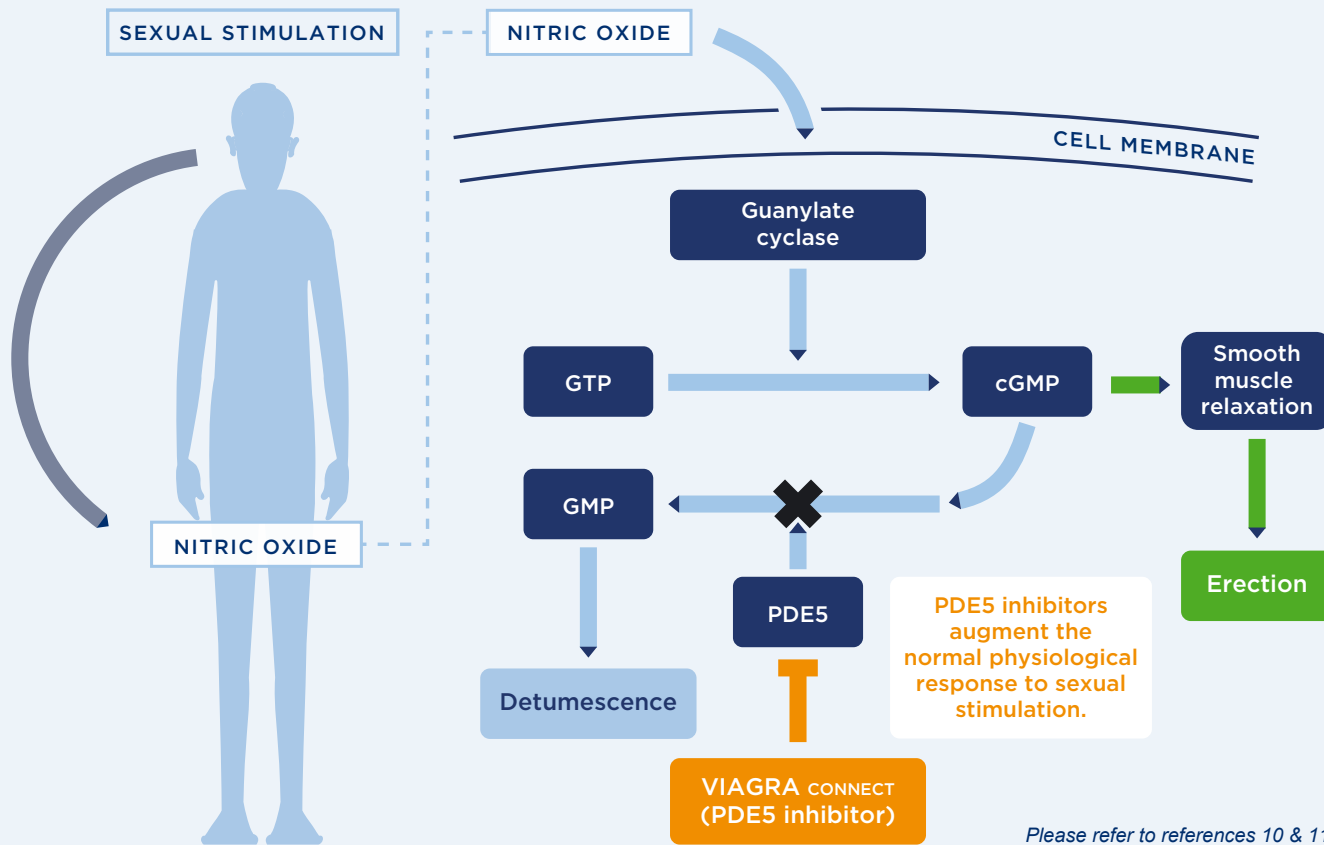
Please refer to references 10 & 11

How does VIAGRA CONNECT® work?



Please refer to references 10 & 11

How does VIAGRA CONNECT® work?



Please refer to references 10 & 11

Helping patients get the best out of VIAGRA CONNECT®



Take no more than one tablet a day whole, with water, approx. one hour before planned sexual activity



It can start to work within 30 minutes, but men can still obtain an erection in response to **sexual stimulation** for up to 4 hours post-dose



Sexual stimulation is required for VIAGRA CONNECT to be effective



Can be taken with or without food but may take longer to work after a high fat meal



For men who have been unable to have sexual intercourse for some time, it may be necessary to try the product on a few separate occasions to achieve satisfactory erection



Avoid taking with a high-fat meal as it may take longer to work



Do not take after drinking alcohol excessively as it may be less effective



Avoid grapefruit or grapefruit juice as this can increase sildenafil levels in the blood

For a full list of side effects of VIAGRA CONNECT please refer to Summary of Product Characteristics. Advise patients to refer to the Patient Information Leaflet in the VIAGRA CONNECT packaging



A vertical stack of three white icons on a dark blue background: a house icon, a document icon with a checkmark, and an eye icon.

Supplying **VIAGRA CONNECT**[®]



The VIAGRA CONNECT[®] Consultation Guide

The Consultation Guide is designed to support the consultation to help identify which patients may or may not be suitable for VIAGRA CONNECT

HCP consultation is required for OTC supply.

VIAGRA CONNECT[®]
50 mg film-coated tablets (sildenafil)

Pharmacy Consultation Guide

The following has been created as a useful aide-memoire to help determine whether your patient is suitable for Viagra Connect, or whether he should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and you should use your professional judgement to decide when and how to use it. The Essential Information for the Supply of Viagra Connect provides additional background information in relation to the supply of this product.

If the patient has previously been supplied with Viagra Connect, he should be asked if anything has changed with respect to his health status or medicines usage. There is no need to repeat the questions below prior to resupply in that case. Remind the patient to make an appointment with his doctor as soon as he can within the first 6 months of starting to use Viagra Connect, to ensure that their 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 (below) can also be given to the man.

1. Who is Viagra Connect for?

Viagra Connect is only intended for men 18 years and older who are experiencing 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 who do not have ED.

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

2. Check patient's cardiovascular (CV) health

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 consider, based on physical status, the patient should not be using this product, refer to the doctor.

- Has your doctor advised that you are not fit enough for any physical and/or sexual activity?
- 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?
- Have you had a heart attack or stroke within the last 6 months?
- Do you have any other heart problems or are you under a doctor's care for any of the following:
- Low blood pressure or uncontrolled high blood pressure
 - Unstable angina (chest pain), irregular heart beat or palpitations (arrhythmia)
 - 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 medication use

Please check what other medicines the patient is taking.

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.

- Are you taking nitrates (nicorandil or other nitric oxide donors (e.g. glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?
- Are you using drugs called 'poppers' for recreational purposes (e.g. amyl nitrite)?
- Are you taking riociguat or other guanylate cyclase stimulators for lung problems?
- Are you taking ritonavir (for HIV infection)?
- 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 or rifampicin (antibiotics) or diltiazem (for high blood pressure)?
- Are you taking any alpha-blockers, such as alfuzosin, doxazosin or tamsulosin, which are medicines to treat urinary problems due to enlarged prostate (benign prostatic hyperplasia) or occasionally to treat high blood pressure?

4. Check concomitant conditions

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

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

Additional advice

You should consider possible causes of erectile dysfunction, such as undiagnosed depression, anxiety, excessive alcohol use and taking certain medicines. Examples of classes of medicines that cause ED include diuretics, anti-hypertensives, corticosteroids, anticonvulsants and recreational drugs. Whilst it may be appropriate to supply the product, you should provide lifestyle advice and recommend a follow-up with a doctor.

Dear Doctor,

Please can you review this patient in relation to erectile dysfunction. We had a discussion in my pharmacy, but he was not suitable for supply of Viagra Connect due to his [delete as appropriate] cardiovascular health/interacting medicines/other condition.

PHARMACY
STAMP

Pharmacist signature:..... Date:.....

Please keep this slip and present to the Pharmacist when you next wish to purchase Viagra Connect.

Before resupply your Pharmacist will need to assess you to ensure that there have been no changes in your health or medications since the last time you received the product.

PHARMACY
STAMP

Pharmacist signature:..... Date:.....

The VIAGRA CONNECT® Consultation Guide

SECTION 1 Who is VIAGRA[®]CONNECT for?

Men
18+

For men aged
18 years and over

Unable to get or keep
an erection firm enough
for sex

VIAGRA[®]CONNECT
50 mg (100 mg) tablet (tablet)

Pharmacy Consultation Guide

The following has been reviewed as a useful aide-memoire to help determine whether your patient is suitable for Viagra Connect, or whether he should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and you should use your professional judgement to decide when and how to use it. The product should be used only in the supply of Viagra Connect (generic sildenafil).

If the patient has previously been supplied with Viagra Connect, he should be asked if anything has changed with regard to his health status or medication usage. There is no need to repeat the questions below prior to supplying a trial supply. Instead the patient is made an appointment with his doctor as soon as he can within the first 6 months of starting to use Viagra Connect, to assess that their erection problems are not caused by any medical health condition. Any changes have already happened in a suitable time frame.

1. Who is Viagra Connect for?
Viagra Connect is only intended for men 18 years and older who are experiencing 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 who do not have ED.

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

2. Additional advice
This should consider possible causes of erectile dysfunction, such as cardiovascular, diabetes, hormonal, psychiatric, neurological, anatomical, vascular, or anatomical. Consideration should be given to the use of other medicines that may interact with sildenafil, such as nitrates, alpha-blockers, and recreational drugs. Whilst it may be appropriate to supply the product, you should provide the patient advice that encourages a follow-up with a doctor.

3. Check concomitant medication use
Please check with other medicines the patient is taking. If the patient answers YES to any of the following he is in a potentially unsafe position: **do not supply the product and refer to the doctor.**

- Are you taking nitrate (nitroglycerin) or other nitrate (such as dinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?
- Are you taking drugs called "poppers" for recreational purposes (e.g. amyl nitrate)?
- Are you taking medicine for other genital health conditions (e.g. fungal infection)?
- Are you taking medicine for HIV infection?
- Are you taking any CYP3A4 inhibitors, e.g. antifungals (to treat HIV infections), antibiotics (to treat bacterial infections), immunosuppressants or anticonvulsants for long-term treatment, or chemotherapy or biological (antibody) treatment (for long-term treatment)?
- Are you taking any alpha-blockers, such as tamsulosin, alfuzosin or terazosin, which are medicines to treat urinary problems? Are the medicines causing blood flow issues (e.g. left ventricular outflow obstruction, acute coronary) or serious cardiac failure?

4. Check concomitant conditions
If the patient answers YES to any of the following he is in a potentially unsafe position: **do not supply the product and refer to the doctor.**

- Do you have Parkinson's disease or any other deterioration of the penis?
- Have you had low or vision because of damage to the optic nerve (such as non-arteritic anterior ischaemic optic neuropathy (NAION)) or have you had low or vision (such as blurred or double vision)?
- Do you have glaucoma (including angle-closure glaucoma, open-angle glaucoma, pseudoexfoliation glaucoma or traumatic glaucoma)?
- Do you have previously diagnosed hepatic liver disease (including cirrhosis of the liver) or severe renal (kidney) impairment?
- Do you have any of the following: sickle cell anaemia, multiple myeloma or leukaemia?
- Do you have any bleeding issues (eg haemorrhoids) or have you taken aspirin?

Pharmacy signature: _____ Date: _____

Pharmacy signature: _____ Date: _____

The VIAGRA CONNECT[®] Consultation Guide

SECTION 2 Check patient's cardiovascular (CV) health

The Consultation Guide includes an assessment of the man's CV health, by assessing:

- Overall fitness for sex, by determining if he gets out of breath or experiences chest pain when he undertakes physical activity
- Cardiovascular (CV) problems, such as a recent history (<6months) of stroke or MI

Low risk cardiovascular patients may be suitable for VIAGRA CONNECT. Those that have been advised to avoid sexual activity should be referred to their doctor

VIAGRA CONNECT[®]
Sildenafil (sildenafil citrate) tablet

Pharmacy Consultation Guide

The following has been reviewed as suitable advice to help determine whether your patient is suitable for Viagra Connect, or whether he should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and should be used as your professional judgement to decide what advice to give. The consultation information on the side of Viagra Connect provides additional background information in relation to the supply of this product.

If the patient has previously been treated with Viagra Connect, he should be asked if anything has changed with regard to his health status or medication usage. There is no need to repeat the questions below prior to supply if that case. Instead the patient is asked an appropriate question to check for additional concerns. The questions below are for patients who have not been treated with Viagra Connect.

1. Who is Viagra Connect for?

Viagra Connect is only intended for men who have not had any recent medical problems. Reduction in ED is a difficulty in getting and/or maintaining an erection satisfactory for sexual performance. This should not be used for treatment of men who have ED.

It is important to confirm if the man is already receiving treatment for his condition. This is usually prescribed 50 mg of sildenafil can be supplied if the product is still used. If there is a history of abnormal supply, provided they do not take more than 20 mg daily. If the man is using a different dose of sildenafil or another ED treatment, he should be referred to his doctor.

2. Check patient's cardiovascular (CV) health

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 consider, based on physical status, the patient should not be using this product, refer to the doctor.

Has your doctor advised that you are not fit enough for any physical and/or sexual activity?

Do you feel any breathless or experience chest pain with light or moderate physical activity, such as walking briskly for 20 minutes or climbing two flights of stairs?

Have you had a heart attack or stroke within the last 6 months?

Do you have any other heart problems or are you under a doctor's care for any of the following:

- Low blood pressure or uncontrolled high blood pressure
- Coronary artery (heart) artery, irregular heart beat or palpitations (arrhythmia)
- A problem with one of the valves in your heart (valvular heart disease)
- A problem where the heart muscle becomes enlarged 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 for contraindications to the supply of Viagra Connect

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

Are you taking nitrate (nitroglycerin) or other nitrate (such as dinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?

Are you taking alpha-blockers (used for high blood pressure) or non-cardiac prostaglandin synthase (NSAID) drugs?

Are you taking any other medicine for chest pain, such as aspirin, clopidogrel or ticagrelor, which are medicines to treat coronary problems?

Are you taking any other medicine, such as rifampin, rifabutin or rifapentine, which are medicines to treat coronary problems?

Are you taking any other medicine, such as diltiazem, verapamil or nifedipine, which are medicines to treat coronary problems?

Are you taking any other medicine, such as sildenafil, tadalafil or vardenafil, which are medicines to treat ED?

4. Check concomitant conditions

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

Do you have Peyronie's disease or any other deformation of the penis?

Have you ever had low or vision because of damage to the optic nerve (such as non-arteritic anterior ischemic optic neuropathy (NAION)) or have you had any other vision problem (such as retinal degeneration)?

Do you have glaucoma (increased eye pressure) or any other eye condition?

Do you have previously diagnosed hepatic (liver) disease (including cirrhosis of the liver) or severe renal (kidney) impairment?


Do you have any of the following: acute or chronic kidney impairment or dysfunction?

Do you have any bleeding issues (eg haemorrhoids) or take anti-thrombotic agents?

PHARMACY STAMP

Pharmacy name: _____ Date: _____

Pharmacy name: _____ Date: _____

 **Please see p14 and p15 of the Essential Information for Supply for more information.**

The VIAGRA CONNECT[®] Consultation Guide

SECTION 3 Check concomitant medication use

Contraindicated concomitant medications include:

- Nitrates and nitric oxide donors (such as amyl nitrite)
- Guanylate cyclase stimulators e.g. riociguat
- Ritonavir
- CYP3A4 inhibitors
- Alpha blockers

VIAGRA CONNECT[®]
50 mg (16-count) tablet (tablet)

Pharmacy Consultation Guide

The following has been reviewed in a careful, side-by-side manner to help determine whether your patient is suitable for Viagra Connect, or whether he should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and you should use your professional judgement to decide when and how to use it. The patient's suitability for the supply of Viagra Connect depends on the background information in relation to the supply of this product.

If the patient has previously been supplied with Viagra Connect, he should be asked if anything has changed with regard to his health status or medicine usage. There is no need to repeat the questions below prior to supplying a trial case. Instead, the patient is asked an appointment with his doctor or pharmacist as he can within the first 6 weeks of starting to use Viagra Connect, to ensure that their medical problems are not caused by any medicines they are taking. Any changes have already happened in a subsequent medical supply. The patient should be asked if any changes can be given to the case.

1. Who is Viagra Connect for?
Viagra Connect is only intended for men who are aged 18 years and older who are experiencing erectile dysfunction (ED) (i.e. difficulty in getting and/or maintaining an erection satisfactory for sexual performance). This cannot be used for treatment in men who do not have ED.

It is important to confirm if the man is already receiving treatment for his condition. This cannot be prescribed 50 mg of sildenafil can be supplied by the pharmacist if they meet the criteria for pharmacy supply, provided they do not take more than 50 mg daily. If the man is using a different dose of sildenafil or another ED treatment, he should be referred to his doctor.

2. Check patient's cardiovascular (CV) health
It is important to confirm if the man has any CV conditions. Do not supply the product and refer to the doctor if you are in any doubt.

Has your doctor advised that you are not fit enough for any physical and/or sexual activity?

Do you feel any breathing or respiratory distress with light or moderate physical activity, such as walking, climbing, or climbing two flights of stairs?

Have you had a heart attack or stroke within the last 6 months?

Do you have any other heart problems or are you under a doctor's care for any of the following:

- Low blood pressure or uncontrolled high blood pressure
- Unstable or long QT (QTc) interval (heart beat) or palpitations (arrhythmia)
- A problem with one of the main blood vessels (atherosclerosis, heart disease)
- A problem where the heart muscle becomes enlarged (cardiomegaly) or use of it should (cardiomyopathy)
- Heart problems causing low blood flow (such as left ventricular outflow tract obstruction, aortic stenosis) or atrial cardiac failure

3. Check concomitant medication use

Please check what other medicines the patient is taking. 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.

Are you taking nitrates (nicorandil) or other nitric oxide donors (e.g. glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate) for chest pain?

Are you using drugs called 'poppers' for recreational purposes (e.g. amyl nitrite)?

Are you taking riociguat or other guanylate cyclase stimulators (for lung problems)?

Are you taking ritonavir (for HIV infection)?

Are you taking any CYP3A4 inhibitors, e.g. lopinavir (to treat HIV infection), cimetidine (a heartburn treatment), itraconazole or telaprevir (to treat fungal infections), azithromycin or rifampicin (antibiotics) or diltiazem (for high blood pressure)?

Are you taking any alpha-blockers, such as alfuzosin, doxazosin or tamsulosin, which are medicines to treat urinary problems due to enlarged prostate (benign prostatic hyperplasia) or occasionally to treat high blood pressure?

Do you have Raynaud's disease or any other 'circulation' of the hands?

Have you ever had loss of vision because of damage to the optic nerve (such as non-arteritic anterior ischaemic optic neuropathy (NAION)) or have you noticed any colour (such as blurred) or double vision?

Do you have glaucoma (cataracts, eye disease between the eyes or glaucoma) or other eye problems?

Do you have previously diagnosed hepatic (liver) disease (including cirrhosis of the liver) or severe liver (hepatic) impairment?


Do you have any of the following: kidney, renal, multiple myeloma or haematuria?

Do you have any bleeding issues (eg haemorrhoids) or have you been on blood thinners?

PHARMACY STAMP

Pharmacist signature: _____ Date: _____

Pharmacist signature: _____ Date: _____

 Please see p15 of the Essential Information for Supply for more information.

The VIAGRA CONNECT[®] Consultation Guide

SECTION 4 Check concomitant conditions

It is also important to understand if the man has any other medical issues that could mean the product is unsuitable for him, such as:

- Deformities of the penis e.g. Peyronie's Disease
- Loss of vision e.g. NAION, inherited eye disease
- Galactose intolerance, LAPP lactase deficiency, glucose-galactose malabsorption
- Hepatic disease or severe renal impairment
- Sickle cell anaemia, multiple myeloma or leukaemia
- Bleeding issues such as haemophilia or active stomach ulcers

VIAGRA CONNECT[®]
50 mg (10-count) tablet (tablet)

Pharmacy Consultation Guide

The following has been reviewed as suitable advice intended to help determine whether your patient is suitable for Viagra Connect, or whether he should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and you should use your professional judgement to decide what advice to give. The overall responsibility for the supply of Viagra Connect remains with you.

If the patient has previously been treated with Viagra Connect, he should be asked if anything has changed with regard to his health status or medication usage. There is no need to repeat the questions below prior to supply if that case. Instead the patient is asked an equivalent with the doctor or nurse as the case within the first 6 months of starting to use Viagra Connect, to ensure that their reaction remains as usual except for any previously noted conditions. Any changes have already been noted in a subsequent consultation. The patient should be asked if any conditions have been given the following:

1. Who is Viagra Connect for?
Viagra Connect is only intended for men who have mild to moderate erectile dysfunction (ED) (i.e. difficulty in getting and/or maintaining an erection satisfactory for sexual performance). This cannot be used for treatment to men who do not have ED.

It is important to confirm if the man is already receiving treatment for his condition. This currently prescribed (20 mg or 40 mg) can be replaced by Viagra Connect if there is no other oral therapy being provided that does not have more than 20 mg daily. If the man is using a different dose of tadalafil or another ED treatment, he should be referred to the doctor.

2. Check patient's cardiovascular (CV) health
If the patient answers YES to any of the following, do not supply the product and refer to the doctor. If the man is unable to consider based on physical status, the patient should be taken to the doctor. If the man is unable to consider based on physical status, the patient should be taken to the doctor.

Are you being treated for any of the following conditions?
 Do you have any heart problems or symptoms such as chest pain or irregular physical activity, such as walking breathing for 20 minutes or climbing two flights of stairs?
 Have you ever had a heart attack or stroke within the last 6 months?
 Do you have any other heart problems or are you under a doctor's care for any of the following:
 Low blood pressure or uncontrolled high blood pressure
 Unstable or angina (chest pain), irregular heart beat or palpitations/arrhythmias
 A problem with the heart muscle (myocardial infarction) that has not fully healed
 A problem with the heart muscle (cardiomyopathy) that has not fully healed
 Heart problems causing blood flow issues (e.g. left ventricular outflow obstruction, aortic stenosis) or severe aortic valve disease

3. Check concomitant medication use
Please check for other medicines the patient is taking. If the patient answers YES to any of the following, do not supply the product and refer to the doctor.

Are you taking nitrates (nitroglycerin) or other nitric oxide donors (e.g. alprostadil, tadalafil, tadalafil mononitrate or tadalafil diester) for chest pain?
 Are you taking drugs called 'ergotams' for migraines or pain relief (e.g. ergotamine)?
 Are you taking medicine to treat psychiatric conditions (e.g. long acting prolampridone)?
 Are you taking medicine (for HIV infection)?
 Are you taking any CYP3A4 inhibitors, e.g. antifungals (the broad class of antifungals, including itraconazole, voriconazole or bosentan) for fungal infections, or statins or fibrinolytics (e.g. alteplase, tenecteplase, streptokinase) for blood clots?
 Are you taking any other medicine, such as antibiotics, diuretics or hormones, which may need to be taken away properly.


4. Check concomitant conditions
Please check for other conditions the patient is taking. If the patient answers YES to any of the following, do not supply the product and refer to the doctor.

Do you have Peyronie's disease or any other deformation of the penis?
 Have you ever had any other deformities of the penis (such as non-erectile, anterior achromic optic neuropathy (NAION) or have an inherited eye disease (such as retinitis pigmentosa)?
 Do you have galactose intolerance, LAPP lactase deficiency or glucose-galactose malabsorption?
 Do you have previously diagnosed hepatic or renal disease (including cirrhosis of the liver) or severe renal (kidney) impairment?
 Do you have any of the following sickle cell anaemia, multiple myeloma or leukaemia?
 Do you have any bleeding issues (e.g. haemophilia) or have active stomach ulcers?

Additional advice: You should consider possible causes of erectile dysfunction, such as uncontrolled hypertension, chronic renal failure, alcohol abuse and taking certain medicines. Check for other medicines that cause ED (nitric oxide synthase inhibitors), antidepressants and cardiovascular drugs. Whilst it may be appropriate to supply the product, you should provide the patient advice and encouragement to follow-up with a doctor.

PHARMACY STAMP

PHARMACY STAMP

 **Please see p13 and p14 of the Essential Information for Supply for more information.**

The VIAGRA CONNECT[®] Consultation Guide

TEAR-OFF SECTION

The tear-off slips at the bottom of the Consultation Guide allows the patient to be given:

- A dated record of their first supply
- or
- Reasons for non-supply that they should take to their GP

VIAGRA CONNECT[®]
50 mg (10-count) tablet (tablet)

Pharmacy Consultation Guide

The following has been reviewed as a useful tool to assist in helping determine whether your patient is suitable for Viagra Connect, or whether they should be seen by a doctor for further advice. Use of the Pharmacy Consultation Guide is optional, and you should use your professional judgement to decide when to use the guide. The guide is intended for the supply of Viagra Connect permissive conditions. Background information in relation to the supply of this product... (text continues)

1. Who is Viagra Connect for?
Viagra Connect is only intended for men who are aged 18 and over, who are experiencing erectile dysfunction (ED) (i.e. difficulty in getting and/or maintaining an erection satisfactory for sexual performance). This cannot be used for treatment of men who do not have ED.

2. Check patient's cardiovascular (CV) health
It is important to confirm if the man is already receiving treatment for his condition. Men currently prescribed 50 mg of sildenafil can be supplied this product if they have the criteria for pharmacy supply, provided they do not take more than 50 mg daily. If the man is using a different dose of sildenafil or another ED treatment, he should be referred to his doctor.

3. Check concomitant medication use
Please check for other medicines the patient is taking. 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 their doctor.

4. Check concomitant conditions
If the patient answers YES to any of the following, do not supply the product and refer to the doctor.

Additional advice
You should consider possible causes of erectile dysfunction, such as uncontrolled hypertension, anxiety, excessive alcohol use and taking certain medicines. Check for all medicines that may interact with Viagra Connect, such as nitrates, antihypertensives and recreational drugs. Whilst it may be appropriate to supply the product, you should provide further advice and encouragement to follow-up with a doctor.

Dear Doctor
Please see you advise this patient is eligible to receive Viagra Connect. We had a discussion in my pharmacy, but he was not suitable for supply of Viagra Connect due to the (select an appropriate cardiovascular health/medicating medicine/other condition).

Dear Patient
Please keep this slip and present to the Pharmacist when you next visit your pharmacy to collect your Viagra Connect. Before supplying your Pharmacist will need to ensure you are aware that there have been no changes to your health or medications since the last time you received the product.

Pharmacy signature: _____ Date: _____
Pharmacist signature: _____ Date: _____

The VIAGRA CONNECT® Consultation Guide

The reverse of the Consultation Guide provides information – enabling pharmacists to offer valuable health advice for men regardless of their suitability for the product

Points for counselling and other information

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

Advice for men who have not been supplied Viagra Connect

Men who have not been supplied Viagra Connect because of their cardiovascular health, interacting medicines 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 Viagra Connect

Men should be advised:

- They should schedule a health check-up with their doctor as soon as possible within the first 6 months of starting to use Viagra Connect to ensure that their erection problems are not caused by any serious health condition
- Viagra Connect is only intended for men 18 years and older who have erectile dysfunction (ED). Men who do not have ED will not benefit from using this product.
- Take one tablet approximately 1 hour before planning to have sexual intercourse. Viagra Connect can start to work within 30 minutes
- Take with or without food, but Viagra Connect may take longer to work after a high-fat meal
- Do not take with grapefruit or grapefruit juice, as it may affect the way the medicine works
- The maximum recommended dosing frequency is one 50 mg tablet per day
- They may need to take Viagra Connect 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 on different dosing occasions, 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 Viagra Connect as this combination may lead to a dangerous fall in blood pressure
- Men should tell their doctor that they have started taking Viagra Connect, especially if they are started on any new medicines
- Remind patients about common side effects. These include: headache, flushing, dyspepsia, nasal congestion, dizziness, nausea, visual disturbance, cyanopsia (blue-tinted vision) and blurred vision

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

Men should be advised to STOP TAKING Viagra Connect and seek medical attention IMMEDIATELY if they experience any of the following SERIOUS side effects. Side effects can be reported by patients or pharmacists via HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 676 4971; Fax: +353 1 676 2517. Website: www.hpra.ie; E-mail: medsafety@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
- A persistent and sometimes painful erection lasting longer than 4 hours
- A sudden decrease or loss of vision
- An allergic reaction. Symptoms include sudden wheeziness, difficulty breathing or dizziness, swelling of the eyelids, face, lips or throat
- 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. hypertension, diabetes mellitus, 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
- Provide appropriate advice on lifestyle factors and general healthy living, including:
 - Losing weight
 - Giving up smoking
 - Cutting back on alcohol/recreational drugs
 - Exercising regularly
 - Reducing stress
- You may also want to check if the man is buying products from unregulated sources. It is important to explain these products are not tested for their safety or effectiveness, may not contain the ingredients listed within them and are therefore potentially dangerous, unlike product sourced from a pharmacy and medicines obtained via prescription from the doctor

Your Pharmacist has supplied you with Viagra Connect today for your personal use.

Please make an appointment to see your GP as soon as you can within 6 months of the date of first receiving Viagra Connect (see date on reverse) to check for underlying medical problems that can sometimes be associated with erectile dysfunction.

You have not been provided with Viagra Connect for ED today as it may not be suitable for you to take without consulting your doctor. You should go to see your doctor to discuss other suitable options.

Please make an appointment to see your GP as soon as you can within the next 6 months and present this slip.


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Patient Scenarios

For situations where the decision to supply VIAGRA CONNECT is less clear-cut, a number of patient scenarios have been developed that can be found in the Essential information for supply document

The scenarios will further prepare pharmacists for more complex cases such as men presenting with underlying CV issues, concomitant medication use and other lifestyle considerations

Although suggested responses are provided, the scenarios are a training tool, so you should still use your professional judgement in all cases

 Please see p27 of the **Essential Information for Supply** for more information.



Advising patients about their suitability for VIAGRA CONNECT®



Suitable patients

Pharmacists should advise patients to see their doctor as soon as possible within 6 months of first VIAGRA CONNECT supply to assess the underlying causes of ED



Unsuitable patients

Pharmacists should advise patients to see their doctor as soon as they can within 6 months. Their doctor can assess their condition and suggest alternative treatment options

Advise patients to refer to the Patient Information Leaflet in the VIAGRA CONNECT packaging

Summary

- VIAGRA CONNECT is now licensed as an OTC medicine for supply through pharmacies. HCP consultation is required for supply
- Talking about ED in the pharmacy presents an opportunity to make a difference to the overall health of men in the community
- Symptoms of ED are treatable in most cases
- Men who may be unsuitable for VIAGRA CONNECT can still benefit from your advice before being signposted to their doctor
- The optional VIAGRA CONNECT Consultation Guide is available to help you accurately assess patients' suitability for treatment with VIAGRA CONNECT
- To assess the underlying cause of their ED, **all men** should be advised to visit their GP as soon as possible within 6 months

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