

# Guidance for Pharmacists on the Safe Supply of Non-Prescription Sildenafil 50mg film-coated tablets (Viagra CONNECT®)

Pharmaceutical Society of Ireland

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# Introduction

The purpose of this guidance is to assist pharmacists in the safe supply of Viagra CONNECT®, in line with the product's marketing authorisation. Viagra CONNECT® 50mg Film-Coated Tablets are licensed as a pharmacy-only medicine for the treatment of men aged 18 years and over, for the management of erectile dysfunction. Due to the patient consultation and assessment required to determine the safe supply of this medicine, Viagra CONNECT® must only be supplied by the pharmacist.

## 1. Guidance

The supply of Viagra CONNECT® must only be made by a pharmacist following a structured consultation with the patient. This allows the pharmacist exercise his or her professional judgment, to assure the supply of the medicine is safe and appropriate for the individual patient.

In determining the appropriateness of the supply, the pharmacist must regard the information in the product's Summary of Product Characteristics (SmPC) available on the Health Products Regulatory Authority's (HPRA) website ([www.hpra.ie](http://www.hpra.ie)).

A pharmacist will take account of all appropriate educational resources and materials, prior to supplying Viagra CONNECT® to a patient, and assure his/her knowledge and understanding of the product is appropriate. In particular, the pharmacist must ensure that the health needs of each patient requesting Viagra CONNECT® be considered, for example, by considering cardiovascular health and other potential causes of erectile dysfunction, concomitant conditions and medication use, as well as advising on the dosing regimen and how to take the tablet. It is important to confirm if the man is already using medication to manage the condition.

Men currently prescribed 50mg of sildenafil may be supplied with this product if they meet the criteria for pharmacy supply, provided they do not take more than 50mg daily. The maximum daily dose that is recommended for non-prescription use is 50mg daily. Doses above 50mg requires referral to a prescriber for further assessment. If the man is using a different dose of sildenafil or an alternative erectile dysfunction treatment, he should be referred to his doctor.

## Patient Counselling

Pharmacists have a unique opportunity to support patients in the rational use of non-prescription medicines. Pre-diagnosis of erectile dysfunction by a doctor is not required for pharmacy supply of Viagra CONNECT®. The correct information must be obtained from a patient to ascertain it is the appropriate product being sought.

A number of screening questions will elicit the information required to ensure supply is appropriate and safe for the patient to use this medicine, and a thorough confidential consultation to ensure the appropriateness of supply of Viagra CONNECT® must be carried out by the pharmacist. Appropriate counselling must be provided, which should include lifestyle advice to help address risk factors. A patient must be advised to consult with his doctor as soon as he can to rule out potential causative serious health condition(s). If a supply is not deemed appropriate, the patient should be advised to be seen by a doctor for further advice.

Non-pharmacist staff members may be the first point of contact for the patient and should have suitable training on how to deal with such a request in an appropriate manner. When assisting patients with requests for Viagra CONNECT® it is important that the patient is facilitated in being confident in sharing all relevant information.

The supply of non-prescription medicines by a pharmacist must also comply with Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which states that, in relation to the sale or supply of any non-prescription medicine, a registered pharmacist must be satisfied that the purchaser is aware of the appropriate use of the medicine, that it is being sought for that purpose and that it is not intended for abuse and/or misuse. The pharmacist may consider it appropriate to make a record of supply in the Patient Medication Record (PMR), but only if the patient gives his consent and requires this. Pharmacists should also consult with, and consider using, any support materials provided by the Marketing Authorisation Holder (MAH).

## 2. Storage of Viagra CONNECT® 50mg

As a 'pharmacy-only' medicine, in accordance with legislation, these medicines must be stored in a part of the pharmacy premises to which the public does not have access<sup>1</sup>.

## 3. Pharmacovigilance

Any suspected adverse reactions to a medicinal product should be reported to the HPRA. There are several options in place for reporting suspected adverse reactions to the HPRA, which are as follows:

- By following the link to 'Report an Issue' on the online reporting options accessible on the HPRA website homepage ([www.hpra.ie](http://www.hpra.ie));
- Using the downloadable report form also accessible from the HPRA website, which may be completed manually and submitted to the HPRA via 'freepost';
- Using the traditional 'yellow card' report, which also utilises a freepost system. 'Yellow cards' are available from the HPRA Pharmacovigilance department on request;
- By telephone to the HPRA Pharmacovigilance section (01 676 4971).

## 4. Policies and Procedures

Superintendent and supervising pharmacists must ensure that documented policies and procedures are in place, which address the supply of Viagra CONNECT® 50mg in the pharmacies under their control. Superintendent and supervising pharmacists must also ensure that there is adequate staff training in place to ensure compliance with policies and procedures and all staff are aware that they must refer requests for Viagra CONNECT® to the pharmacist.

<sup>1</sup> Regulation 5(1)(ea) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended)

## 5. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Is the pharmacist and all relevant staff members aware of the licensed indications for Viagra CONNECT®?				
Are members of staff aware that all requests for Viagra CONNECT® must be referred to the pharmacist?				
Does the pharmacist carry out a thorough consultation with each patient to determine if Viagra CONNECT® is safe and suitable for them to use?				
Does the pharmacist counsel the patient on the safe use of Viagra CONNECT® including information on maximum dose and when advice should be sought from a doctor?				
Is Viagra CONNECT® stored in a part of the pharmacy premises to which the public does not have access?				
Are there written policies and procedures in place for all aspects of the supply of the product?				
Are the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant non-pharmacist staff members, are trained on, and following, the relevant policies and procedures?				