

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 HPRA 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