

PHOSPHODIESTERASE TYPE-5 (PDE-5) INHIBITORS FOR ERECTILE DYSFUNCTION

Information about your condition from The British Association of Urological Surgeons (BAUS)

You have been given this leaflet because you have been diagnosed with erectile dysfunction (impotence). The aim of the leaflet is to provide you with detailed information about how the condition may be treated with drugs to enhance your erections.

We have consulted specialist surgeons during its preparation, so it represents best practice in UK urology. You should use it in addition to any advice already given to you.

To view the online version of this leaflet, type the text below into your web browser:

http://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Viagra.pdf

Key Points

- The commonly used PDE-5 inhibitors are sildenafil (generic or Viagra[™]), tadalafil (generic or Cialis[™]), vardenafil (Levitra[™]) and avanafil (Spedra[™])
- They increase blood flow into the penis by blocking the naturally occurring enzyme (PDE-5) which turns off an erection
- You should only obtain PDE-5 inhibitors from a doctor, pharmacist or nurse practitioner
- Side-effects occur in approximately 1 in 9 patients (11%) but only 3% of men stop treatment because of side-effects
- You should not use PDE-5 inhibitors if you are taking nitrate medications for angina or heart disease

What are they used for?

You should only take tablets for erectile dysfunction (impotence) which have been prescribed by a doctor or nurse practitioner, or after advice from a pharmacist. They should only be used in men with erectile dysfunction because they can have serious side-effects. They will have no effect on your libido (sexual desire), ejaculation or fertility.

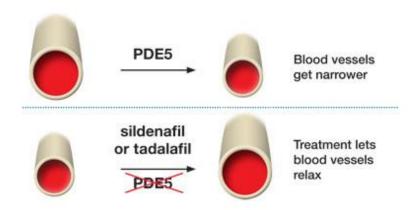
What do they do?

These drugs boost the body's natural mechanism for getting an erection.

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This allows erections to be achieved and maintained more easily but they **do require sexual stimulation** to be effective.

They may not work in severe erectile dysfunction or where the natural erectile mechanism has been irreversibly damaged. The drugs work by dilating (opening) the blood vessels supplying the penis; this causes a greater blood flow into the penis and improves your erection.



How should they be taken?

Depending on the medication you are prescribed, a tablet should be taken between 30 minutes and 1 hour before anticipated sexual activity. Most of the drugs are affected by drinking alcohol or eating a heavy or fatty meal before taking the drug. We normally advise you to take them on an empty stomach, or two to three hours after a meal.

You should read the manufacturer's instruction leaflet carefully because this gives you full instructions. You should not take more than one dose per day. Treatment is usually long-term.

Because of its long half-life, **Tadafil** (Cialis[™]) may be taken at a lower, daily dose so that the drug is always in your system to provide a background boost to erections. This can help with night-time and morning erections.

We normally advise you to try treatment for four to six weeks (at least 12 tablets) to see whether it works. Your specialist will suggest a starting dose for you and you will be followed up to see if an increased dosage is needed.

When should they not be taken?

You must not use PDE-5 inhibitors if you take nitrate medications (GTN spray, isosorbide or amyl nitrate) for angina, heart disease or other reasons, even if you have not used it for some time. If you are not sure whether you are taking these medications, please check with your doctor. PDE-5 inhibitors interact with nitrates and can cause a dangerous drop in blood

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pressure. This may result in cardiac arrest, or even death.

You should probably avoid taking these drugs with alcohol. If you are unsure as to whether PDE-5 inhibitors are safe for you, consult your GP, specialist or cardiologist who will be able to advise you.

PDE-5 inhibitors are not appropriate if you have been told that sexual activity is inadvisable (e.g. if you suffer from unstable angina or severe heart failure). They should not be used at the same time as other treatments for erectile dysfunction, unless you have been advised to do so by a specialist.

What are the side-effects?

The most common side-effects include headache (12%), flushing (10%) and indigestion (7%). Some patients develop altered (blue-tinged) vision and dizziness (3%). If dizziness does occur, you should not drive or operate heavy machinery. It is important that you report any severe side-effect to your doctor and consider stopping the drug until you discuss it with your doctor.

Overall, 1 in 9 patients (11 to 12%) experience side-effects overall, although only a small number (3% overall) stop treatment because of side-effects alone. The table below shows the relative risks of the different drugs (*complete long-term figures are not yet available for avanafil):

Side-effect	Sildenafil	Tadalafil	Vardenafil	Avanafil
Headache	12.8%	14.5%	16%	10%
Flushing	10.4%	4.1%	12%	4%
Indigestion	4.6%	12.3%	4%	<2%
Nasal congestion	1.1%	4.3%	10%	2%
Dizziness	1.2%	2.3%	2%	1.2%
Abnormal vision	1.9%	-	<2%	<1% *
Back pain	-	6.55%	-	2%
Muscle aching	-	5.7%	-	<1% *

How do I get these drugs?

You can get these drugs on prescription from your doctor or nurse practitioner. In addition, sildenafil is available over the counter at larger pharmacies (as Viagra Connect $^{\text{\tiny M}}$).

We do not recommend that you buy them through advertisements in newspapers, magazines or on the internet because the amount of active ingredient (if any) in such tablets is unknown, and they may be dangerous to your health.

Generic sildenafil is now available on the NHS, free of any restrictions, but other PDE-5 inhibitors are only available on the NHS under the following specific conditions (and in limited amounts per month, usually four tablets, increasing to eight in severe circumstances – Schedule 2):

- diabetes mellitus, multiple sclerosis, Parkinson's disease, poliomyelitis;
- renal failure treated by dialysis or transplantation;
- previous radical pelvic surgery (e.g. radical prostatectomy) or previous treatment for prostate cancer (using surgery and other treatments);
- have severe pelvic injury, single-gene neurological disease, spinal cord injury or spina bifida; or
- are not included in the above categories but were receiving NHS treatment (such as Caverject[™], Viagra[™] or Viridal[™]) for their erectile dysfunction on or before 14 September 1998.

Originally, the Department of Health guidance stated that prescribing for those with erectile dysfunction causing "severe distress" should only be done by specialist services.

As sildenafil is now available in generic form, is significantly cheaper and is free of Schedule 2 restrictions, we usually recommend it as the first choice PDE-5 inhibitor.

Should I stop smoking?

Smoking can seriously impair your erectile function, and we would advise you to stop smoking completely if you have problems with erections. For advice on stopping, you can:

- contact your GP;
- access your local NHS Smoking Help Online; or
- ring the free NHS Smoking Helpline on **0300 123 1044**.

What sources were used to prepare this leaflet?

This leaflet uses information from consensus panels and other evidence-based sources including:

- the Department of Health (England);
- the Cochrane Collaboration; and

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• the National Institute for Health and Care Excellence (NICE).

NHS hospitals have local arrangements with their Clinical Commissioning Groups (CCGs) about which medicines can be prescribed. Thus, some drugs mentioned cannot be prescribed by local hospitals.

Your treatment will be planned with the doctors responsible for your care, considering not only which drugs are, or are not, available at your local hospital but also what is necessary to give you the best quality of care.

Healthcare professionals are advised to check prescribing arrangements with their local hospital or CCG.

This leaflet also follows style guidelines from:

- the Royal National Institute for Blind People (RNIB);
- the Information Standard;
- the Patient Information Forum; and
- the Plain English Campaign.

Disclaimer

We have made every effort to give accurate information in this leaflet, but there may still be errors or omissions. BAUS cannot accept responsibility for any loss from action taken (or not taken) as a result of this information.

PLEASE NOTE

The staff at BAUS are not medically trained, and are unable to answer questions about the information provided in this leaflet. If you do have any questions, you should contact your urologist, specialist nurse or GP.

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