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PATIENT GUIDE

Oral medicines *for erectile dysfunction*

Sildenafil, tadalafil and vardenafil are taken by mouth, and pharmacies compound the same drugs as capsules and troches. The labels, the trials and the regulatory status are set out below.

CLASS	DRUGS	FORMS	STATUS	SOURCES
PDE5 inhibitors	Sildenafil, tadalafil	Tablet, film, troche	Approved, compounded	31 · PMID linked

§ 01

Overview

Erectile dysfunction means trouble getting or keeping an erection firm enough for sex, and it becomes more common with age. In the Massachusetts Male Aging Study, a community sample of men aged 40 to 70, 52 percent reported minimal, moderate or complete difficulty, and complete difficulty rose from 5 percent at age 40 to 15 percent at age 70.[1] The arteries that fill the penis are narrow, so they often show strain before the heart does. Among 300 men admitted with chest pain who were then shown on angiography to have coronary artery disease, 49 percent had erectile dysfunction, and of the men who had both, 67 percent said the erection problem came first, on average by 38.8 months.[2] Pooling 12 prospective cohorts of 36,744 men, the relative risk of cardiovascular disease was 1.48 in men with erectile dysfunction.[3] The American Urological Association asks that every man be told erectile dysfunction is a risk marker for heart disease and other conditions that may need attention of their own, so the assessment comes before the prescription.[4]

This guide covers the medicines for erectile dysfunction that are taken by mouth: sildenafil, tadalafil and vardenafil as swallowed tablets, the forms of those drugs that dissolve in the mouth, compounded capsules and troches of the same three drugs, and compounded troches that add apomorphine. Every dose and side effect figure below comes from a current FDA label or a published trial. Injection treatment given into the penis is covered in our penile injection guide (OCW WP 063), and PT 141, which acts through the brain, in our PT 141 guide (OCW WP 014).

82%	**Improved on sildenafil 100 mg.** Across four fixed dose placebo controlled studies in 1,797 men, 63, 74 and 82 percent on 25, 50 and 100 mg reported better erections, against 24 percent on placebo.[5]
36	**Hours one tadalafil tablet can cover.** The label states that tadalafil taken as needed improved erectile function against placebo up to 36 hours after the dose.[6]
67%	**Noticed the erection problem first.** Of 147 men with both erectile dysfunction and angiographically confirmed coronary disease, 99 said the erection problem preceded the cardiac symptoms.[2]
3	**FDA approved ways to take them by mouth.** A swallowed tablet, a tablet that disintegrates on the tongue, and a film that dissolves on it. A compounded capsule or troche is none of these.[5][8][9]

§ 02

What these medicines are

Sildenafil, tadalafil and vardenafil belong to one family, the phosphodiesterase type 5 inhibitors, usually shortened to PDE5 inhibitors. All three are FDA approved for erectile dysfunction as tablets swallowed by mouth, and tadalafil is approved for the signs and symptoms of an enlarged prostate as well.[5] [6] [7] Two of them also have an approved form that is put in the mouth rather than swallowed with water: a 10 mg vardenafil tablet that disintegrates on the tongue, and a sildenafil film in four strengths that dissolves on the tongue and is then swallowed with saliva. [8] [9]

A compounding pharmacy can prepare the same drugs in forms no manufacturer makes, as a capsule or as a troche, which is a soft lozenge held under the tongue or against the cheek and left to dissolve. Some troches add apomorphine, a dopamine agonist that acts in the brain rather than on blood flow, and that is approved in the United States only for Parkinson disease.[11] [12] A compounded preparation of any of these drugs is not FDA approved, and the agency does not review its safety, effectiveness or quality before it is dispensed. [29]

THE ORAL MEDICINES ON OUR MENU	
Sildenafil tablets	25, 50 and 100 mg, swallowed; FDA approved for erectile dysfunction as Viagra and as generics[5] [11]
Tadalafil tablets	2.5 to 20 mg, swallowed; FDA approved for erectile dysfunction, for the signs and symptoms of benign prostatic hyperplasia, and for both together[6]
Vardenafil tablets	2.5, 5, 10 and 20 mg, swallowed; FDA approved for erectile dysfunction, the brand Levitra now discontinued and generics marketed[7] [11]
Forms that dissolve in the mouth	A 10 mg vardenafil orally disintegrating tablet, and a sildenafil oral film of 25, 50, 75 or 100 mg; both FDA approved, both placed on the tongue and taken without water[8] [9]
Compounded capsules	The same drugs put into a capsule by a licensed pharmacy on a prescription; no single ingredient capsule of any of the three is FDA approved[11] [29]
Compounded troches	A lozenge that dissolves under the tongue or in the cheek; no sublingual or buccal product of these drugs has FDA approval[11]
Troches with apomorphine	A PDE5 inhibitor compounded together with apomorphine; no apomorphine product has been approved in the United States for erectile dysfunction,[11] [27] and no published trial has tested the pairing

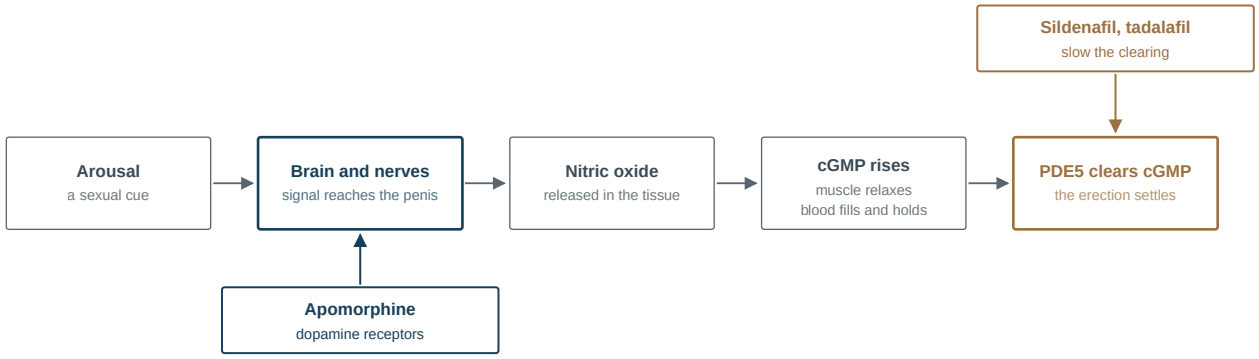
§ 03

How they work

An erection is a plumbing event with a nerve switch. When a man is aroused, the nerve endings and the lining of the blood vessels in the erectile bodies release nitric oxide, which switches on an enzyme that makes cyclic guanosine monophosphate, or cGMP. The cGMP relaxes the smooth muscle in the walls of the penile arteries, blood flows in faster than it drains away, and the penis becomes firm. An enzyme called PDE5, the most plentiful of its kind in that tissue, then breaks cGMP down and the erection settles.[7]

A PDE5 inhibitor slows that last step, so the cGMP made during arousal lasts longer and works harder. The vardenafil label puts the consequence plainly: because sexual stimulation is what releases nitric oxide in the first place, inhibiting PDE5 has no effect in the absence of sexual stimulation.[7] A tablet amplifies a signal your own body sends, so arousal, privacy and time all still matter.

Apomorphine comes at the problem from the other end. It is a non ergoline dopamine agonist, and dopamine signalling in the brain is part of how sexual arousal is generated, so apomorphine was studied in the 1990s and 2000s as a treatment that would start the signal rather than preserve it.[12] [17] Its approved use in the United States is for the sudden loss of mobility that comes with advanced Parkinson disease, given by injection under the skin. [12]



The two kinds of oral medicine act on the same chain at opposite ends. A PDE5 inhibitor works at the last step, protecting the cGMP that arousal has already made, which is why the vardenafil label states that inhibiting PDE5 has no effect without sexual stimulation.[7] Apomorphine works at the start, on dopamine receptors in the brain, and it is approved in the United States only for Parkinson disease. [12]

KEY POINT

Where a medicine is put in the mouth changes how fast it is absorbed, and the labels show that it does not always change it in the direction people expect. Swallowing a vardenafil orally disintegrating tablet with water instead of letting it melt cut the total drug absorbed by 29 percent, and the label warns that the melting tablet is not interchangeable with the swallowed tablet of the same strength because it delivers more drug.[8] The approved sildenafil oral film reaches its peak at a median of 80 minutes, slower than the 60 minutes of the swallowed tablet. [5] [9]

§ 04

What the research shows

Sildenafil was studied in 21 randomized, double blind, placebo controlled trials in more than 3,000 men aged 19 to 87 and improved erectile function in all 21; tadalafil in 22 trials of up to 24 weeks in over 4,000 patients; vardenafil in four fixed dose trials in 2,431 men of mean age 57.[5] [6] [7] The compounded capsules and troches have no trials of their own.

What the evidence supports

All three work, and the differences between them are modest. A dose specific network meta analysis published in 2026, covering 83 double blind placebo controlled trials and 6,029 participants, found the highest odds of reaching a normal erectile function score with sildenafil 100 mg (odds ratio 9.06) and 50 mg (7.90), then vardenafil 10 mg (7.78) and tadalafil 20 mg (7.13). In the same analysis the odds of a treatment related side effect were highest for vardenafil and lowest for tadalafil.[13]

Timing separates them more than strength does. Sildenafil and vardenafil peak in the blood at a median of about an hour and have a half life of roughly 4 to 5 hours.[5] [7] Tadalafil peaks at a median of 2 hours and has a half life of 17.5 hours, and in a study of 348 men given 20 mg, 64 percent reported at least one successful attempt at intercourse 33 to 39 hours after the dose, against 37 percent on placebo. [6]

Tadalafil also treats prostate symptoms. Five milligrams once daily is approved for the signs and symptoms of benign prostatic hyperplasia, and for an enlarged prostate and erectile dysfunction together. In two 12 week trials the International Prostate Symptom Score fell by 4.8 points against 2.2 on placebo in the first, and by 5.6 against 3.6 in the second.[6]

The approved form that melts on the tongue has its own trials. Two matched studies of the 10 mg vardenafil orally disintegrating tablet, half of whose participants were 65 or older, raised the erectile function domain score by 8.7 and 8.5 points against 1.6 and 1.5 on placebo, and raised the proportion of attempts ending in successful intercourse to 65 and 60 percent against 26 and 27 percent.[8]

What is not yet known

No published study measures how much sildenafil, tadalafil or vardenafil is absorbed from a compounded troche, and none has measured erections after one, so the figures above cannot be carried across to a troche. Two published studies did put sildenafil under the tongue in a manufactured form. In a double blind study of 40 men, 20 mg of sildenafil given sublingually produced satisfying erections and intercourse in 65 percent against 15 percent on placebo, with a mean onset of 15.5 minutes.[14] In 20 men with psychogenic erectile dysfunction, a 50 mg sildenafil film dissolved under the tongue gave blood levels at 15 minutes of 13.5 ng/mL against 2.24 ng/mL for the swallowed tablet, with headache after 1 percent of doses against 35 percent; that study measured drug levels and tolerability, not erections.[15] A review of the pharmacokinetics of these drugs concluded that the manufactured orally disintegrating tablets and films behave much like the film coated tablets they replace.[16]

Apomorphine given under the tongue was tested properly in its own right, and the results were real but smaller than those of a tablet. In an eight week trial of 569 men, 48 to 53 percent across the apomorphine groups achieved and kept an erection firm enough for intercourse against 35 percent on placebo, and 45 to 51 percent of attempts ended in intercourse against 33 percent; nausea was the commonest side effect and was dose related, with 2 and 4 mg giving the best balance.[17] A crossover study of 296 men found 3 mg better than placebo with a median time to erection of 18.8 minutes, and found no efficacy advantage from 4 mg, only more side effects: nausea in 14.1 percent on 4 mg against 3.3 percent on 3 mg.[18] Measured head to head in a randomized crossover study, sublingual apomorphine 3 mg produced a firm erection in 44 percent of attempts against 85 percent for sildenafil 50 mg.[20] No published trial has tested a troche that combines apomorphine with a PDE5 inhibitor.

THE MAIN HUMAN EVIDENCE These trials were run separately and cannot be compared with each other unless the study itself made the comparison.

STUDY	N	DESIGN	MAIN FINDING
Sildenafil label[5]	1,797	Four fixed dose, placebo controlled, 12 to 24 weeks	Better erections in 63, 74 and 82 percent on 25, 50 and 100 mg against 24 percent
Tadalafil label US trials[6]	402	Double blind, placebo controlled, 12 weeks	Erectile function domain rose 6.9 and 9.3 points on 20 mg against a 0.2 fall and a 0.3 rise
Vardenafil label North American trial[7]	762	Double blind, fixed dose, 3 months	Erections kept to intercourse in 51, 64 and 65 percent on 5, 10 and 20 mg against 32 percent
Vardenafil melting tablet label[8]	686	Two matched placebo controlled trials, 3 months	Function domain rose 8.7 and 8.5 points against 1.6 and 1.5 on placebo
Salonia 2026[13]	6,029	Systematic review and network meta analysis, 83 trials	Odds of a normal score 9.06 for sildenafil 100 mg, 7.13 for tadalafil 20 mg; fewest side effects with tadalafil
Deveci 2004[14]	40	Double blind, 20 mg sildenafil under the tongue	Satisfying erections in 65 percent against 15 percent; mean onset 15.5 minutes
De Toni 2018[15]	20	Crossover drug level study, three sildenafil forms	Sublingual film 13.5 ng/mL at 15 minutes against 2.24 for the tablet; no erection endpoint
Dula 2000[17]	569	Eight week, double blind, sublingual apomorphine	Erections firm enough for intercourse in 48 to 53 percent against 35 percent; dose related nausea
Pavone 2004[20]	62	Randomized crossover, apomorphine 3 mg against sildenafil 50 mg	Firm erection in 44 percent of attempts against 85 percent

SUMMARY

A swallowed tablet is where the evidence is strongest, and the choice between the three is about timing and tolerance: sildenafil and vardenafil act within an hour and clear quickly, tadalafil covers a day and a half with fewer side effects, and a 5 mg daily dose of tadalafil also eases prostate symptoms. The approved forms that melt on the tongue have trials behind them and labels that set a dose. A compounded capsule or troche of the same drug has neither, and apomorphine added to a troche rests on trials of apomorphine given alone, where it worked but worked less well than sildenafil and caused more nausea.

§ 05

How these medicines are given

The doses below come from the current FDA labels, or from published studies where no label exists. Where no regulator has set a dose, we say so and your physician sets it. The AUA asks that the dose of a PDE5 inhibitor be titrated to the best effect a man can tolerate, which is a strong recommendation in the guideline.[4]

Tablets swallowed by mouth

Sildenafil comes as 25, 50 and 100 mg tablets. The label recommends 50 mg about an hour before sex, taken anywhere from 30 minutes to 4 hours beforehand, raised to 100 mg or lowered to 25 mg, and no more than once a day. It may be taken with or without food, though a high fat meal delays the peak by about an hour and lowers it by 29 percent.[5] Vardenafil comes as 2.5, 5, 10 and 20 mg tablets, starting at 10 mg about 60 minutes before sex and adjusted to 20 mg or 5 mg, no more than one a day. A high fat meal lowers its peak by 18 to 50 percent, men aged 65 or over should consider starting at 5 mg, and men with moderate liver impairment start at 5 mg and should not exceed 10 mg.[7]

Tadalafil comes as 2.5, 5, 10 and 20 mg tablets and can be used two ways.[11] As needed, the label starts at 10 mg before sex, adjusted up to 20 mg or down to 5 mg, no more than once a day, with the effect lasting up to 36 hours. Once daily, it gives 2.5 mg for erectile dysfunction, raised to 5 mg if needed, and 5 mg at about the same time each day for prostate symptoms or for the two conditions together. Food makes no difference to tadalafil.[6]

Approved forms that dissolve in the mouth

The vardenafil orally disintegrating tablet comes in one strength, 10 mg, taken about 60 minutes before sex and no more than once a day. The label asks for it to be placed on the tongue and taken without liquid, and it carries three cautions the swallowed tablet does not: it is not interchangeable with the 10 mg film coated tablet because it delivers more drug, it should not be the form used to start treatment in a man already taking an alpha blocker, and it should not be used in moderate or severe liver impairment or by a man on dialysis.[8]

The sildenafil oral film comes in 25, 50, 75 and 100 mg, with the same recommended 50 mg starting dose and the same timing as the tablet. It is placed directly on the tongue, where it disintegrates and is then swallowed with saliva, so no water is needed; it should not be cut or chewed.[9]

Compounded capsules and troches

A compounded capsule or troche is prepared by a licensed pharmacy for one patient against that patient's own prescription.[30] No single ingredient capsule of sildenafil, tadalafil or vardenafil is FDA approved, and no sublingual or buccal product of any of them is approved, so no regulator has set a dose or a strength for either form and your physician sets both.[11] The nearest published figures come from manufactured products rather than compounded ones: 20 mg of sildenafil under the tongue in a 40 man study, and 50 mg as a dissolving film in a 20 man drug level study.[14][15]

Troches that add apomorphine are compounded the same way. No apomorphine product is approved in the United States for erectile dysfunction, so no label dose exists,[11] and no published trial has tested apomorphine together with a PDE5 inhibitor. Trials of apomorphine on its own used 2 to 6 mg under the tongue about 15 to 25 minutes before sex, and reported that 2 and 4 mg gave the best balance against nausea.[17][19]

COMPARING THE ORAL FORMS

	SWALLOWED TABLET	APPROVED FORM THAT MELTS	COMPOUNDED CAPSULE OR TROCHE
Needs arousal	Yes[7]	Yes[7]	Yes[7]
Timing before sex	30 minutes to 4 hours for sildenafil; up to 36 hours for tadalafil[5][6]	About 60 minutes for vardenafil; about 1 hour for the sildenafil film[8][9]	Not established; no label exists[11]
Effect of food	Cuts the sildenafil peak 29 percent; none for tadalafil[5][6]	Cuts the vardenafil peak 35 percent without changing the total absorbed[8]	Not studied
Dose set by	FDA label[5]	FDA label[8]	Your physician; no label exists[11]
FDA approved product	YES	YES	NO

§ 06

What to expect

The first dose. Sildenafil and vardenafil reach their peak in the blood at a median of about an hour, tadalafil at a median of two hours.[5][6][7] Some men are ready sooner than that: in a study of 223 men, 52 percent of those on tadalafil 20 mg had a successful erection at or before 30 minutes, against 35 percent on placebo.[6] A first dose that does little is not a verdict on

the medicine, and the AUA advises titrating to the dose that works. [4] Headache is the side effect most men notice, then flushing, indigestion and a blocked nose, and sildenafil at 100 mg also causes a mild, passing change in colour vision in about one man in nine. [5]

A form that melts in the mouth. These forms were designed for convenience, and the labels show they are not faster: the vardenafil melting tablet peaks at a median of 1.5 hours and the sildenafil film at a median of 80 minutes, both a little later than the swallowed tablets. [8] [9] Taken as the label asks, without water, the vardenafil form delivers more drug than the tablet of the same strength, so the label states that the two are not interchangeable. [8]

Over months and years. Men stop these medicines more often than the trial results would predict. Pooling 22 observational studies of 162,936 patients, the mean discontinuation rate was 4 percent per month, close to half within a year, and the commonest reasons given were lack of effect and difficulties with a partner rather than side effects. [25] Telling us early that something is not working gives us more to change than telling us late.

DURING TREATMENT

- An erection lasting longer than 4 hours needs emergency care the same day, and every one of these labels says so. [5] [6] [7]
- Stop the medicine and seek care at once for sudden loss of vision in one or both eyes, or sudden loss or reduction of hearing. [5] [6] [7]
- Chest pain or breathlessness during sex is a reason to stop and be assessed, not a reason to try a larger dose. [22]
- Tell us about any new medicine started while you are using one of these, because several common antibiotics and antifungals raise the level of all three drugs. [7] [8]

§ 07

Safety

None of these labels carries a boxed warning, and the three drugs share the same set of cautions. [5] [6] [7]

- **Nitrates.** Every PDE5 inhibitor is contraindicated in a man taking nitrates or any other nitric oxide donor, in any form, whether regularly or now and then, because together they can drop blood pressure sharply. [5] [6] [7] That covers nitroglycerin tablets or spray, isosorbide, and the amyl nitrite products sold as poppers. In 18 healthy subjects, vardenafil 20 mg given one or four hours before 0.4 mg of nitroglycerin under the tongue lowered blood pressure further than nitroglycerin alone, with no additional effect when the gap was 24 hours. [7] Riociguat is contraindicated for the same reason. [5]
- **Alpha blockers.** Tamsulosin, doxazosin and the rest can combine with a PDE5 inhibitor to lower blood pressure enough to cause faintness, so the labels ask that a man be stable on the alpha blocker first and that the PDE5 inhibitor start low, at 25 mg of sildenafil or 5 mg of vardenafil. Tadalafil is not recommended with an alpha blocker for prostate symptoms, and the vardenafil melting tablet should not be the form used to start treatment in a man on one. [5] [6] [7] [8]
- **Whether your heart is fit for sex.** The labels state that treatments for erectile dysfunction should not generally be used in men for whom sexual activity is inadvisable because of their cardiovascular status. [5] The Princeton IV consensus asks that a man with erectile dysfunction be treated as at risk of a cardiac event until shown otherwise, with coronary artery calcium scoring where the risk is hard to place. [22] That assessment belongs before the prescription.
- **Priapism.** An erection that will not go down is uncommon with a tablet and it is an emergency when it happens. The AUA and the Sexual Medicine Society of North America class acute ischemic priapism as a medical emergency that can scar the erectile tissue and leave lasting erectile dysfunction, and ask for every case to be assessed urgently. [24]
- **Eyes, ears and heart rhythm.** All three labels ask a man to stop the drug and seek care for sudden loss of vision, which can signal non arteritic anterior ischemic optic neuropathy, and for sudden loss or reduction of hearing. [5] [6] [7] The sildenafil label reports observational studies suggesting roughly a twofold increase in the risk of that eye condition, with a risk

estimate of 2.15 (95 percent confidence interval 1.06 to 4.34), and states that the findings do not establish cause; the background rate in men over 50 is 2.5 to 11.8 cases per 100,000 a year. [5] A later systematic review and meta analysis of four observational studies found no association with definite cases, with an odds ratio of 1.16 (95 percent confidence interval 0.89 to 1.52). [23] The vardenafil label asks men with congenital long QT syndrome, or taking class IA or class III antiarrhythmic drugs, to avoid it. [7]

SIDE EFFECTS ON THE LABELS Percent of men reporting each effect, with the placebo group of the same trials in brackets. Each label reports its own separate trials, so the columns are not a head to head comparison. [5 6 7 8]

SIDE EFFECT	SILDENAFIL 100 MG	TADALAFIL 20 MG	VARDENAFIL 5 TO 20 MG	VARDENAFIL MELTING TABLET
Headache	28% (7%)	15% (5%)	15% (4%)	14.4% (1.8%)
Flushing	18% (2%)	3% (1%)	11% (1%)	7.6% (0.6%)
Indigestion	17% (2%)	10% (1%)	4% (1%)	2.8% (0%)
Blocked or runny nose	9% (2%)	3% (1%)	9% (3%)	3.1% (0.3%)
Back pain	4% (2%)	6% (3%)	2.0% (1.7%)	2% (0.3%)
Change in colour vision	11% (1%)	Not listed	Not listed	Not listed
Stopped because of a side effect	2.5% (2.3%)	3.1% (1.4%)	3.4% (1.1%)	1.4% (0.6%)

What apomorphine adds

Nausea is the side effect that limited apomorphine when it was studied for erectile dysfunction, and the rates rose with the dose: 3.3 percent on 3 mg against 14.1 percent on 4 mg in one crossover study, and 7.0 percent on 3 mg against 1.1 percent on placebo in the same trial's placebo comparison. [18] In a European study of 507 men pushed up to 4 mg, nausea was reported by 9.8 percent, dizziness by 7.1 percent and headache by 6.7 percent, against 0.4, 2.4 and 4.0 percent on placebo. [19] At the much higher doses used for Parkinson disease, the approved label reports nausea in 31 percent and vomiting in 11 percent even with an antiemetic given beforehand. [12]

Blood pressure matters too. The Parkinson label reports syncope in about 2 percent of patients, orthostatic hypotension, hypotension or syncope in 59 of 550 men, and a contraindication against ondansetron and the other 5HT3 antiemetics after reports of profound hypotension and loss of consciousness. [12] In 162 men taking blood pressure medicines or nitrates, sublingual apomorphine 5 mg lowered standing systolic pressure further in the men on alpha blockers or calcium channel blockers, and by 5 to 9 mm Hg in the men on long acting nitrates, with symptomatic hypotension in two men in each nitrate group. [21]

TELL YOUR PHYSICIAN BEFORE STARTING IF ANY OF THESE APPLY

- You take a nitrate in any form, including nitroglycerin tablets or spray, isosorbide or inhaled poppers, or you take riociguat. [5 6 7]
- You take an alpha blocker such as tamsulosin or doxazosin, or more than one blood pressure medicine, or you feel faint on standing. [5 7 21]
- Your heart has limited what you can do, or you have had a heart attack, stroke, unstable angina or a dangerous rhythm, or your heart has not been assessed recently. [5 22]
- You have had an erection that would not go down, or you have sickle cell disease or trait, multiple myeloma or leukemia. [24]

- You have had sudden loss of vision or hearing, you have been told you have a crowded optic disc, or you have congenital long QT syndrome or take a class IA or class III antiarrhythmic drug.[5] [7]
- You have serious liver or kidney disease or are on dialysis, or you take ritonavir, ketoconazole, itraconazole, clarithromycin or erythromycin, which raise the level of these drugs.[7] [8]
- Please bring the full list of everything you take, prescription, over the counter and supplement.[4]

The trials behind these labels ran for weeks to months, with the longest controlled exposures in the tadalafil programme at 24 weeks and in the vardenafil programme at 6 months.[6] [7] Trials covering many continuous years have not been published for any of these medicines, and no trial of any length has been published for a compounded capsule or troche.

§ 08

Is this right for you

Treatment suits a man who wants it, whose heart can take sexual activity safely, and whose causes have been looked for rather than assumed. The AUA sets out the assessment as a clinical principle: a thorough medical, sexual and psychosocial history, a physical examination with pulse and resting blood pressure, and selective laboratory testing, with a short validated questionnaire to measure change against.[4] That same guideline asks that the conversation include the fact that erectile dysfunction is a risk marker for cardiovascular disease and other conditions, which the chest pain series makes concrete: two thirds of the men who had both noticed the erection problem about three years before their cardiac symptoms.[4] [2]

Before we begin

- [ ] Your medical history, how the problem started and changed, your current medications and supplements, and your partner's view where that helps[4]
- [ ] Pulse, resting blood pressure and an examination, so we know your heart can take sexual activity[4] [22]
- [ ] Baseline bloodwork of the kind the guideline describes, including a morning total testosterone, which it recommends in every man with erectile dysfunction[4]
- [ ] A written note of your goals, so we can judge progress together

Finding the cause comes first. Diabetes, high blood pressure, high cholesterol, smoking, sleep apnea, depression and several common medicines all contribute, and treating them helps the erection as well as the man. If your testosterone is low, our testosterone guide (OCW WP 055) covers that question in detail, and the AUA notes that a PDE5 inhibitor may work better when low testosterone is replaced alongside it.[4]

Reviewing your progress

The first review is about dose and instructions, because a PDE5 inhibitor that has not been titrated has not really been tried.[4] If a full dose tablet used properly on several occasions is not enough, the next steps are a different one of the three, a daily low dose of tadalafil, or treatment given another way. A meta analysis of 44 studies in 3,853 men found that adding a second treatment to a PDE5 inhibitor improved the erectile function score by a mean of 1.76 points overall, and by 4.38 points in the men whose single treatment had failed, without a rise in side effects.[26] Injection treatment is set out in our penile injection guide (OCW WP 063). Your physician will set your own review schedule, and you are welcome to stop at any time.

QUESTIONS TO ASK YOUR PHYSICIAN

What is causing my erectile dysfunction, and has it been looked for? Is my heart fit for sexual activity, and does anything need checking first? Which of these three drugs suits my timing and my other prescriptions? Is the preparation you are writing for me FDA approved or compounded, and why that one? What dose change would you try before deciding a tablet has not worked? What should I do if an erection will not go down?

We are glad to answer all of these.

§ 09

Regulatory status

The tablets. Sildenafil, tadalafil and vardenafil tablets are FDA approved for the treatment of erectile dysfunction, and tadalafil is additionally approved for the signs and symptoms of benign prostatic hyperplasia and for the two conditions together.[5] [6] [7] Generic versions of all three are approved and marketed. None is a biologic and none is a controlled substance.

The forms that dissolve in the mouth. Two are FDA approved: a 10 mg vardenafil orally disintegrating tablet, where the brand Staxyn has been discontinued and generic versions are marketed, and a sildenafil oral film in four strengths.[8] [9] [11] Both are swallowed in saliva rather than absorbed under the tongue, and both have their own label dose.

Compounded capsules and troches. No single ingredient capsule of sildenafil, tadalafil or vardenafil is FDA approved; the only approved capsule containing any of them pairs tadalafil 5 mg with finasteride 5 mg to start treatment for an enlarged prostate for up to 26 weeks.[10] [11] No sublingual or buccal product of the three has ever been approved, so a troche of any of them is a compounded medicine. [11] A compounded sublingual troche of these drugs is not FDA approved, no published study has measured how much of the drug is absorbed from such a troche, and the FDA does not review the safety, effectiveness or quality of a compounded preparation before it is dispensed. [29] It is prepared by a state licensed pharmacy or physician on a prescription for one named patient under section 503A of the federal law, or by an outsourcing facility registered with the FDA under section 503B. [30]

Troches containing apomorphine. Apomorphine is not FDA approved in the United States for erectile dysfunction, and it never has been. Every approved apomorphine product is for Parkinson disease: a subcutaneous injection, a subcutaneous infusion, and a sublingual film that has been discontinued.[11] [12] The sublingual apomorphine tablet developed for erectile dysfunction, Uprima, was authorised in the European Union on 28 May 2001 and its authorisation was withdrawn on 28 May 2006, when the company chose not to renew it for commercial reasons; it was never approved here. [27] [11] A compounded troche combining apomorphine with a PDE5 inhibitor is therefore not FDA approved in any form, and no published trial has tested it. [29]

Athletes. The World Anti Doping Agency Prohibited List in force from 1 January 2026 does not name sildenafil, tadalafil, vardenafil, avanafil, phosphodiesterase inhibitors or apomorphine anywhere in its classes, so none of these medicines is prohibited in or out of competition.[28] The list is reviewed every year, so a tested athlete should confirm it with his own anti doping organisation each season. [28]

If you would like details about the preparation used in your treatment, please ask.

§ 10

Common questions

Which of these is FDA approved?

Sildenafil, tadalafil and vardenafil tablets are FDA approved for erectile dysfunction, as are the 10 mg vardenafil tablet that disintegrates on the tongue and the sildenafil oral film.[5 6 7 8 9] Compounded capsules and troches of the same drugs are not, and neither are troches that add apomorphine.[11 29] If you would like details about the preparation used in your treatment, please ask.

Does a troche work faster or better than a tablet?

Nobody can say, because no published study has measured how much drug a compounded troche delivers or what it does to erections. Manufactured sildenafil given under the tongue does reach the blood faster and caused much less headache in a 20 man drug level study, and a small double blind study of 20 mg sublingual sildenafil reported satisfying erections in 65 percent against 15 percent on placebo.[14 15] Against that, a review of these drugs found the manufactured melting tablets and films behave much like the swallowed tablets, and the approved sildenafil film peaks later than the tablet does.[16 9]

Can I take one if I use nitroglycerin or poppers?

No. All three drugs are contraindicated with nitrates and with any other nitric oxide donor, in any form, taken regularly or occasionally, because together they can drop blood pressure dangerously.[5 6 7] Tell us about nitroglycerin tablets or spray, isosorbide and inhaled nitrites sold as poppers before anything is prescribed. Apomorphine is not a way around that rule: in men on long acting nitrates it lowered standing blood pressure by 5 to 9 mm Hg, and two men in each nitrate group had symptomatic hypotension.[21]

What does apomorphine add to a troche?

In its own trials sublingual apomorphine helped, with 48 to 53 percent of men achieving and keeping an erection firm enough for intercourse against 35 percent on placebo, and a median time to erection of about 19 minutes.[17 18] Measured directly against sildenafil 50 mg it did less, producing a firm erection in 44 percent of attempts against 85 percent.[20] Nausea was the usual reason men disliked it, reported by 9.8 percent in a 507 man European study and by 14.1 percent of men taking 4 mg in a crossover study, and no trial has tested apomorphine together with a PDE5 inhibitor.[18 19]

Which of the three should I start with?

Timing usually decides it. Sildenafil and vardenafil act within an hour and clear in 4 to 5 hours, so they suit a planned occasion, while tadalafil lasts up to 36 hours and can also be taken as a low daily dose, which suits men who would rather not think about timing or who have prostate symptoms as well.[5 6 7] In the 2026 network meta analysis of 83 trials, sildenafil 100 mg had the highest odds of a normal erectile function score and tadalafil the lowest odds of a side effect.[13]

Can I take one of these every day?

Only tadalafil has a daily dose on its label, 2.5 mg raised to 5 mg if needed for erectile dysfunction, and 5 mg at about the same time each day when an enlarged prostate is being treated too.[6] Sildenafil, vardenafil and the two forms that dissolve in the mouth are labelled for no more than one dose in 24 hours.[5 7 8 9]

What if an erection will not go down?

An erection lasting more than 4 hours needs emergency care that day, and all three labels say so.[5 6 7] The AUA and the Sexual Medicine Society of North America class acute ischemic priapism as a medical emergency, because without prompt treatment it can scar the erectile tissue and leave lasting erectile dysfunction.[24] Go to an emergency department rather than waiting for office hours, and tell them which medicine you took.

Where is a compounded medicine made, and who oversees it?

Federal law sets out two kinds of compounding. Under section 503A, a state licensed pharmacy or physician prepares a medicine for one patient against that patient's own prescription, and the state board of pharmacy carries the day to day oversight while the FDA inspects for cause and on surveillance.[29] Under section 503B, an outsourcing facility registers with the FDA, works to federal manufacturing quality standards, reports adverse events and the products it makes to the agency, and is inspected by the FDA on a risk based schedule; it may also supply a clinic directly rather than for one named patient.[30] We use both kinds, and which one prepares your medicine depends on the preparation.

Is a compounded medicine the same as an FDA approved one?

No, and the difference matters. A compounded preparation is not FDA approved, and the agency does not check its safety, effectiveness or quality before it is sold, which is why an approved product is the first choice whenever one fits your situation.[29] What a prescription from a licensed pharmacy or a registered outsourcing facility does give you is a named prescriber, a facility answerable to a state board or to the FDA, ingredients that meet federal requirements, and a route for reporting a problem. A vial or lozenge bought online and labelled for research use only has none of that: the FDA treats those products as unapproved new drugs when they are meant for people, and has written to the companies selling them.[31] Please do not use one.

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