

Generic/TRADE (Strength & forms)	Class / Pregnancy category <sup>9</sup>	Side effects / Contraindications <b>C</b>	√ = therapeutic use / Comments / Drug Interactions <b>DI</b> / Monitor <b>M</b>	INITIAL;MAX; USUAL DOSE	\$ <b>CA</b> 8 doses
<b>Sildenafil</b> <b>VIAGRA</b> =S 25, 50, 100mg tab <b>X</b> ⊗ 10,11,12,13,14; approved 1999 (Revatio 20-80mg tab tid ⊗ ≥\$1050 per month, new: USA IV form → PAH) <b>Tadalafil</b> <b>CIALIS</b> =T 2.5,5,10,20mg tab <sup>15,16</sup> <b>X</b> ⊗ (Adecirca 20-40mg tab od <b>X</b> ⊗ FDA 09; USA is IV form → PAH) <b>Vardenafil</b> <b>LEVITRA</b> =V 5,10, 20mg tab <b>X</b> ⊗ 17,18,19,20,21,22,23,24,25,26	<b>Oral selective phosphodiesterase-5 PDE5 inhibitor:</b> -reduce catabolism of cGMP resulting in smooth muscle relaxation of the corpus cavernosum and ↑ blood flow into penis (need sexual stimulation to produce actual erection) -considered <b>FIRST LINE</b> unless CI, but ~30% of men may still not respond to PDE5's monotherapy.	<b>Common:</b> flushing <sup>10%</sup> , diarrhea <sup>4%</sup> , dizziness <sup>2%</sup> , headache <sup>&gt;10%</sup> , dyspepsia <sup>&lt;8%</sup> , blurry vision (visual disturbance > with S,V), myalgia (T=6% <sup>35</sup> ), nasal congestion & rash <sup>2% esp S</sup> ; GI upset <sup>dose-related</sup> & visual disturbance (>10% at dose high, ?(↓smell, amnesia, hearing loss). [hot flashes if used in ♀] <b>Serious:</b> rare MI & priapism; QT prolongation -V, very rare cases of NAION <sup>23</sup> , seizures, ?sickle cell crisis <b>CI:</b> nitrates: ↑↑ hypotensive effect & ↑↑ heart rate (AVOID within 24h of S,V; 48h of T <sup>31</sup> ); α-1 blockers (if new pt or if given ≤ 4hrs) S >25mg, T,V <b>Precautions:</b> anatomical penis deformation; CV dx (eg. arrhythmia, recent MI/stroke, uncontrolled HTN, coronary ischemia, HF); ↑ risk of priapism (eg, sickle cell anemia, multiple myeloma, or leukemia); liver dx; anti BP meds; ↓ renal fx; NAION <sup>27</sup> ;	√ idiopathic, postencephalitic, symptomatic (Option: SSRI induced ED) (Onset similar: generally 30-60min v.S.T; as early as 10-15min v.S); S&T: pulmonary arterial HTN. <b>Peak effect:</b> S & V ~1hr; T ~2hr; <b>Duration:</b> S&V ~4-12hr T ≤ 36hr <b>DI:</b> ↑ hypotension: α-1 blockers (especially in new pt; avoid or space by >4hrs); nitrates (C) or caution; antihypertensives (esp. vasodilators) & alcohol <b>Nitrate washout period:</b> S & V ~24hr; T ~48hr. V:QT see QT chart p.17 <b>↑ levels of PDE5 by:</b> CYP 3A4 inhibitors (azole antifungals, cimetidine, cipro, erythromycin/macrolides, tacrolimus), doxycycline, grapefruit juice, isoniazid, protease inhibitors, quinidine, verapamil. (PDE5: use lowest dose; S,V: Max interval q24h T: Max interval q72h) <b>↓ effect:</b> enzyme inducers (carbamazepine, phenytoin, phenobarb, rifampin); ↓S&T by bosentan. high fat meals may delay and reduce efficacy of S & V. <b>M:</b> S,T = liver & renal fx, V=liver fx tests (Initial workup usually: glucose, lipid, TSH, testosterone) <b>Dose Adjustments:</b> >65years old: initial; S=25 mg T= by CrCl V=5mg Liver dx: Initial S=25 mg. T=10mg V=5mg Renal dx CrCl <30ml/min: Initial S=25 mg T=5mg V= no adjustment <b>Daily or 3x/week</b> dosing may be more efficacious for <b>poor responders</b> <sup>36</sup> < 5% of Non-responders will respond to a different PDE-5 inhibitor <sup>36</sup>	S 25-50mg → \$99-102 100mg x1/24h \$109 50-100mg, 30-60min pre-sex T 5-10mg → \$125 20mg x1/24h \$122 10-20mg 1-2hr pre-sex 2.5-5mg daily option \$132 30days V 5-10mg → \$102-111 20mg x1/24h \$119 10-20mg, 30-60min pre-sex	
<b>Frequently as adulterants in herbs:</b> Acai Berry products, Actra-Sx, Adam Free, Armstrong Natural, Aspire36 & Aspire Lite, Aspire Lite, Axcil, 4Everon, Actra-Rx, Blue Steel, China Vigor, Chong Cao Jiu Wang, Chongcaoliubian Jiaonang, Darling Caps, Dali Caps, DeguoZhanjiang, DeguoZonghengTianxia, Desirin, Dr. Life, Ehanix New Extra Men's Formula, Encore tabs for Men, Energy Max, Erexta, Excite, Firm Dose, Granite Rooster, Herb Vigour, Hero, HS Joy of Love, Jia Yi Jian, Jolex, Jiu Bian Wang, Kang Da, King Power Oral Soln, Lady Shangai, Libidit, Libidus, Libimax, Libipower Plus, Liviro3, Max V8 Rtno, Lover Liquid Nutriment, Lu Qian, Meng Rong, Nangen Zengzhangsu, Nasutra, Natural Super Plus, NaturalUp, Natural Vigour, Neophase, Once More, Onyo, Oyster Plus, Platinum Power 58 Extra, Power 58, Power 1 Walnut, Power tabs, Power Up, Santi Scalper Penis Erection, Rise 2 The Occasion Caps, Rockhard Weekend, Rose 4 Her Capsules, Sanbianwan, Satis 60hr Ever Lasting, Shangai Regular & Ultra X, Spanish Fly, Stamina Rx, Steam, Stiff Nights, Stretch Up, Strong Testis, Super Shangai, Super X, Sweet Energizer Vitality, Tian Li, Tian Huang Gu Shen Dan, Top Gun for Men Herbal Extracts, True Man, Ultimates, Urat Madu, Valentino, Vigoureux, VG, Vigor-25, Vigorect, Viril-ity Power vpxl No.1, Yilishen, Yixinjiaonang, Xiadafil VIP, XOJ for men, XP Tongkat Ali Supreme, Viaporo, Viril-ity-Power, Wodibo, Zencore & Plus, Zhong Guo Shen Fang, Zhong Hua Niu Bian, Zhuang Yao Gu Shen, Zhuang Tjar Gere, Zui Xian Dan Gong Shi Z, Zimaxx etc...					
<b>Alprostadil</b> <b>X</b> ⊗ <b>CAVERJECT,</b> 20 ug vial (powder) <b>intracavernosal inj.</b> <b>MUSE</b> <sup>28</sup> 250, 500, 1000 ug <b>urethral supp</b> (refrigerate; otherwise 14days at RT) <sup>29,30,31</sup> Prostaglandin <b>X</b> ⊗ E1 <sup>32</sup> (PGE1) = E1 inj corpora cavernosa; transurethral gel	<b>Prostaglandin E</b> -activates cAMP which relaxes smooth muscle and produces vasodilation (also inhibition of platelet aggregation and gastric secretion, stimulation of intestinal smooth muscle, uterine smooth muscle) -most efficacious of injectable agents	<b>Common:</b> ↓ HR <sup>7%</sup> , dizziness, fever <sup>14%</sup> , headache, hypotension <sup>4%</sup> , penile pain <sup>37%</sup> , penile fibrosis <sup>3%</sup> , tachycardia <sup>3%</sup> , urethral burning, vaginal itch (in partner with transurethral systems) <b>Serious:</b> seizures <sup>4%</sup> , priapism <sup>~4%</sup> , HF, second degree heart block, supraventricular tachycardia, ventricular fibrillation <sup>&lt;1%</sup> , disseminated intravascular coagulation <sup>1%</sup> & cortical proliferation of long bones <b>CI:</b> anatomical penis deformation, penile implant, predisposition to priapism (sickle cell anemia or trait, leukemia, myeloma), Peyronie's disease <b>Precautions:</b> concurrent anticoagulant, vasoactive agents or bleeding abnormalities	√ vasculogenic, psychogenic, neurogenic & mixed Onset = rapid Duration = <1hr Initial dosage/titration should occur under medical supervision (due to risk of syncope). Pts receiving intracavernosal inj should be assessed by Dr. q12months <b>Vascular ED requires larger doses (&gt;20ug) vs neurogenic ED (2-5ug)</b> <sup>33</sup> Injection: no more than 3 doses/week (with 24 hours between doses) Suppositories: no more than 2 within 24 hours ↓ dose if erection lasts greater than one hour with either system Seek medical assistance if tx results in erection that lasts >4 hr. <b>DI:</b> heparin (↑ partial thromboplastin time & thrombin time); ↑ risk of symptomatic hypotension, syncope with vasodilators, antihypertensives, alcohol <b>M:</b> priapism (erection lasting >4hr) tx=needle aspiration of penile blood; intracavernosal inj phenylephrine 200ug q5min up to 500ug if needed <sup>34</sup>	<b>Neurogenic ED:</b> \$248 Titrate from 1ug Usual: 2-5ug <b>Vascular ED:</b> Titrate from 4ug Usual: 5-20ug Severe: 40-60ug Inject 10-30mins pre-sex 125-250ug; 1000ug x1/24h 250-500ug 10-30mins pre-sex (dose depends on venous anatomy not ED etiology) 5ml vial 0.5-1ml/dose compounded 8 doses MUSE \$55-85	
<b>Papaverine</b> = P 30mg/ml inj. soln (2ml vials) <b>X</b> ⊗	<b>Vasodilator</b> (non-selective PDE <sup>2,3,4</sup> inhibitor) -produces generalized arteriolar dilation & smooth muscle relaxation -can be combined with prostaglandin &/or phentolamine	<b>Common:</b> abdominal discomfort, anorexia, constipation, diarrhea, nausea, vomiting, drowsiness, headache, vertigo, hypertension, tachycardia, pruritis, rash & blurred vision? <b>Serious:</b> acidosis, ↑ intracranial pressure, hepatotoxicity & priapism <b>CI:</b> complete atrioventricular block <b>Precautions:</b> glaucoma, liver dx, recent MI, stroke, Parkinsonism & sickle cell anemia	√ idiopathic, postencephalitic & symptomatic (not FDA indication) Papaverine in any ischemic type condition is not recommended. Do not use more than 3 times weekly or 2 days in succession. <b>Combos:</b> -0.5-1 mg phentolamine intracavernosal; phentolamine & alprostadil by intracavernosal inj Consult Dr. if erection lasts more than 4 hours after self inj T <sub>1/2</sub> = 0.5-2hr <b>DI:</b> levodopa (↓ levodopa affect), ginkgo (↑ SE of papaverine) <b>M:</b> intraocular pressure in glaucoma patients, liver fx	30 mg 60mg \$40 30mg-60mg 10x2ml intracavernosal vials over 1-2 min	
<b>Phentolamine</b> <b>X</b> ⊗ = Pt <b>Rogitine.</b> generic 5mg lyophilized powder for injection As adulterants in: Desire	<b>Alpha-Adrenergic Blocker</b> -antagonizes anti-erectile sympathetic tone, ↑ perfusion - poor efficacy alone so usually combined with prostaglandin &/or papaverine	<b>Common:</b> chest pain, diarrhea, dizziness <sup>3%</sup> , headache <sup>3%</sup> , hypotension <sup>2%</sup> , nasal congestion <sup>10%</sup> , nausea, palpitations <sup>1%</sup> , ↑ HR <sup>1-7%</sup> & vomiting <b>Serious:</b> arrhythmia <b>CI:</b> myocardial infarction, CAD, angina pectoris, hypersensitivity to phentolamine or mannitol, renal impairment, coronary or cerebral arteriosclerosis <b>Precautions:</b> arrhythmia, cerebral vascular spasm or occlusion, hypertension, ↑HR	√ idiopathic, postencephalitic & symptomatic (not FDA indication) Take one hour prior to sexual activity Peak activity: 30-60min Onset of action: 30-40min Duration: 5-7hr Compounded mixes may ↑ efficacy and ↓ pain associated with prostaglandin <b>DI:</b> ↑ hypotension: beta blockers, tadalafil & vardenafil; disulfiram like rx with alcohol: ↓ effect with ephedrine (OTC cough/cold products, diet & "wake-up" pills) <b>M:</b> blood pressure changes, heart rate	<b>Compounded Products</b> <b>Bi-mix inj = Pt + P</b> 6ml vial = \$60 0.5-1 ml/dose <b>Tri-Mix inj = Pt + P + E1</b> in 3 strengths \$60-80 per 5ml vial 0.2-1ml per dose <b>TriMix also available in Transurethral gel</b> \$40-120 / 5x1ml syr 0.5-1ml per dose	

⊗=dose for renal dysfx ⊕=scored tab X=Non-formulary SK ⊖=Exception Drug Status Sk ⊗=not covered by NIHB ▼=covered by NIHB ac=before meal BP=blood pressure cc=with meal C=contraindication CrCl=creatinine clearance DI=drug interaction Dx=disease ED=Erectile dysfx fx=function HF=heart failure HR=heart rate MI=myocardial infarction NAION=nonarteritic ischemic optic neuropathy n/v=nausea/vomiting pc=after meal Pt=patient RT=room temp. Sx=symptom SE=side effect T<sub>1/2</sub>=half life Tx=treatment

**Remedy for penile inj pain:** Sodium bicarbonate to restore isotonicity. **Other Meds:** apomorphine<sup>42</sup>, testosterone<sup>33</sup>, yohimbine<sup>34</sup> ? Prelox, surgical (eg. revascularization/penile prosthesis implantation)<sup>35</sup> & vacuum devices<sup>35,50</sup>. priapism=any erection lasting >4hr  
**Diagnosis:** ED is a couple's entity. Involve partner; may be reasons not to tx **Rule out:** low sex drive, relationship & psychological problems **Non Drug:** Quit smoking, regular exercise avoid prolonged cycling >3hr/wk<sup>36</sup>, ↓ excess wt, & ↓ alcohol consumption.  
**Drug induced:** acetazolamide, alcohol, barbiturate, beta-blocker, carbamazepine, cimetidine, clonidine, cocaine, cyproterone, digoxin, finasteride, flutamide, ketoconazole, labetalol, lithium, MAOI, methadone, methylodopa, marijuana, methotrexate, opioid, phenytoin, phenothiazine, spironolactone, SSRI, TCA & thiazide.

See also: Sexual Dysfunction Chart: <http://www.rxfiles.ca/rxfiles/uploads/documents/members/CHT-Sexual-Dysfx-Drugs-Overview.pdf>

## Erectile Dysfunction Comparison Chart (ED) Treatment Chart

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<sup>42</sup>

<p>Apomorphine (CR sublingual tabs) <b>ApoKyn</b> (USA)</p>	<p>Centrally acting agent stimulates dopamine sites in the hypothalamus</p> 	<p>SE: nausea (↓with time, CR SL tabs);headache, dizziness, sedation, yawning Not affected by food or alcohol</p>	<p>Onset &lt;30min Peak ~1h Duration ~1-2h Safe with nitrates so may be preferred in select cardiac patients Can be used in combination with PDE5 inhibitors for increased effect Limited efficacy compared to PDE5 inhibitors generally<sup>39</sup></p>	<p>2-3mg <b>6mg</b></p>	
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- FDA May 2007 FDA chemical analysis revealed that **Energy Max** contains thione analog of sildenafil, a substance with a structure similar to sildenafil, the active ingredient in Viagra, an FDA-approved drug for ED. Substances like this are called analogs because they have a structure similar to another drug and may cause similar side effects and drug interactions. **True Man** contains a thione analog of sildenafil or piperadino vardenafil, an analog of vardenafil, the active ingredient in Levitra, another FDA-approved prescription drug for ED. Neither the thione analog of sildenafil nor piperadino vardenafil are components of approved drug products.
- FDA: Sept 21, 2007 -- TWC Global LLC, Inc., issued nationwide recall of **Axcl** and **Desirin**, both marketed as dietary supplements, because they contain potentially harmful, undeclared ingredients. FDA laboratory analysis of **Axcl and Desirin** found that the lot of 02B07 contained 3mg/g of sildenafil, the active ingredient of a FDA approved drug used for erectile dysfunction (ED).
- FDA Feb/08 Palo Alto Labs and FDA notified consumers and healthcare professionals of a voluntary nationwide recall of two dietary supplements, **Aspire36** and **Aspire Lite**. The products were recalled because they were found to contain Aildenafil in trace amounts and Dimethyl sildenafil thione, an analog of Sildenafil, a drug used to treat erectile dysfunction.
- FDA May/08 The U.S. Food and Drug Administration is advising consumers not to purchase or use "**Blue Steel**" or "**Hero**" products, marketed nationally as dietary supplements, because these products contain undeclared ingredients similar to sildenafil.
- FDA May/08 is requesting that the manufacturer of **Xiadafil** — an "all natural" dietary supplement sold to treat erectile dysfunction — recall all its stock from natural food stores & discontinue marketing it on the Web since it contains an analog of sildenafil.
- FDA May/08 notified consumers and healthcare professionals that supplement products sold under the brand name of **Viril-ity Power (VIP)** Tablets is being recalled because one lot was found to contain a potentially harmful undeclared ingredient, hydroxyhomosildenafil, an analog of sildenafil.
- FDA July/08 Jack Distribution, LLC issued a voluntary nationwide recall of selected lots of **Rize 2 The Occasion Capsules** and **Rose 4 Her Capsules**, marketed as dietary supplements. The products were recalled because certain lots contained thiomethisosildenafil, an undeclared analog of sildenafil, a FDA-approved drug used for Erectile Dysfunction.
- FDA July/08 not to buy or use **Viapro** 375mg Capsules because one lot of the product was found to contain a potentially harmful undeclared ingredient, thio-methisosildenafil, an analog of sildenafil.
- FDA Aug/08 chemical analysis of **Xiadafil VIP** tablet lots 6K029 and 6K029-SEI found that the product contained an undeclared ingredient, hydroxyhomosildenafil
- FDA Mar/09- Bodee LLC and FDA notified consumers and healthcare professionals of a nationwide recall of all the company's supplement product sold under the name **Zencore Plus**. FDA lab analysis of Zencore Plus samples found the product contains benzamidenafil, an undeclared drug product and a PDE5 inhibitor.
- FDA Apr/09 Nature & Health Co. and FDA notified healthcare professionals of a recall of a supplement product, **Libimax**. FDA analysis found the product contains tadalafil.
- FDA July/09 and Haloteco notified healthcare professionals and consumers of a nationwide voluntary recall of Libipower Plus. Lab analysis of **Libipower Plus** samples were found to contain undeclared Tadalafil.
- FDA July/09 found **Steam** (Nutracoastal Trading LLC's dietary supplement) product contains sulfoildenafil, an analog of sildenafil.
- FDA Nov/09 notified consumers that **Stiff Nights**, a product sold as a dietary supplement, contains sulfoildenafil, a chemical similar to sildenafil (Viagra).
- FDA Nov/09 & RockHard Laboratories notified consumers that **RockHard Weekend**, a product sold as a dietary supplement, contains sulfoildenafil, an analogue of sildenafil.
- FDA Dec/09 warned that **Atlas Operations, Inc.** notified consumers of a nationwide recall of the company's dietary supplements for sexual enhancement. These products are sold as dietary supplements throughout the USA. FDA lab analyses found that the products tested from certain batches contain Sulfoildenafil.
- FDA Mar/10 & Natural Wellness notified consumers that **MasXtreme**, a product sold as a dietary supplement contains aildenafil close in structure to sildenafil and is expected to possess a similar pharmacological and adverse event profile as well as the drug phentolamine which is an alpha-adrenergic blocker.
- FDA Apr/10 & Kanec USA notified healthcare professionals of a nationwide recall of **Stud Capsule For Men** [Lot #060607-01/060108-01, Exp 6-2013], after being informed by FDA that laboratory analysis of a sample found the product to be adulterated with sildenafil, an FDA approved drug.
- FDA June/10 **Magic Power Coffee**: Product marketed as a dietary supplement for sexual enhancement contains the drug ingredient hydroxythiohomosildenafil.
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- Health Canada Jan/06 Natural health product **Libidfit** may pose health risks (promoted for sexual enhancement and erectile dysfunction, but contains an undeclared amount of a pharmaceutical ingredient similar to sildenafil) [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/2006\\_02\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2006/2006_02_e.html)
- Health Canada May/06 is warning consumers not to use the product **Nasutra** because it has been found to contain the undeclared ingredient sildenafil (chemical name for Viagra) that could lead to serious health risks, especially for patients with existing medical conditions such as heart problems, those who may be taking heart medications, or those who may be at risk for strokes.
- Health Canada Feb/07 is advising consumers not to use the following product listed in the table below due to concerns about possible side-effects. More info **Power 58; Platinum Power 58; Ehanix; Jolex; Onyo; Deguozechengtianxia** because they contained acetildenafil. Acetildenafil is an analogue of sildenafil, a prescription medication indicated for treatment of erectile dysfunction.
- Health Canada Mar/07 is warning consumers not to use the unauthorized natural health product **XOX For Men**, because it contains an undeclared pharmaceutical ingredient, tadalafil, an ingredient found in the prescription drug Cialis. The use of XOX For Men could pose serious health risks, especially for patients with existing medical conditions such as heart problems, those taking heart medication, or those at risk of stroke.

Health Canada Mar/07 is warning consumers not to use the unauthorized product **Vigorect Oral Gel Shooter**, because it contains an undeclared drug substance tadalafil, which should only be available by prescription.

Health Canada Apr/07 is warning consumers from the United States FDA found **V.MAX and Rhino Max (Rhino V Max)** to contain undeclared amounts of aminotadalafil, an analogue of tadalafil, used to treat erectile dysfunction.

Health Canada May/07 is warning consumers **Urat Madu** capsules are marketed for the treatment of erectile dysfunction. The product is adulterated with **sildenafil**, a prescription drug that has been associated with serious side effects including sudden vision loss, penile tissue damage and urinary tract infection.

Health Canada May/07 is advising consumers that **HS Joy of Love** product is marketed as a dietary supplement and was found to contain piperadino **varденафил**.

Health Canada May/07 is advising consumers not to use 6 foreign health products due to concerns about possible side-effects: **Power 58 Extra, Platinum Power 58 Extra, Enhenix New Extra Men's Formula, Valentino, King Power Oral Solution, and Stretch Up** Capsules are marketed as treatments for erectile dysfunction. The products contain analogues of **sildenafil** and **varденафил**, which are prescription drugs used for the treatment of erectile dysfunction.

Health Canada June/07 is warning consumers not to use the product **Encore Tabs for Men**, because it contains an undeclared pharmaceutical ingredient similar to the approved drug tadalafil.

Health Canada July/07 is warning consumers not to use **Zencore** Tabs, a product advertised as a dietary supplement for sexual enhancement, because it contains an undeclared pharmaceutical ingredient similar to the approved drug tadalafil.

Health Canada July/07 & the US Food and Drug Administration (FDA) found **Liviro3** to contain tadalafil, a prescription drug that should only be taken under the guidance of a health professional.

Health Canada Aug/07 via Medsafe, the New Zealand health regulatory authority, advised the public not to use the products **Darling Capsules, Dali Capsules, Spanish Fly Capsules**, and an unnamed product, because they were found to contain sildenafil.

Health Canada Aug/07 Consumers who use **Excite for women or Ultimates for men** may be at risk of serious side effects similar to those associated with sildenafil.

Health Canada Sept/07 is advising consumers not to use **Satis 60 Hours Ever Lasting Formula** is used for the treatment of erectile dysfunction/sexual enhancement. It was found to contain piperidenafil an analogue of vardenafil.. **True Man** and **Energy Max** are used as sexual enhancement/ erectile dysfunction products and were found to contain an analogue of sildenafil or vardenafil.

Health Canada Sept/07 is advising consumers not to use 5 foreign health products due to concerns about possible side-effects: **Top Gun for Men Herbal Extracts** has been found to contain a substance similar to tadalafil. **Oyster Plus** has been found to contain tadalafil. **Dequozhanjiang** contains sildenafil and tadalafil, prescription drugs used for the treatment of erectile dysfunction. **Chongcaoliubian Jiaonang** and **Santi Scalper Penis Erection** Capsule contain sildenafil.

Health Canada Nov/07 is advising consumers not to use **Axcil** and **Desirin**, are promoted as natural sexual enhancement/ erectile dysfunction products. Consumers are warned not to use Axcil and Desirin because both products were found to contain the prescription drug sildenafil.

Health Canada Mar/08 is warning consumers not to use **ADAM**, an unauthorized product that contains an undeclared pharmaceutical ingredient similar to the prescription drug sildenafil.

Health Canada Mar/08 is warning consumers not to use **Libidus**, an unauthorized product promoted on the web site of the manufacturer for the treatment of erectile dysfunction.

The product may pose serious health risks, as it was found to contain the undeclared prescription drug sildenafil.

Health Canada April/08 warns that Singapore's Health Sciences Authority (HSA) advised the public not to use the product **Power 1 Walnut**, because it was found to contain the prescription drugs sildenafil and glibenclamide

Health Canada April/08 is advising consumers not to use 2 foreign health products, **Aspire 36** and **Aspire Lite**, because they were found to contain undeclared sildenafil analogues.

Health Canada April/08 is warning consumers not to use **Vigoureux**, an unauthorized product promoted for the treatment of erectile dysfunction. The product may pose serious health risks, as it was found to contain the prescription drug sildenafil

Health Canada April/08 is advising consumers not to use 2 foreign health products due to concerns about possible side-effects: **Tian Li** was found to contain tadalafil and hydroxyhomosildenafil. Xian Zhi Wei II was found to contain sibutramine and phenolphthalein, which are not meant for self-care and may cause serious side effects.

Health Canada May/08 is advising consumers not to use **vp1 No1** Dietary Supplement for Men was found to contain tadalafil

Health Canada May/08 is warning consumers not to use **Desire**, an unauthorized product promoted to enhance male sexual performance as this product may pose serious health risks in certain patients. Lot 0070263 of the product was found to contain the prescription drug phenolamine.

Health Canada June/08 **Nangen Zengzhangsu** (may also be known as Nangen or Nangeng), Sanbianwan, Jiu Bian Wang, Tian Huang Gu Shen Dan, Zui Xian Dan Gong Shi Zi, and Power Up. The Hong Kong Department of Health has warned consumers not to use these herbal/proprietary Chinese medicine products promoted for erectile dysfunction because they have been found to contain sildenafil and/or glibenclamide.

Health Canada June/08 **Zhong Hua Niu Bian**. Zhong Hua Niu Bian is an herbal/proprietary Chinese medicine product promoted for erectile dysfunction. Singapore's Health Sciences Authority has warned against the use of this product because it has been found to contain sildenafil, glibenclamide, tadalafil and sibutramine

Health Canada July/08 Foreign Product Alerts: **Super Shangai, Strong Testis, Shangai Ultra, Shangai Ultra X, Lady Shangai, Shangai Regular (also known as Shangai Chaojimengnan), Actra-Sx, An unknown product containing the plant Lycium barbarum L., Adam Free, NaturalUp, Ereextra, Yilishen, Blue Steel, Hero, & Natural Super Plus**. These products have been found to contain sildenafil or an unapproved substance similar to sildenafil.

Health Canada July/08 is advising consumers not to use foreign health products due to concerns about possible side-effects: Wodibo. **Wodibo** is promoted as an all-natural Chinese potency-enhancing product for the treatment of erectile dysfunction. The Danish Medicines Agency has warned against the use of Wodibo because it was found to contain sildenafil and tadalafil, prescription drugs authorized for treatment of erectile dysfunction. **Viril-Ity-Power (VIP)** Tabs. The U.S. Food and Drug Administration has warned consumers not to use Viril-Ity-Power (VIP) Tabs because it was found to contain an undeclared ingredient similar to the prescription drug sildenafil.

Health Canada Aug/08 is warning consumers not to use **Rize 2 The Occasion** capsules (Rize2), an unauthorized product promoted for the treatment of erectile dysfunction, because it may pose serious health risks. Rize 2 contains an undeclared pharmaceutical ingredient similar to the prescription drug sildenafil.

Health Canada Aug/08 is advising consumers not to use 5 foreign health products due to concerns about possible side-effects: **Oyster Extract** Caps. The Hong Kong Department of Health has recalled Oyster Extract Caps because they were found to contain an undeclared ingredient similar to the prescription drug sildenafil. **Xiadafil** VIP Tabs. At the request of the U.S. Food and Drug Administration, U.S. federal authorities seized all Xiadafil VIP Tabs sold in 8 tablet bottles (Lot #6K029) and blister cards of 2 tablets (Lot #6K029-SE1) because they were found to contain an undeclared ingredient similar to the prescription drug sildenafil. **Herb Vigour, Natural Vigour and China Vigour**. The Netherlands Health Care Inspectorate, the U.K. Medicines and Healthcare Products Regulatory Agency, and the Danish Medicines Agency has warned against the use of Herb Vigour, Natural Vigour and China Vigour because they were found to contain undeclared pharmaceutical ingredients used for the treatment of erectile dysfunction that should only be taken under the supervision of a health care professional.

Health Canada Aug/08 is advising consumers not to use 9 foreign health products due to concerns about possible side-effects: **Armstrong Natural Herbal Supplement, Enhenix New Extra Men's Formula, Power 58 Extra, and Platinum Power 58 Extra** were adulterated with tadalafil or unapproved substances with structures similar to tadalafil and vardenafil.

Health Canada Sep/08 is advising consumers not to use 3 foreign health products due to concerns about possible side-effects: The Hong Kong Department of Health warned consumers not to buy or use **Lover Liquid Nutriment Herbal Supplement and Onyo** because they were found to contain undeclared pharmaceutical ingredients. **Lover Liquid Nutriment Herbal Supplement** was found to contain sildenafil while **Onyo** was found to contain sildenafil, as well as unapproved substances with structures similar to sildenafil and vardenafil. The U.S. Food and Drug Administration warned consumers not to use the product **Rose 4 Her** because it was found to contain an undeclared ingredient similar to the prescription drug sildenafil.

Health Canada Sep/08 is advising consumers not to use 6 foreign health products due to concerns about possible side-effects: The Hong Kong Department of Health warned consumers not to buy or use **Dr. Life or Chong Cao Ju Wang** because they were found to contain undeclared pharmaceutical ingredients. **Dr. Life** contains an unauthorised substance similar in structure to tadalafil while **Chong Cao Ju Wang** contains sildenafil.

Health Canada Oct/08 is advising consumers not to use 2 foreign health products due to concerns about possible side-effects: Swissmedic warned consumers not to buy or use the product **Powertabs** because it contains an unauthorised substance similar in structure to sildenafil. The Hong Kong Department of Health warned consumers not to buy or use **Sweet Energizer Vitality** Candy because it was found to contain an unauthorised substance similar in structure to tadalafil.

Health Canada Oct/08 is warning consumers not to use **Eros Fire**, a product promoted to enhance sexual performance, as this product may pose serious health risks. The product was found to contain xanthoantrafil (also known as benzamidenafil), which is not indicated on the label.

Health Canada Nov/08 is advising consumers not to use 5 foreign health products due to concerns about possible side-effects: The Hong Kong Department of Health warned consumers not to buy or use **Lu Quan** because it contains undeclared glibenclamide and sildenafil. The Hong Kong Department of Health warned consumers not to buy or use **Fat Killer, Carbohydrate Cut and Sugar-Carbohydrate Cut** because they contain sibutramine and an unauthorised substance similar in structure to sibutramine, and **Zhuang Yao Gu Shen** Capsule because it contains sildenafil.

Health Canada Nov/08 is warning consumers not to use **Firm Dose** and **Granite Rooster**, two products promoted to enhance male sexual performance, as these products may pose serious health risks. **Firm Dose** was found to contain an undeclared pharmaceutical ingredient similar to sildenafil, while the product **Granite Rooster** was found to contain an undeclared pharmaceutical ingredient similar to tadalafil.

Health Canada Jan 2009 is advising consumers not to use 4 foreign products: **Zhuang Tjar Gere** because it contains the undeclared prescription drugs sildenafil & tadalafil, **Zhixhue** Capsules manufactured by Vital Pharmaceutical Holdings Ltd. due to concerns of serious side-effects including liver dysfunction, **Tonik Warisan Banjar** because it contains undeclared dexamethasone & **Healthily Slim** because it

contains the undeclared prescription drug sibutramine.

Health Canada Mar/09 Foreign Product Alerts: 68 Weight Loss Products; Best-life Fat Burning Capsules; Bevidan; Huiji Yin Chiao Chieh Tu Pien; Relacore

[http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape\\_2009/index-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape_2009/index-eng.php)

Health Canada June/09 Foreign Product Alerts: **Jia Yi Jian** (undeclared sibutramine & tadalafil); **Zencore Plus** (undeclared benzamidenafil) & **Zhong Guo Shen Fang** (undeclared med like sildenafil).

Health Canada July/09 is warning that the Singapore Health Sciences Authority (HSA) warned consumers to not buy or use **XP Tongkat Ali Supreme** after it was found to contain undeclared tadalafil.

Health Canada Oct/09: **Dynasty Worldwide Jinglida So Young Formula**- The Singapore Health Sciences Authority (HSA) warned consumers to not buy or use since contained undeclared aminotadalafil.

**STEAM** lot#80214, 90260 -The U.S. FDA informed consumers of a voluntary manufacturer recall of two lots of STEAM after FDA testing found these lots to contain undeclared sulfoildenafilafil (lot# 80214) & undeclared tadalafil (lot# 90260).

**Syntrex Fyre (contained Yohimbine), Kam Yuen Brand Wan Ying Yang Gan Wan (contained sildenafil)** - The Hong Kong Department of Health warned consumers not to buy or use these products.

Health Canada Nov/09 is warning consumers not to use Herblex "**Once More**" since it was found to contain sildenafil.

Health Canada Dec/09 is advising Canadians not to use certain Acai Berry products after a large number of shipments of adulterated products were stopped at the border. The product names include: **Anti-Aging Acai Berry, Guarana Blast, Brazillian Pure, Anti-aging Vital Rez V, Weight Loss VitalAcai, Dietary Supplement Acai Power Blast and Muscle Mass**. These products advertised for anti-aging and weight loss were found to contain undeclared sildenafil.

Health Canada Dec/09 is advising consumers not to use the following foreign health products: 1. **Power-Plus P**: The Singapore Health Sciences Authority issued a recall notice for Power-Plus P (expiry date 03/03/2011) after it was found to contain undeclared tadalafil. 2. **Zeng Da Yan Shi Wan**: The Hong Kong Department of Health warned consumers not to buy or use after it was found to contain undeclared sildenafil.

Health Canada Jan/10 informs that Finish Food Safety Authority: **Full Contact Max Potency** contains thio-sildenafil and thio-homosildenafil; Singapore Health Sciences Authority: **M-Action** contains desmethylacetildenafil and acetic acid. U.S. FDA: **RockHard Weekend** contains sulfoildenafilafil.

Health Canada Jan/10 is advising consumers not to use the unauthorized product "**Stiff Nights**" after the U.S Food and Drug Administration (FDA) found that this product contains an undeclared substance similar to the prescription drug sildenafil.

Health Canada Feb/10: **2H & 2D**- Hong Kong Department of Health (HKDH) warned consumers not to buy or use 2H & 2D after it was found to contain undeclared tadalafil. Products distributed by **Atlas Operations Inc**. The FDA informed consumers of a voluntary recall by Atlas Operations Inc. of certain lots of some products that were found to contain undeclared sulfoildenafilafil, which is an unauthorized substance similar to sildenafil. **STRO Emperor** Capsules The Irish Medicines Board warned consumers not to buy or use STRO Emperor Capsules after it was found to contain undeclared tadalafil.

Health Canada Mar/10 is warning Canadians that an unapproved health product, **POWER-MAX** that contains sildenafil.

Health Canada May/10 is advising consumers not to use the following foreign health products due to concerns about possible adverse reactions: 1. **Man Power** The Hong Kong Department of Health warned consumers not to buy or use Man Power product after it was found to contain undeclared tadalafil.

Health Canada June/10 is warning Canadians that the unauthorized health products "**Vigofit**" and "**Once More**," which are promoted to enhance male sexual performance, have been seized by Health Canada inspectors from retail stores in Abbotsford and Surrey, British Columbia. These two products contain sildenafil.

Health Canada July/10 is advising consumers not to use the following foreign health product(s) due to concerns about possible adverse reactions: 1. **Stud Capsule For Men** The U.S. FDA informed consumers of a voluntary recall of one lot (Lot #060607-01/060108-01 Exp 6-2013) after it was found to contain undeclared Sildenafil.

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Philip A, Ramchandani S, Dorrance K, Dorrance C. **Sildenafil-induced thrombocytopenia**. *Ann Intern Med*. 2008 Sep 16;149(6):437-9.

Porst H, et al. Evaluation of the Efficacy and Safety of **Once-a-Day** Dosing of Tadalafil 5mg and 10mg in the Treatment of Erectile Dysfunction: Results of a Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial. *Eur Urol*. 2006 Aug;50(2):351-9. Epub 2006 Mar 20. 12-week study enrolled 268 men

Pryor JL, et al.; Dapoxetine Study Group. Efficacy and tolerability of **dapoxetine** in treatment of premature ejaculation: an integrated analysis of two double-blind, randomised controlled trials. *Lancet*. 2006 Sep 9;368(9539):929-37. (InfoPOEMs: In this study, dapoxetine (an investigational new short-acting selective serotonin reuptake inhibitor) taken 1 to 3 hours before sexual activity delayed ejaculation in men with moderate-to-severe premature ejaculation. The net improvement due to medication was less than 2 minutes compared with baseline, but patients and partners were satisfied with this small amount of improvement. (LOE = 2b) )

Qaseem A., Snow V., Denberg T. D., et al and for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. **Hormonal Testing and Pharmacologic Treatment of Erectile Dysfunction: A Clinical Practice Guideline From the American College of Physicians**. *Ann Intern Med* 2009; 60520-151.

Recommendation 1: The American College of Physicians recommends that clinicians initiate therapy with a **PDE-5 inhibitor** in men who seek treatment for erectile dysfunction and who do not have a contraindication to PDE-5 inhibitor use (Grade: strong recommendation; high-quality evidence).

Recommendation 2: The American College of Physicians recommends that clinicians base the choice of a specific PDE-5 inhibitor on the individual preferences of men with erectile dysfunction, including ease of **use, cost of medication, and adverse effects profile** (Grade: weak recommendation; low-quality evidence).

Recommendation 3: The American College of Physicians does **not recommend for or against routine use of hormonal blood tests or hormonal treatment** in the management of patients with erectile dysfunction (Grade: insufficient evidence to determine net benefits and harms).

Raina R, Pahlajani G, Agarwal A, Zippe CD. The early use of transurethral alprostadil after radical prostatectomy potentially facilitates an earlier return of erectile function and successful sexual activity. *BJU Int*. 2007 Dec;100(6):1317-21. Epub 2007 Sep 11. Initiating **MUSE** shortly after RP is safe and tolerable, and appears to shorten the recovery time to regain erectile function.

Rees J, Patel B. **Erectile dysfunction**. *BMJ*. 2006 Mar 11;332(7541):593.

Reffellmann T, Kloner RA. Pharmacotherapy of erectile dysfunction: focus on cardiovascular safety. *Expert Opin Drug Saf*. 2005 May;4(3):531-40.

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Saigal CS, Wessells H, Pace J, et al. **Predictors and prevalence** of erectile dysfunction in a racially diverse population. *Arch Intern Med* 2006; 166:207-212. 1

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Striano P, Zara F, Minetti C, Striano S. **Epileptic seizures** can follow high doses of oral vardenafil. *BMJ*. 2006 Oct 14;333(7572):785.

Thompson IM, Tangen CM, Goodman PJ, Probstfield JL, Moinpour CM, Coltman CA. Erectile dysfunction and **subsequent cardiovascular disease**. *JAMA*. 2005 Dec 21;294(23):2996-3002.

Tsertsvadze A, Yazdi F, Fink HA, et al. Oral **Sildenafil Citrate (Viagra)** for Erectile Dysfunction: A Systematic Review and Meta-analysis of Harms. *Urology*. 2009 Jul 8. [Epub ahead of print]

Oral PDE-5 inhibitors improved erectile functioning and had similar efficacy and safety profiles. Results on the efficacy of hormonal treatments and the value of hormone testing in men with ED were inconclusive.

Tsertsvadze A., Fink H. A., Yazdi F., et al. **Oral Phosphodiesterase-5 Inhibitors and Hormonal Treatments** for Erectile Dysfunction: A Systematic Review and Meta-analysis. *Ann Intern Med* 2009; 60520-150.

Wilkins MR, Paul GA, Strange JW, et al. Sildenafil versus endothelin receptor antagonist for pulmonary hypertension (SERAPH) study. *Am J Respir Crit Care Med* 2005;171:1292-97. (InfoPOEMs: Is sildenafil (Viagra) more effective than bosentan (Tracleer) in patients with class III pulmonary hypertension? In this small study, sildenafil and bosentan had similar effects on patients with moderately severe pulmonary hypertension. (LOE = 1b) )

#### Web Links:

American Academy of Family Physicians Web site: <http://familydoctor.org>

American Urological Association Foundation Web site: <http://www.urologyhealth.org/adult/index.cfm?cat=11&topic=174>

National Institutes of Health Web site: <http://www.nlm.nih.gov/medlineplus/erectiledysfunction.html>