Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

Bayer HealthCare

Clinical Trial Results Synopsis

Study Design Description		
Study Sponsor:	Bayer HealthCare AG	
Study Number:	12093	NCT00631969
Study Phase:	III	
Official Study Title:	Pivotal phase III trial to investigate the efficacy and safety of an Orodispersible Tablet vardenafil versus placebo in the treatment of men with erectile dysfunction (ED) – a fixed-dose, double-blind, raNdomized multi-center Trial – POTENT I	
Therapeutic Area:	Men' s Health	
Test Product		
Name of Test Product:	Vardenafil (Levitra, BAY38-9456)	
Name of Active Ingredient:	Vardenafil	
Dose and Mode of Administration:	Vardenafil orodispersible 10 mg tablets (ODT) to be placed on the tongue without chewing taken on demand (PRN) 1 hour before sexual activity (no more than 1 tablet per day).	
Reference Therapy/Placebo		
Reference Therapy:	Matching placebo	
Dose and Mode of Administration:	Matching placebo tablets with the same peppermint flavor as the vardenafil ODT 10 mg tablets taken on demand 1 hour before sexual activity (no more than 1 tablet per day).	
Duration of Treatment:	Four-week run-in period without study medication followed by a 12-week treatment period with either vardenafil 10 mg or matching placebo.	
Studied period:	**Date of first subjects' first visit:**	25 APR 2008
	Date of last subjects' last visit:	19 JAN 2009
Premature Study Suspension / Termination:	No	
Substantial Study Protocol Amendments:	Amendment no. 1 (dated 25 FEB 2008), affected all participating centers, specified the following changes: • Two safety-relevant exclusion criteria were added. • The number of variables on which the conclusion of efficacy was based was changed (conclusion of efficacy based on simultaneous statistical significance of difference in score changes of the international index of erectile function-erectile function [IIEF-EF] domain, and success rates changes from baseline in the sexual encounter profile questions 2 and 3 [SEP2 and SEP3] in the intent-to-treat [ITT] population). • Three more questions were added to the subject diary. Amendment no. 2 (dated 03 JUN 2008) affected all participating centers specified the following changes: • Safety-relevant exclusion criterion "history of syncope" was	

	added. • Statistical testing procedures were adjusted according to regulatory requirements. • Use of the services of a centralized electrocardiogram (ECG) recording and reading procedure was added. Amendment no. 3 (dated 27 AUG 2008), affected all participating centers, and specified the following changes: • Exclusion criterion "history of hearing loss" was added. • In Amendment no. 2, Version 1 (dated 03 Jun 2008) the efficacy variables were adapted in the efficacy variable section of the protocol. This was also done in the section for the study objectives. In addition the following text was added under secondary efficacy variables under study objectives "Number of sexual attempts under medication till first successful attempt (SEP3)."
Study Centre(s):	This fixed dose, double-blind, randomized, parallel-group, placebo-controlled, multi-center study was conducted at 40 active investigational centers in 6 countries: Belgium (4), France (8), Germany (9), Spain (3), South Africa (11), and the Netherlands (5).
Methodology:	The duration of the study for each subject was 16 weeks and the study comprised of four periods: • A 4-week non-medicated run-in period during which no treatment (medication or devices) for erectile dysfunction (ED) was given, • A 12-week treatment period during which the subject received vardenafil 10 mg ODT or matching placebo. Dosing was recommended to occur approximately one hour before intended intercourse, • A 48-hour follow-up period after the last intake of study medication in order to record any (serious) adverse events, • In a subgroup of subjects and at selected sites only, a special visit was scheduled 48 to 168 hours after Visit 4 to conduct drug concentration measurements. A separate and additional administration of vardenafil 10 mg ODT in a planned subset of subjects (N=12, aged 18 to 64 years and N=12 aged ≥65 years) was carried out, for the purpose of collecting blood samples for determining the plasma concentrations of vardenafil and it's metabolite BAY 44-5576 and for describing their pharmacokinetics at various time-points for up to 24 hours. This visit was again followed by a 48-hour follow-up period to record any (serious) adverse events. Each subject was required to visit the site on 4 separate occasions over a period of 16 weeks (Visit 1/Week -4; Visit 2/Week 0; Visit 3/Week 4; Visit 4/Week 12). IIEF-EF domain score was assessed at visit 4. Global assessment questionnaire (GAQ) was administered at the final visit only. Overall SEP2 and SEP3 were assessed at visit 4. Percentage of subjects achieving "back to normal" erectile function (IIEF-EF ≥26) was assessed at Visit 4. TSS was administered at the randomization visit and the final visit (or at premature discontinuation). All diary questions other than SEP2 and SEP3 that concerned erectile function were assessed over the

	entire treatment period.
Indication/ Main Inclusion Criteria:	Indication: Erectile dysfunction Main Inclusion Criteria: Men, 18 years-of-age or older with erectile dysfunction (defined according to the National Institutes of Health [USA] [NIH] Consensus Development Panel on Impotence) for more than 6 months. Approximately 50% of the subjects on treatment were 65 years-of-age or older. Subjects were in a stable, heterosexual relationship for at least 6 months and they were highly motivated to obtain treatment for ED.
Study Objectives:	**Primary:** The primary objective of this study was to compare the efficacy and safety of vardenafil ODT 10 mg (PRN) after 12 weeks of treatment or Last observation carried forward (LOCF) with placebo in a general population of men with erectile dysfunction. In this study, approximately 50% of the men on active treatment had to be 65 years-of-age or older. **Secondary:** Not applicable
Evaluation Criteria:	**Efficacy (Primary):** • Change from baseline in IIEF-EF Domain score at Visit 4 (Week 12) or LOCF • Change in percentage from baseline in success of penetration (SEP item) at Visit 4 (Week 12) overall • Change from baseline in success of erection maintenance (SEP item) at Visit 4 (Week 12) **Efficacy (Secondary):** • Percentage of subjects achieving "back to normal" erectile function (IIEF-EF ≥26) at Visit 4 (Week 12) or LOCF • Change in percentage from baseline in ability to obtain erection (SEP item) at Visit 4 (Week 12) • Change in percentage from baseline in satisfaction with hardness of erection (SEP item) at Visit 4 (Week 12) • Change in percentage from baseline in overall satisfaction (SEP item) at Visit 4 (Week 12) • Change in percentage from baseline in ability to ejaculate (SEP item) at Visit 4 (Week 12) • Number of sexual attempts under medication till first successful attempt (SEP3) • Change from baseline in ease with erections (Treatment Satisfaction Scale (TSS) item) at Visit 4 (Week 12) or LOCF • Change from baseline in erectile function satisfaction (TSS item) at Visit 4 (Week 12) or LOCF • Change from baseline in pleasure of sexual activity (TSS item) at Visit 4 (week 12) or LOCF • Change from baseline in satisfaction with orgasm (TSS item) at Visit 4 (Week 12) or LOCF • Change from baseline in confidence for completion (TSS item) at Visit 4 (week 12) or LOCF

	• Satisfaction with medication (TSS item) at Visit 4 (Week 12) • Patient self-reported improvement of erectile function under treatment using a categorical rating scale (Global Assessment Question (GAQ)) **Safety:** • Blood and urine samples for routine hematology, serum chemistry, and semi-quantitative urinary dipstick testing • Complete physical examination • 12-lead electrocardiogram • Vital signs • Collection of adverse event data
	Pharmacokinetics: Primary parameters: AUC, C_{max} of vardenafil and its metabolite M-1 (BAY44-5576); Secondary parameters: $AUC_{(0\text{-}tn)}$, AUC_{norm}, AUC/D, $C_{max,norm}$, C_{max}/D, CL/f, MRT, t_{max}, $t_{1/2}$ Other parameters: $AUC_{(tn\text{-}\infty)}$, points terminal
Statistical Methods:	All quantitative clinical variables were tabulated as descriptive statistics using sample sizes, means, standard deviations, minimum, and maximum, and the median per item, domain, visit, LOCF, and treatment group. For the primary and co-primary variables, tables were generated for two samples: ITT population, and PP (per-protocol population). Also, means, and standard deviations were plotted against time, and per-treatment group (primary and co-primary). **Efficacy (Primary):** The statistical analysis of the IIEF-EF, SEP2, and SEP3 were conducted via an analysis of covariance (ANCOVA) with baseline as covariate, and with treatment, and center as factors. The ANCOVA was conducted in 3 versions: (1) Main effects (treatment, age, and center) plus baseline as a covariate plus baseline by treatment interaction (2) Main effects (treatment, age, and center) plus baseline as covariate (3) Main effects (treatment, age, and center) plus baseline as covariate plus center by treatment interaction. **Efficacy (Secondary):** The statistical analysis of the secondary efficacy variables were provided only for the ITT sample. Categorical efficacy variables such as the number of subjects who answered "yes"/"no" to the Global Assessment Question, and those achieving <25/≥25 points in the IIEF-EF at Week 12 or LOCF were analyzed by the Fisher's exact test. The TSS and IIEF-EF domains as well as all additional diary items were analyzed using the same aforementioned ANCOVA model which was selected as the main analysis of the primary efficacy variable. Some of the domains (TSS) did not have a baseline

	measurement and were therefore analyzed with an ANOVA. P-values of <0.05 were referred to as "nominally" significant values and were not interpreted in a confirmatory way. **Safety:** Safety variables were analyzed using descriptive statistics.
	Pharmacokinetics: For each age group, the descriptive statistics of plasma concentrations were presented for each sampling time and for the derived pharmacokinetic parameters. AUC, C_{max}, AUC_{norm}, and $C_{max,norm}$ were analyzed assuming log-normally distributed observations. For each of these four pharmacokinetic characteristics a linear regression line was fitted to describe a possible relationship between age and the logarithm of the variable. The hypothesis of a zero slope was tested using the two-sided t-test at α=0.05. Pair-wise comparisons of groups were performed for AUC, C_{max}, AUC_{norm}, and $C_{max,norm}$ using two-sided 90% confidence intervals for the ratio of geometric means.
Number of Subjects:	Altogether 409 male subjects were screened, 362 subjects randomized (186 subjects given vardenafil 10 mg ODT, and 176 subjects given placebo).

Study Results

Results Summary — Subject Disposition and Baseline

Out of 362 randomized subjects, four subjects did not fulfill the safety criteria because there was no evidence that these subjects took study medication although they were randomized. The safety population therefore comprised 98.9% of all randomized subjects. Three additional subjects did not meet the ITT criteria because they had no post-baseline efficacy assessment in any of the clinical variables. However, they were valid for safety. The ITT population therefore corresponds to approximately 98% of all randomized subjects. The subjects valid for per-protocol population which needed to fulfill a more comprehensive number of inclusion criteria was smaller and reduced to 165 subjects (89% vardenafil subjects) and 146 (83%; placebo) subjects. This was approximately 85.9% of all randomized subjects. The most common reason for exclusion from the per-protocol analysis was taking prohibited medication/therapy during the study with 6.3% of the placebo group and 3.8% of the vardenafil group. Demographic data for the safety population are presented in Table 1.

Table 1: Major demographic characteristics (Safety population)

Parameter		Vardenafil 10 mg ODT		Placebo	
		< 65 years	≥ 65 years	< 65 years	≥ 65 years
Race	White	55	68	53	64
n (%, rounded)	Black	3	4	2	5
	Asian	6	3	2	2
	Missing	20	16	19	16
Age (years)	Mean±SD	52.8±9.0	69.7±4.2	52.7±8.5	69.8±4.9
Weight (kg)	Mean±SD	87.1±11.7	81.6±11.4	88.0±15.0	82.6±11.9
BMI (kg/m^2)	Mean±SD	27.5±3.5	26.9±3.2	27.9±4.3	27.1±3.6

Results Summary — Efficacy

Primary variables:

In the ITT and PP populations, vardenafil 10 mg ODT treatment was significantly superior ($p<0.0001$) to placebo with respect to change from baseline to Week 12/LOCF in the IIEF-EF domain (LS mean difference of 7.1 percentage points [95% confidence interval (CI): 5.66 to 8.56]).

Similarly, vardenafil 10 mg ODT treatment also showed significant superiority ($p<0.0001$) compared with placebo in the change from baseline to Week 0 to 12 overall in the diary item SEP2 (penetration) success rate (LS mean difference of 27 percentage points [95% CI: 20.43 to 33.66]), and the diary item SEP3 (maintenance of erection) success rate (LS mean difference of 38.2 percentage points [95% CI: 31.37 to 45.02]).

Secondary variables:

All secondary efficacy measures demonstrated nominally significant differences in favor of vardenafil 10 mg ODT.

Vardenafil 10 mg ODT treatment also showed nominally significant superiority ($p<0.0001$) compared with placebo in the change from baseline to Week 0 to 12 overall with respect to the diary success rates reported for SEP1, SEP4, SEP5, SEP6.

Vardenafil 10 mg ODT treatment showed nominally significant superiority ($p<0.0001$) compared with placebo in all Treatment Satisfaction Scale domains.

Significantly ($p<0.0001$) higher percentages of subjects taking vardenafil 10 mg ODT reported "back to normal erectile" function (40% compared with 12% in the placebo group).

A significantly ($p<0.0001$) higher percentage of subjects treated with vardenafil 10 mg ODT responded positively to the Global Assessment Question (72% compared with 26% of all placebo treated subjects) indicating general satisfaction of subjects with vardenafil treatment.

Subjects treated with vardenafil 10 mg ODT needed to initiate fewer sexual attempts until their first successful attempt (SEP3; 1.2 attempts compared with 3.6 in the placebo group).

South Africa:

In a subset of 62 subjects from South Africa that consisted of subjects with different ethnic background, the response for all primary efficacy variables was generally less pronounced compared with all other countries. Treatment by country interactions showed nominally significant effects ($p<0.05$) in SEP2 as well as in SEP1 (Enlargement), SEP6 (Ejaculation), indicating that the treatment effects might have been different in these participating areas. The reasons for the inferior response of the South African subjects remained undetermined.

Results Summary — Safety

Adverse events

Higher incidence of treatment-emergent adverse events (AEs) were observed in the vardenafil group compared with placebo (38.6% versus 20.7% respectively). Higher incidence of treatment-emergent AEs among younger subjects compared with elderly subjects were observed in the vardenafil group (42.5% versus 35.1% respectively).

Treatment-emergent AEs reported in the study were mostly of mild or moderate severity.

The incidence of common treatment-emergent AEs was higher in vardenafil compared to placebo subjects: headache (16.3% versus 1.1%), flushing (7.6% versus 0%), and dyspepsia (3.8% versus 0%). The incidence of study drug-related AEs was higher in the vardenafil group compared with placebo subjects (28.3% versus 9.2% respectively). Most frequent drug-related AEs under vardenafil treatment included: headache, flushing, feeling hot, dyspepsia, dysgeusia, dizziness, and nasal congestion. With the exception of dysgeusia, all of the treatment-related AEs that occurred at a higher frequency in the vardenafil group were known adverse reactions associated with vardenafil treatment.

The taste sensations coded as dysgeusia were observed in 4 subjects in each treatment group (overall frequency 2.2% to 2.3%). All of these cases were reported in only one center in South Africa (altogether 8 out of 11 subjects). In this particular center, all subjects were asked about how the study drug tasted while allowing the study drug to dissolve in their mouths. Any changes or experiences of each subject were documented as e.g., "sour taste", "wine like taste", or "bitter taste in mouth". These subjective experiences were mistakenly documented on the AE page of the case report form (CRF) and coded under the category dysgeusia which is the closest category in Medical Dictionary for Regulatory Activities (MedDRA) used to record taste experience (as confirmed in writing by the investigator at the site). No sequels were reported. The occurrence of adverse reactions termed "dysgeusia" appears to be highly unlikely.

Severe treatment-emergent AEs reported for 3 elderly subjects in the vardenafil group included acute coronary syndrome [serious adverse event (SAE) premature discontinuation], gastrointestinal hemorrhage [SAE], and erythema.

The incidence of SAEs reported in vardenafil group was higher as compared with placebo during study treatment (4 subjects in the vardenafil group and 1 in the placebo group). None of the SAEs reported in the vardenafil group were treatment-related; all of the subjects recovered. All subjects who developed SAEs were ≥65 years-of-age. SAEs included acute coronary syndrome and pneumothorax (premature discontinuation), femoral arterial stenosis, gastrointestinal hemorrhage; one moderate (syncope). One moderate and treatment-related SAE in the placebo group (neurosensory deafness) led to premature discontinuation of study. In addition, 2 subjects had SAEs before the start of study drug treatment (1 subject with atrial fibrillation and 1 subject with a prostate tumor).

Premature discontinuation due to AEs were reported for 3 subjects: 2 in the vardenafil group, 1 subject with acute coronary syndrome and pneumothrax (SAE, severe, no treatment relationship, recovered), and 1 subject with increased levels of alanine aminotransferase (mild intensity, treatment-related, outcome status unchanged); 1 subject in the placebo group with neurosensory deafness (SAE, moderate, treatment-related, outcome status unchanged).

Potentially medically relevant AEs included tongue induration (after study completion, not previously reported during vardenafil treatment; not treatment-related, was diagnosed as an infectious disease without causal connection to topical administration of study drug; subject recovered), rash, and photosensitivity reaction (treatment-related, subject recovered).

Clinical laboratory evaluation

There were no notable differences between treatment groups with regard to high, or low

laboratory value abnormalities not observed at baseline examinations.

Vital signs

No notable changes in the mean values from baseline to Week 12 (LOCF) in heart rate, systolic, or diastolic blood pressure within and between treatment groups were observed.

ECG findings

There were no notable treatment or age group differences with respect to change from baseline in heart rate, PR interval, and QRS interval. There was no sign of a prolongation of the QT/QTc interval irrespective of age of subjects. There were no consistent treatment group differences with respect to ECG findings pointing to safety issues.

Results Summary — Pharmacokinetics

The pharmacokinetics of vardenafil and its metabolite M-1 were studied in a sub-group of the ED subject population comprising n=25 subjects receiving a single dose of 10 mg ODT on a separate visit. Derived non-compartmental parameters for vardenafil are presented in Table 2.

Table 2: Pharmacokinetic parameters of vardenafil following single dose administration of 10 mg vardenafil ODT (geometric mean/%CV (range), all subjects valid for PK, n=25)

Parameter	Unit	ED patients 18 to 64 years (n=12) mean age (range): 53.2 (38-63) years		ED patients ≥ 65 years (n=12b) mean age (range): 70.9 (65-80) years	
AUC	µg*h/L	47.16/70.2	(18.97-112.8)	55.37/48.9	(21.23-104.4)
AUC_{norm}	kg*h/L	0.4387/67.0	(0.1869-0.9987)	0.4752/47.1	(0.2081-0.8592)
AUC/D	h/ml	4.716/70.2	(1.897-11.28)	5.537/48.9	(2.123-10.44)
$AUC_{(0\text{-}tn)}$	µg*h/L	44.61/72.0	(15.54-101.2)	52.66/51.2	(18.36-100.7)
C_{max}	µg/L	10.09/74.8	(3.134-19.04)	13.43/60.2	(2.913-27.91)
$C_{max,norm}$	kg/L	0.09385/70.9	(0.03087-0.1778)	0.1126/57.1	(0.02855-0.2297)
C_{max}/D	1/ml	1.009/74.8	(0.3134-1.904)	1.343/60.2	(0.2913-2.791)
$t_{½}$	h	5.387/35.0	(2.731-8.051)	5.898/29.3	(3.966-10.05)
CL/f	L/h	212.1/70.2	(88.61-527.1)	180.6/48.9	(95.83-471.0)
t_{max} [a]	h	1500	(0.5000-2.500)	1000	(0.4833-3.500)

a Median (Range)
b n=13 for Cmax, Cmax,norm, Cmax/D and tmax

Point estimates and 90% confidence intervals of ratios (subjects aged ≥65/subjects aged 18 to 64 years) of AUC and C_{max} are shown in Table 3.

Table 3: Point estimators (LS-means) and two-sided 90% confidence intervals for the ratios of the primary parameters AUC and C_{max} of vardenafil and its metabolite M-1 (BAY 44-5576) (all subjects valid for PK, n=22-25)

Ratio	Analyte	Parameter	n	Estimated ratio (%)	90% confidence interval (%)
Men aged ≥ 65 years/ Men aged 18 to 64 years	Vardenafil	AUC	24	117.42	[79.59; 173.23]
		C_{max}	25	133.07	[87.46; 202.46]
Men aged ≥ 65 years/ Men aged 18 to 64	M-1 (BAY 44-	AUC	22	125.28	[73.65; 213.11]
		C_{max}	25	123.84	[80.12; 191.42]

Vardenafil was rapidly absorbed from the 10 mg ODT with median t_{max} values of 1 to 1.5 hours and eliminated from plasma with half-lives of 5.4 hours to 5.9 hours (geometric mean values). Vardenafil AUC and C_{max} were increased by 17% and 33% (point estimates), respectively, in subjects aged ≥65 years (mean age 71 years) compared to subjects aged 18 to 64 years (mean age 53 years). This effect of age was not statistically significant. Metabolite M-1 plasma exposure accounted for approximately 70% to 90% of parent exposure and showed similar effects of age with increases in AUC and C_{max} by 25% and 24%, respectively (subjects ≥65 years compared to 18 to 64 years).

Conclusion(s) In this study of 362 subjects, Vardenafil 10 mg ODT treatment was shown to be significantly superior to placebo with respect to all primary and secondary efficacy variables. Subjects <65 years-of-age had higher success rates in the IIEF-EF, SEP2, and SEP3 than subjects ≥65 years-of-age. The generally known safety profile of vardenafil was confirmed with the 10 mg ODT formulation.

Publication(s):	Debruyne FM, Gittelman M, Sperling H, Börner M, Beneke M. Time to onset of action of vardenafil: a retrospective analysis of the pivotal trials for the orodispersible and film-coated tablet formulations. J Sex Med. 2011 Oct;8(10):2912-23.

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Investigational Site List

Marketing Authorization Holder in Germany	
Name	Bayer Pharma AG
Postal Address	D-13342 Berlin Deutschland
Sponsor in Germany	
Legal Entity Name	Bayer HealthCare AG
Postal Address	D-51368 Leverkusen, Germany

List of Investigational Sites

No	Facility Name	Street	ZIP Code	City	Country
1	AZ St-Lucas Campus St-Lucas	Campus St-Lucas Dienst Urologie Groenebriel 1	9000	GENT	BELGIUM
2	CHU de Liège	Hôpital du Sart Tilman Service Urologie Domaine Universitaire du Sart Tilman Bâtiment B35	4000	LIEGE	BELGIUM
3	Clinique Saint-Jean/Kliniek Sint Jan	Boulevard du Jardin Botanique 32 Kruidtuinlaan	1000	BRUXELLES - BRUSSEL	BELGIUM
4	Dr Bongaerts - Dr Denier	Huisartsenpraktijk Heeldstraat 58	3600	GENK	BELGIUM
5	Cabinet Médical - Gambetta - Lyon	Cabinet Médical 68, cours Gambetta	69000	LYON	FRANCE

6	Cabinet medical Magellan	Cabinet Médical 11 rue Magellan	75008	PARIS	FRANCE
7	Cabinet Médical - Martinon - Mont de Marsan	Cabinet Médical 26 rue Martinon	40000	MONT-DE-MARSAN	FRANCE
8	Cabinet Médical - Morgiou - Marseille	Cabinet Médical 2, chemin de Morgiou	13009	MARSEILLE	FRANCE
9	Cabinet Médical - Puget - Marseille	Cabinet Médical 22 cours Pierre Puget	13006	MARSEILLE	FRANCE
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11	CETPARP - Carolus - Lille	Centre d'Etude et de Traitement de la pathologie de l'appareil reproducteur et de la psychosomatique Résidence de l'Ile au Bois Le Grand Hunier 3. allée Carolus	59000	LILLE	FRANCE
12	Hôpital Edouard Herriot - Lyon Cedex	Hospices Civils de Lyon Hôpital Edouard Herriot Service d'Urologie 5, place d'Arsonval	69437	LYON CEDEX	FRANCE
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14	Klinikum Osnabrück GmbH	Urologie Am Finkenhügel 1	49076	Osnabrück	GERMANY
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26	huisartsenpraktijk Systole	Lutterstraat 2-A	7581 BV	LOSSER	NETHERLANDS
27	Centre for Diabetes & Endocrinology	81 Central Street Houghton	2198	Johannesburg	SOUTH AFRICA
28	DJW Navorsing	70/72 Shannon Road Noordheuwel Ext 3	1739	Krugersdorp	SOUTH AFRICA

29	Entabeni Hospital	148 Ridge Road South Glenwood	4001	Durban	SOUTH AFRICA
30	Florence Medical Centre	1900 Sycamore Street Dhlamini Extention 2 Soweto	1818	Johannesburg	SOUTH AFRICA
31	I. Engelbrecht Reseach (Pty) Ltd	174 Cradock Ave Lyttelton	0140	Centurion	SOUTH AFRICA
32	Intercare Medical and Dental Centre Bellville	43 Old Oak Road Bellville	7530	Cape Town	SOUTH AFRICA
33	Mary Seeber Private Practice	Medi-Clinic Heart Hospital Cnr Park & Hamilton Streets Arcadia	0083	Pretoria	SOUTH AFRICA
34	Newkwa Medical Centre	909 - 913 Inanda Road Newlands	4037	Durban	SOUTH AFRICA
35	Quatro Clinical Trials Institute	202 Medpark Building, Syfred Douglas Street N1 City Goodwood	7463	Cape Town	SOUTH AFRICA
36	Randles Road Medical Centre	468 Randles Road Syndenham	4091	Durban	SOUTH AFRICA
37	Zuid Afrikaans Hospital	293 Bourke Street Muckleneuk	0001	Pretoria	SOUTH AFRICA
38	Hospital del Mar	Servei de Urologia Paseig Marítim, 25-29	08003	Barcelona	SPAIN
39	Hospital Policlínico de Vigo - Clínica Povisa	Servicio de Urología Salamanca, 5	36211	Vigo	SPAIN
40	Hospital Universitario de Canarias	Servicio de Urología c/ Ofra, s/n	38320	La Laguna	SPAIN

Product Identification Information

Product Type	Drug
US Brand/Trade Name(s)	Levitra, STAXYN
Brand/Trade Name(s) ex-US	Levitra, Vivanza, Yaila, Levitra 10mg orodispersible tablets, STAXYN, Vivanza 10mg orodispersible tablets
Generic Name	Vardenafil
Main Product Company Code	BAY38-9456
Other Company Code(s)	
Chemical Description	Vardenafil: 1-[[3-(3,4-Dihydro-5-methyl-4-oxo-7propylimidazo[5,1-f]-as-triazin-2-yl)-4-ethoxyphenyl]sulfony]-4-ethylpiperazine
Other Product Aliases	

Date of last Update/Change: 18 March 2014