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 Pharmaceuticals Inc.	
Study Number:	11336	NCT00492635
Study Phase:	IIIb	
Official Study Title:	A randomized, double-blind, double-dummy, multi-center, parallel group study to compare the tolerability and efficacy of once daily vardenafil versus vardenafil PRN versus placebo in men immediately after nerve-sparing prostatectomy for improving erectile function REINVENT (Recovery of Erections: INtervention with Vardenafil Early Nightly Therapy)	
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 was administered orally in a tablet form (5 mg, 10 mg, and 20 mg tablets). There were two active treatment regimens: • Vardenafil 5 mg, 10 mg, or 20 mg NIGHTLY + vardenafil matching placebo *pro re nata* (PRN). • Vardenafil 5 mg, 10 mg, or 20 mg PRN + vardenafil matching placebo NIGHTLY. At Visit 4 (Month 1), Visit 5 (Month 3), and Visit 6 (Month 6), the investigator could increase the dose to 20 mg, keep the dose at 10 mg, or reduce it to 5 mg. The maximal allowable NIGHTLY dose was 10 mg, even in cases when the overall study medication dose was up-titrated to 20 mg. Therefore, only the PRN dose was up-titrated to 20 mg. At Visit 9 (Month 11), all subjects were started on the 10 mg vardenafil PRN dose; the investigator could increase the dose to 20 mg, keep the dose at 10 mg, or reduce it to 5 mg at the next visit (Visit 10).	
Reference Therapy/Placebo		
Reference Therapy:	Reference Therapy: No active comparator was used. Placebo: Matching placebo tablets were taken in the comparator group, which was the third treatment arm of the study.	
Dose and Mode of Administration:	Treatment regimen: Vardenafil matching placebo NIGHTLY + vardenafil matching placebo PRN. Mode of administration: oral	
Duration of Treatment:	• Nine-month double-blind ([DB] NIGHTLY, PRN or placebo) treatment period. • Two-month single-blind (SB) placebo (and no devices) washout period (SBPW period). • Two-month open-label PRN period (OL PRN period).	

Studied period:	Date of first subjects' first visit:	13 DEC 2004
	Date of last subjects' last visit:	26 SEP 2007
Premature Study Suspension / Termination:	No	
Substantial Study Protocol Amendments:	Amendment no. 2 (dated 10 JAN 2005) was approved after 4 subjects had been enrolled in the study, and specified the following changes: • The phase of the study was changed from Phase IV to Phase IIIb. • The evaluation of biomarkers was restricted to a subset of subjects only (approximately 150 subjects at selected sites). • The definition of the "Per-Protocol" population was added. • Safety evaluation at Visit 6 was added. • Some exclusion criteria were added and further specifications for the existing ones were made. Amendment no. 5 (dated 21 MAR 2005) was approved after 77 subjects had been enrolled in the study, and specified the following change: • Measurements of penile length were done.	
Study Centre(s):	The study was conducted at 87 active centers: Austria (2), Belgium (6), Canada (10), Finland (3), France (5), Germany (12), Italy (8), The Netherlands (3), Norway (2), South Africa (5), Spain (7), Sweden (6), Switzerland (1), United Kingdom (6), and United States (11).	
Methodology:	This randomized, double-blind, double-dummy, multi-center, parallel group, placebo-controlled study comprised of a screening visit (Visit 1: one month before surgery), up to 14 day period after bilateral nerve-sparing radical retropubic prostatectomy (BNSRRP) before randomization (Visit 2), 9-month DB double-dummy treatment period (Visit 3 to 7), 2-month SBPW period (Visits 8 and 9) to determine the extent of recovery, and 2-month OL PRN period (Visits 10 and 11). During the treatment period, subjects were randomized to vardenafil NIGHTLY (Vardenafil 10 mg NIGHTLY + vardenafil matching placebo PRN), vardenafil PRN (Vardenafil 10 mg PRN + vardenafil matching placebo NIGHTLY), or placebo (Vardenafil matching placebo NIGHTLY + vardenafil matching placebo PRN) in a 1:1:1 ratio. The double-dummy design was also used during the single-blind placebo washout. During Months 10 and 11, subjects participated in a single-blind washout period. Thus, at Visit 7 (end of Month 9) and Visit 8 (end of Month 10) subjects were dispensed placebo. When subjects were being enrolled in the open-label PRN period at Visit 9 (Month 11), they were offered open-label PRN active medication treatment with a starting dose of 10 mg for 1 month, which at the next visit (Visit 10; Month 12), based on efficacy and tolerability, could be increased to 20 mg, kept at 10 mg, or reduced to 5 mg. The International Index of Erectile Function (IIEF) Questionnaire was administered at Visit 1, Visit 5 (Month 3), Visit 6 (Month 6), Visit 7 (Month 9), Visit 8 (Month 10), Visit 9 (Month 11), Visit 10 (Month 12), Visit 11 (Month 13), and at the premature discontinuation up to the end of single blind treatment period (PD1) or during the open-label period (PD2). The CES-D and Duke Health Profile was assessed at Visits 1, 6, 7, 9, and PD1. The Per-subject success rates for diary questions [such as penetration (SEP2), maintenance (SEP3)], hardness, and overall satisfaction with sexual experience were	

	assessed at Visit 4 (Month 1), Visit 5 (Month 3), Visit 6 (Month 6), Visit 7 (Month 9), Visit 8 (Month 10), Visit 9 (Month 11), Visit 10 (Month 11), and Visit 11 (Month 13). Data regarding the adverse events were collected at all visits after screening (Visits 2 - 7, PD1, or PD2).
Indication/ Main Inclusion Criteria:	Indication: Erectile dysfunction after BNSRRP Main inclusion criteria: Males aged 18 - 64-years after BNSRRP, as selected according to the investigator's usual clinical practice, without pre-operative erectile dysfunction.
Study Objectives:	Overall: The objective of this study was to compare the efficacy and safety of 2 modes of vardenafil therapy versus placebo to treat erectile dysfunction starting within 14 days following BNSRRP Primary: • To determine whether early, NIGHTLY dosing with vardenafil significantly improves recovery of erectile function after surgery as compared to placebo. • To determine whether early PRN dosing with vardenafil also improves recovery of function as compared to placebo. Secondary: • To assess whether early dosing of either NIGHTLY or PRN vardenafil over 9 months, followed by 2 months of withdrawal, increases efficacy of subsequent PRN use significantly better than placebo.
Evaluation Criteria:	Efficacy (Primary): Percentage of subjects with the erectile function Domain Score of the International Index of Erectile Function (IIEF-EF Domain Score was calculated as the sum of scores from Questions 1-5 and 15) of ≥22 after 9 months of DB treatment plus 1 to 2 months of SBPW. The observations collected during the 2-month SBPW period were only included in the SBPW last observation carried forward (LOCF) analysis. Efficacy (Secondary): • Percentage of subjects who, during the DB period, LOCF, and single-blind period had IIEF-EF Domain Score ≥22. • Per-subject success rates for diary questions such as Sexual Encounter Profile (SEP) items penetration (SEP2), maintenance (SEP3) during the DB and SBPW separately. • Duke Health Profile during the DB and SBPW separately. • RigiScans: number of erectile episodes, duration of erectile episodes, duration of tip rigidity >60%, RAU tip, RAU base, TAU tip, TAU base, and duration of base rigidity. • Change from baseline in flaccid and stretched length at 6 months, 9 months and double-blind LOCF. Safety: Treatment groups were compared with respect to the incidence rates

	of treatment-emergent adverse events and concomitant medication use emerging during the DB, SBPW and OL PRN period. Incidence rates of laboratory abnormalities, treatment-emergent electrocardiogram (ECG) abnormalities, and mean ECG measurements were limited to the DB treatment period and SBPW periods. Treatment groups were also compared with respect to premature termination rates. An independent Data Monitoring Committee (DMC) was also appointed for the evaluation of safety.
Statistical Methods:	Population: In addition to the intent-to-treat (ITT) and per-protocol (PP) population, a further analysis set was introduced, namely modified intent-to-treat (mITT) population. This included those subjects who had taken at least one dose of the study drug, had baseline, and at least one IIEF-EF measurement during the SBPW period. The mITT population was defined as the primary analysis set. Efficacy (Primary): The primary efficacy variable was the percentage of subjects with IIEF-EF Domain Scores ≥22 at SBPW LOCF. The primary population for this variable was the mITT. The last observation carried forward method to account for dropouts was based on only the SBPW visits (SBPW LOCF) was used as the primary efficacy time point. The primary comparison was a test for overall treatment differences between the three treatment groups, and if significant at the 0.05 level, pairwise comparisons between vardenafil nightly and placebo, as well as vardenafil PRN and placebo were performed, each at the 0.05 level. If both vardenafil NIGHTLY and vardenafil PRN were superior to placebo, as a secondary analysis, the comparison between two active groups was to be tested for superiority. Efficacy (Secondary): Open-Label PRN (OL PRN) Phase: T The percent of subjects who achieved an IIEF-EF score of greater than or equal to 22 at OL PRN period LOCF was summarized and analyzed as in the single blind placebo washout period. Secondary efficacy variables such as all IIEF individual items, IIEF-EF Domain Scores, and per-subject success rates for diary questions, were presented as summary statistics by visit, at OL PRN period LOCF, and in the case of per-subject success rates for diary questions, overall OL PRN period success rates were summarized. Double-Blind Period and in Single-Blind Placebo Washout Period Secondary efficacy variables such as IIEF-EF Domain Scores, and per-subject success rates of diary questions were analyzed by visit, at DB LOCF, at single-blind washout LOCF. In the case of per-subject success rates for diary questions, the overall single-blind washout and double-blind success rates were also analyzed. For these variables analysis of variance (ANOVA) with effects for treatment and country was performed. For the CES-D and Duke scales, analysis of co-variance (ANCOVA) with baseline as covariate and effects for treatment and center (country) was conducted on the total score at each visit and LOCF.

	Individual items and domains were summarized with descriptive statistics. Secondary efficacy variables such as all IIEF individual items, IIEF-EF Domain Scores, and per-subject success rates for diary question were presented as summary statistics by visit and at OL PRN period LOCF. In the case of per-subject success rates for diary questions, overall OL PRN period success rates were summarized. Safety: Measurements and changes from baseline in vital signs (blood pressure and pulse rate), continuous laboratory variables, and ECG parameters were summarized using descriptive statistics (i.e., n, mean, standard deviation, minimum, median, maximum) by treatment group and visit. Statistical tests were not planned for safety variables. The presentation of all safety variables was done with regard to the treatment group and no analysis was done by dose.
Number of Subjects:	Of the 628 subjects randomized, 210 were randomized to placebo, 208 to vardenafil PRN, and 210 to vardenafil NIGHTLY. The number of subjects valid for safety analyses were 617, of these 206 subjects received placebo, 204 received vardenafil PRN, and 207 received vardenafil NIGHTLY. The mITT population, i.e., the primary analysis set, comprised of 445 subjects (153 on placebo, 149 on vardenafil PRN, and 143 on vardenafil NIGHTLY).

Study Results

Results Summary — Subject Disposition and Baseline

In this study, 997 subjects were enrolled and screened. A total of 369 subjects were randomized because they did not fulfill the inclusion/exclusion criteria. Thus, a total of 628 subjects were randomized to receive placebo, vardenafil PRN, or vardenafil NIGHTLY.

Of all the randomized subjects, 11 subjects (4 in the placebo, 4 in the vardenafil PRN, and 3 in the vardenafil NIGHTLY treatment groups, respectively) were invalid for the safety analysis. Therefore, a total of 617 subjects were included for safety analysis (206 on placebo, 204 on vardenafil PRN, and 207 on vardenafil NIGHTLY).

A total of 8, 5, and 5 subjects in the placebo, vardenafil PRN, and vardenafil NIGHTLY treatment groups, respectively, had no post-treatment efficacy data and therefore were excluded from the ITT population. Before breaking the random code it was decided to introduce a modified ITT population. Therefore, a total of 445 subjects (71% of all randomized) were included in this primary efficacy population. A total of 377 subjects remained in the PP population which was about 60% of the randomized sample.

Of the 617 subjects valid for safety, the average age was 57.1 years (range: 40 to 68). The mean of body mass index (BMI) was 26.8 kg/m^2 (range: 18.1 - 41.6). Majority of subjects were Caucasians except 12 Blacks, 1 Hispanic, and 5 uncodable (4 mixed, and 1 South African Indian) subjects.

Results Summary — Efficacy

Primary efficacy:

The primary efficacy analysis was based on the percentage of subjects with IIEF-EF Domain Scores ≥22 at SBPW LOCF, mITT being the primary analysis set. After up to 8 weeks of SBPW following completion of a 9-month postoperative course of treatment with either placebo, vardenafil PRN, or vardenafil NIGHTLY, the estimated rates of subjects with IIEF-EF Domain Score ≥22 were 28.9%, 29.1%, and 24.1%, respectively. The chi-square test from the logistic regression model was not significant. The hypothesis of better recovery of erectile

function during a 1 to 2-month placebo washout following 9 months of treatment with vardenafil PRN or NIGHTLY compared to 9 months of treatment with placebo was not confirmed.

Secondary efficacy:

With regard to the secondary efficacy during the SBPW period, there were no differences between the treatment groups, except for SEP2 and Duke Health Profile. At SBPW LOCF and over the entire SBPW period (overall time point), there were nominally statistically significant differences between the vardenafil PRN and vardenafil NIGHLTY groups in SEP2 (successful penetration). The Least Square (LS)-mean SEP2 in the vardenafil PRN group was approximately 10% higher than in the vardenafil NIGHLTY group.

The LS-mean General Health Domain Scores at SBPW LOCF were nominally statistically significantly higher (better) in the placebo group than in the vardenafil NIGHTLY group. LS-mean Mental Health Domain Scores at Visit 9 and SBPW LOCF were nominally statistically significantly higher (better) in the placebo group than in the vardenafil PRN group.

With respect to secondary efficacy during the DB period (mITT), there were several nominally statistically significant differences from placebo, notably in the proportion of subjects with IIEF-EF Domain Scores ≥22 (Table 1) and in SEP2 and SEP3 (Table 2).

For IIEF-EF Domain Score ≥22, pairwise comparisons between vardenafil PRN and placebo were nominally statistically significant at all DB visits. At DB LOCF, 23.4% more of vardenafil PRN subjects compared with placebo subjects had IIEF-EF Domain Scores ≥22. Pairwise comparisons between vardenafil NIGHTLY and placebo were nominally significant only at Visit 5 (Month 3). At that visit, compared to placebo subjects, 11.2% more of vardenafil NIGHTLY subjects had IIEF-EF Domain Scores ≥22.

Table 1: Logistic regression results and estimated rates of subjects with IIEF-EF Domain Score ≥22 double-blind visits and double-blind LOCF (mITT)

Time	Estimated rate ± SE of rate		
	Placebo (N=152)	Vardenafil PRN (N=149)	Vardenafil NIGHTLY (N=143)
Visit 5 (Month 3)	12.4 ± 3.0	32.7 ± 5.1 *P* =0.0001 [a]	23.6 ± 4.4 *P* =0.0144 [a]
Visit 6 (Month 6)	15.8 ± 3.4	38.2 ± 5.3 *P* <0.0001 [a]	22.9 ± 4.2 *P* =0.1341
Visit 7 (Month 9)	24.9 ± 4.2	48.7 ± 5.3 *P* <0.0001 [a]	31.6 ± 4.7 *P* =0.2135
Double-blind LOCF	24.8 ± 4.2	48.2 ± 5.2 *P* =0.0001 [a]	32.0 ± 4.7 *P* =0.1806

a: nominally statistically significant
All *P* values are for the comparison of the vardenafil group with placebo.
IIEF-EF: Index of Erectile Function - Erectile Function
LOCF: last observation carried forward, mITT: modified intent-to-treat, SE: standard error

As for SEP2 and SEP3, the vardenafil PRN group was nominally statistically significantly different from both the placebo and vardenafil NIGHTLY groups over the entire DB period in the mITT population. For both SEP2 and SEP3, vardenafil PRN estimated rates were more than 19% higher (better) than placebo and thus clinically meaningful. SEP2 and SEP3 were nominally statistically significantly better for vardenafil NIGHTLY than for placebo over the entire DB period in the mITT population.

Table 2: LS mean and SE for SEP2 and SEP3 over the entire double-blind period (overall time point) (mITT)

	LS mean ± SE		
	Placebo (N=147)	Vardenafil PRN (N=144)	Vardenafil NIGHTLY (N=135)
SEP2 (penetration)	30.3 ± 4.8 [ab]	49.7 ± 5.0 [b]	39.9 ± 4.9
SEP3 (maintenance)	25.0 ± 4.7 [ab]	45.9 ± 4.8 [b]	34.5 ± 4.7

a: nominally significantly different from vardenafil PRN
b: nominally significantly different from vardenafil NIGHTLY
SEP2: Sexual Encounter Profile Question 2 (successful penetration)
SEP3: Sexual Encounter Profile Question 3 (maintenance of erection)
LS mean: last square mean, SE: standard error, mITT: modified intent-to-treat

As suggested by all the secondary results from the 9-month DB period, vardenafil PRN was better than placebo in treating ED after BNSRRP.

Results Summary — Safety

Extent of exposure:

The subjects valid for safety spent an average of 231 days or 7.5 months in the DB phase, 60 days in the SBPW, and 55 days in the OL PRN phase. The DB treatment exposure ranged from 2 days to 362 days, with 617 subjects being exposed to DB medication. The OL PRN vardenafil exposure ranged from 1 day to 129 days, with 425 subjects being exposed to OL vardenafil. This was because a large percentage (31%) of safety subjects did not take vardenafil OL PRN. Of those subjects exposed to vardenafil OL PRN, 47% were exposed for at least 56 days.

Double-blind period:

A total of 56%, 67%, and 68% of subjects in the placebo, vardenafil PRN, and vardenafil NIGHTLY groups, respectively, reported treatment-emergent events (TEEs) during the DB period (Table 3). A total of 16%, 41%, and 30% of subjects in the placebo, vardenafil PRN, and vardenafil NIGHTLY groups, respectively, had TEEs assessed to be drug-related; in 4%, 5%, and 8% of subjects, treatment was discontinued due to these events.

Table 3: Incidence rates of treatment-emergent adverse events during the double-blind period (Safety)

Incidence rate	Placebo (N=206)	Vardenafil PRN (N=204)	Vardenafil NIGHTLY (N=207)
Treatment-emergent adverse events	115 (55.8%)	136 (66.7%)	141 (68.1%)
Drug-related treatment-emergent adverse events	33 (16.0%)	84 (41.2%)	61 (29.5%)
Treatment-emergent adverse events leading to discontinuation	8 (3.9%)	11 (5.4%)	16 (7.7%)
Treatment-emergent serious adverse events	11 (5.3%)	17 (8.3%)	20 (9.7%)

Open-label period:

A total of 21%, 26%, and 27% of subjects in the placebo, vardenafil PRN, and vardenafil NIGHTLY groups, respectively, reported treatment-emergent events (TEEs) during the OL PRN period (Table 4). A total of 14%, 16%, and 15% of subjects had TEEs assessed to be drug-related. None of the TEEs starting in the OL PRN period were the cause of

discontinuation of the treatment.

Table 4: Incidence rates of treatment-emergent adverse events during the open-label PRN period (Safety)

Incidence rate	Placebo (N=148)	Vardenafil PRN (N=140)	Vardenafil NIGHTLY (N=137)
Treatment-emergent adverse events	31 (20.9%)	36 (25.7%)	37 (27.0%)
Drug-related treatment-emergent adverse events	20 (13.5%)	22 (15.7%)	20 (14.6%)
Treatment-emergent adverse events leading to discontinuation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Treatment-emergent serious adverse events	1 (0.7%)	1 (0.7%)	2 (1.5%)

x

Deaths:
Two subjects died in this study. Neither of the 2 deaths was treatment-emergent. One subject was a 64-year old man with a recent medical history of intestinal polypectomy, surgery for prevention of detached retina, glans phimosis, and left and right inguinal hernia. After 39 days of the last intake of OL PRN vardenafil, the subject experienced a motorcycle accident with the following diagnoses: coma, concussion of brain, hematuria, left renal cyst break, multiple rib fractures, and hemothorax. The subject died of sepsis 9 days later. At the time of the accident, the subject was still in the OL PRN phase. The accident was not considered related to the study drug.

The second subject (not valid for safety) died before being randomized. This 65-year old man had a past medical history of left side renal duplication. After 12 days following the BNSRRP, the subject died of lung embolism. As the subject had not taken any study drug, this lung embolism was not considered to be drug-related.

Serious adverse events:
Over the entire study, treatment-emergent serious adverse events were reported for 7% of placebo subjects, 10% of vardenafil PRN subjects, and 12% of vardenafil NIGHTLY subjects. Out of these, there were 5 serious adverse events judged to be related to the study drug according to the investigator, 1 with placebo, 1 with vardenafil PRN, and 3 with vardenafil NIGHTLY.

Treatment-emergent serious cardiac events were reported for 3 placebo subjects, 2 subjects receiving vardenafil PRN, and 2 subjects receiving vardenafil NIGHTLY. Serious treatment-emergent myocardial infarctions occurred in 2 subjects of the placebo group (preferred term: myocardial infarction; drug-related in 1 subject) and 1 subject of the vardenafil PRN group (preferred term: acute myocardial infarction; not drug-related). None of the treatment-emergent serious adverse events classified as "vascular disorders" (1, 0, and 2 subjects) were considered to be related to vardenafil.

Conclusion(s)

In this study, after SBPW, vardenafil did not significantly improve recovery of erectile function after bilateral nerve-sparing radical retropubic prostatectomy as compared to placebo. After up to 8 weeks of SBPW following completion of a 9-month postoperative course of treatment with placebo, vardenafil PRN, and vardenafil NIGHTLY, respectively, an IIEF-EF Domain Score ≥22 was seen in an estimated rate of 28.9%, 29.1% and 24.1% of mITT subjects.

With respect to secondary efficacy during the DB period (mITT), there were several nominally statistically significant differences from placebo, notably in the proportion of subjects with IIEF-EF Domain Scores ≥22, in SEP2 (successful penetration), and SEP3 (maintenance of erection). At DB LOCF, 23.4% more of vardenafil PRN subjects compared with placebo subjects had IIEF-EF Domain Scores ≥22. For both SEP questions, vardenafil PRN estimated rates were more than 19% higher (better) than placebo and thus clinically meaningful. As suggested by these secondary results from the 9-month DB period, vardenafil PRN was more effective than placebo in treating ED after BNSRRP. These results are in line with the label indication for vardenafil.

The adverse event profile based on this study is consistent with that presented in the Development Core Safety Information. There were no clinically important differences related to vital signs, laboratory parameters, and ECG data at any time-point.

Publication(s):	Montorsi F, Brock G, Lee J, Shapiro J, Stief C. Effect of Nightly versus On-Demand Vardenafil on Recovery of Erectile Function in Men Following Bilateral Nerve-Sparing Radical Prostatectomy. Eur Urol. 2008: Jul 9		
Date Created or Date Last Updated:	08 MAY 2012	Date of Clinical Study Report:	27 OCT 2008

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	Landeskrankenhaus Salzburg	Abteilung f. Urologie Müllner Hauptstrasse 48	5020	Salzburg	AUSTRIA
2	Medizinische Universität Graz	Universitätsklinik f. Urologie Auenbruggerplatz 7	8036	Graz	AUSTRIA
3	CHU de Liège	Hôpital du Sart Tilman Service Cardiologie Domaine Universitaire du Sart Tilman Bâtiment B35	4000	LIEGE	BELGIUM
4	Clinique Saint-Jean/Kliniek Sint Jan	Boulevard du Jardin Botanique 32 Kruidtuinlaan	1000	BRUXELLES - BRUSSEL	BELGIUM

5	CU Saint-Luc/UZ St-Luc	Pharmacothérapie/Farmacotherapie Avenue Hippocrate 10 Hippocrateslaan Tour Pasteur Unité FATH	1200	BRUXELLES - BRUSSEL	BELGIUM
6	Dr Van Renterghem	Privé Praktijk Consultatie Urologie Luikersteenweg 232	3500	HASSELT	BELGIUM
7	UZ Antwerpen	Wilrijkstraat 10	2650	EDEGEM	BELGIUM
8	UZ Leuven Gasthuisberg	Herestraat 49	3000	LEUVEN	BELGIUM
9	CAN-MED Clinical Research, Inc	1641 Hillside Ave. Suite #330	V8T 5G1	Victoria	CANADA
10	Cente Hospitalier Universitaire de Sherbrooke-Fleurimont	3001, 12e Avenue Nord	J1H 5N4	Sherbrooke	CANADA
11	Clinique d'Urologie du Saguenay	475, boul. Talbot Suite RC001	G7H 4A3	Chicoutimi	CANADA
12	Coburg Street Medical Clinic	95 Coburg Street	E2L 3J8	St. John	CANADA
13	Edmonton Prostate & Urological Centre	1800 College Plaza 8215 112th Street	T6G 2C8	Edmonton	CANADA
14	Male/Female Health & Research Centre	Royal Court Medical Centre 1 Quarry Ridge Suite 206	L4M 7G1	Barrie	CANADA
15	Prostate Cancer Institute	Suite 100 1011 Glenmore Tr. SW	T2V 4R6	Calgary	CANADA

16	St.Joseph's Health Care-London	St. Joseph's Hospital 268 Grosvenor	N6A 4V2	London	CANADA
17	Sunnybrook Health Sciences Centre	MG-405 2075 Bayview Avenue	M4N 3M5	Toronto	CANADA
18	The Male Health Centres	1235 Trafalgar Road North Suite 407	L6H 3P1	Oakville	CANADA
19	Oulun yliopistollinen sairaala	Kajaanintie 50	90220	Oulu	FINLAND
20	Suomen Terveystalo Oyj / Gynekologi- ja Urologikeskus	Rautatienkatu 27	33100	Tampere	FINLAND
21	Terveystalo Oulu	Sepänkatu 21	FI-90100	Oulu	FINLAND
22	Hopital Carrémeau - Nimes	Hôpital Carrémeau Service d'urologie rue du Professeur Robert Debré	30000	NIMES	FRANCE
23	Hôpital Claude Huriez - Lille	C.H.R.U. Hôpital Claude Huriez Service d'Urologie Place de Verdun	59037	LILLE	FRANCE
24	Hôpital Edouard Herriot - Lyon Cedex	Hospices Civils de Lyon Hôpital Edouard Herriot Service d'Urologie 5, place d'Arsonval	69437	LYON CEDEX	FRANCE

25	Hôpital Henry Gabrielle - Saint Genis Laval Cedex	Hôpital Henry Gabrielle Service d'Urologie Route de Vourles	69230	SAINT GENIS LAVAL CEDEX	FRANCE
26	Synergia - Carpentras	Synergia Polyclinique Service d'urologie Rond Point de l'Amitié	84200	CARPENTRAS	FRANCE
27	Kliniken Nordoberpfalz AG - Klinikum Weiden	Klinik für Urologie und Kinderurologie Söllnerstr. 16	92637	Weiden	GERMANY
28	Klinikum der Eberhard-Karls-Universität Tübingen	Universitätsklinik für Urologie Hoppe-Seyler-Str. 3	72076	Tübingen	GERMANY
29	Klinikum Dortmund gGmbH	Klinikzentrum Nord Urologische Klinik Münsterstr. 240	44137	Dortmund	GERMANY
30	Klinikum Leverkusen gGmbH	Klinik für Urologie Dhünnberg 60	51375	Leverkusen	GERMANY
31	Klinikum Mannheim gGmbH	Urologische Klinik Theodor-Kutzer-Ufer 1-3	68167	Mannheim	GERMANY
32	Klinikum Offenbach	Urologische Klinik Starkenburgring 66	63069	Offenbach	GERMANY
33	Klinikum Osnabrück GmbH	Urologie Am Finkenhügel 1	49076	Osnabrück	GERMANY
34	Klinikum rechts der Isar	Urologische Klinik und Poliklinik Ismaninger Straße 22	81675	München	GERMANY

35	LMU Klinikum der Universität München - Großhadern	Urologische Klinik und Poliklinik Marchioninistr. 15	81377	München	GERMANY
36	Marienhospital Herne Klinik Börnig	Urologische Klinik Widumer Straße 8	44627	Herne	GERMANY
37	Städtisches Klinikum Braunschweig gGmbH	Urologische Klinik Salzdahlumer Str. 90	38118	Braunschweig	GERMANY
38	Universitätsklinikum Hamburg Eppendorf (UKE)	Klinik und Poliklinik für Urologie Martinistr. 52	20246	Hamburg	GERMANY
39	A.O.U. Careggi	Clinica Urologica II - Centro Polivalente Viale Pieraccini, 6	50139	Firenze	ITALY
40	A.O.U. Careggi	Clinica Urologica I - Centro Polivalente Viale Pieraccini, 6	50139	Firenze	ITALY
41	A.O.U. Federico II	Urologia CIRMS - Centro Interdipartimentale Ricerca Medicina Sessuale Via S. Pansini, 5	80131	Napoli	ITALY
42	A.O.U. Ospedali Riuniti Trieste	Clinica Urologica Ospedale di Cattinara Strada di Fiume, 447	34149	Trieste	ITALY
43	A.O.U. Policlinico Consorziale	Urologia I Piazza Giulio Cesare, 11	70124	Bari	ITALY

44	IRCCS A.O.U. San Martino e IST Ist.Nazionale Ricerca Cancro	Clinica Urologica - Padiglione 12 Dip. Medicina Interna e Specialità Mediche (DIMI) Largo R. Benzi, 10	16132	Genova	ITALY
45	IRCCS Fondazione San Raffaele	Urologia Istituto Scientifico Universitario San Raffaele Via Olgettina, 60	20132	Milano	ITALY
46	IRCCS Fondazione San Raffaele	Urologia Casa di Cura Privata "Ville Turro" Via Stamira d'Ancona, 20	20127	Milano	ITALY
47	Erasmus Medisch Centrum	Afdeling Urologie Dr. Molewaterplein 40	3015 GD	ROTTERDAM	NETHERLANDS
48	Leids Universitair Medisch Centrum	Afd. Poli-Urologie, J-3-P Albinusdreef 2	2333 ZA	Leiden	NETHERLANDS
49	Universitair Medisch Centrum St. Radboud	Afd. Urologie G. Grooteplein Zuid 16	6525 GA	NIJMEGEN	NETHERLANDS
50	Moelv Spesialistsenter	Storgaten 150 Postboks 207	2390	Moelv	NORWAY
51	Vestfold sentralsykehus	Halfdan Wilhelmsens allè 17	3103	Tønsberg	NORWAY
52	Cape Town Medi-Clinic	21 Hof Street Oranjezicht	8001	Cape Town	SOUTH AFRICA

53	Pretoria Urology Hospital	PRETORIA UROLOGY HOSPITAL COR. PRETORIUS & GROSVENOR STREETS HATFIELD	0083	PRETORIA	SOUTH AFRICA
54	St Annes Hospital Medical Centre	331 Burger Street	3200	Pietermaritzburg	SOUTH AFRICA
55	University of Stellenbosch	Tygerberg Hospital Francie van Zijl Drive Parrow	7505	Cape Town	SOUTH AFRICA
56	University of Witwatersrand	University of the Witwatersrand Medical School 7 York Road Parktown	2193	Johannesburg	SOUTH AFRICA
57	Hospital Clínic i Provincial de Barcelona	C/ Villarroel, 170	08036	Barcelona	SPAIN
58	Hospital Fundació Puigvert	C/. Cartagena, 340 08025 Barcelona	08025	Barcelona	SPAIN
59	Hospital Policlínico de Vigo - Clínica Povisa	Salamanca, 5	36211	Vigo	SPAIN
60	Hospital Regional Carlos Haya	Avda. Carlos Haya s/n	29010	Málaga	SPAIN
61	Hospital Universitari i Politècnic La Fe	Avda. Bulevar Sur, s/n	46026	Valencia	SPAIN
62	Hospital Universitario "La Paz"	Paseo de la Castellana, 261	28046	Madrid	SPAIN
63	Instituto Valenciano de Oncología	C/ Profesor Beltrán Báguena, 19	46009	Valencia	SPAIN

64	Centrallasarettet	Urologkliniken	721 89	Västerås	SWEDEN
65	ED-Kliniken	Långgatan 18	541 30	Skövde	SWEDEN
66	Länssjukhuset	Urologkliniken	301 85	Halmstad	SWEDEN
67	Lundby Sjukhus AB	Urologen Forskningsenheten	417 17	Göteborg	SWEDEN
68	Sahlgrenska Universitetssjukhuset	Urologkliniken	413 45	Göteborg	SWEDEN
69	Skånes Universitetssjukhus	Urologmottagningen	221 85	Lund	SWEDEN
70	Inselspital Bern	Urologische Universitätsklinik Anna-Seiler Haus Freiburger Strasse	3010	Bern	SWITZERLAND
71	Charing Cross Hospital	Department of Urology Fulham Palace Road	W6 8RF	London	UNITED KINGDOM
72	Christie Hospital	Department of Urology 550 Wilmslow Road Withington	M20 4BX	Manchester	UNITED KINGDOM
73	Royal United Hospital	Coombe Park	BA1 3NG	Bath	UNITED KINGDOM
74	Southmead Hospital	Department of Urology Westbury on Trym	BS10 5NB	Bristol	UNITED KINGDOM
75	Taunton and Somerset Hospital	Department of Urology Musgrove Park	TA1 5DA	Taunton	UNITED KINGDOM
76	Wexham Park Hospital	Department of Urology Wexham	SL2 4HL	Slough	UNITED KINGDOM
77	Columbus Urology Research, LLC	500 Thomas Lane Suite 3-C	43214-1419	Columbus	UNITED STATES

78	Hudson Valley Urology Center	1 Columbia Street Suite 390	12601	Poughkeepsie	UNITED STATES
79	Iowa Clinic,PC/ Iowa Urololgy	1215 Pleasant Street Suite 520	50309	Des Moines	UNITED STATES
80	Metropolitan Urology Associates, PC	101 Hospital Boulevard	47130	Jeffersonville	UNITED STATES
81	Mississippi Urology Clinic	1421 North State Street Suite 403	39202	Jackson	UNITED STATES
82	Office of Dr. Roger Fincher, MD	12 East Fifth Avenue Suite 205	99202	Spokane	UNITED STATES
83	Oklahoma University Health Science Center	Department of Urology WP-3150 920 Stanton L. Young Blvd.	73104	Oklahoma City	UNITED STATES
84	South Coast Urological Medical Group	25200 LaPaz Road Suite 200	92653	Laguna Hills	UNITED STATES
85	The Urology Group	Tristate Urologic Services PSC, Inc. 4700 Smith Road Suite L	45212-2787	Cincinnati	UNITED STATES
86	University Urological Research Institute	195 Collyer Street Suite 201	02904	Providence	UNITED STATES
87	Urological Associates of Lancaster	2106 Harrisburg Pike Suite 200	17604	Lancaster	UNITED STATES

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