

The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No. AVO106740	
Title: A scientific study to evaluate the efficacy and safety of Avodart® in patients treated for Benign prostatic hyperplasia	
Rationale: Post marketing study to provide additional safety & efficacy data on Avodart® (dutasteride) in a real life setting.	
Phase: post-marketing scientific study	
Study Period: First Subject First Visit : 15 April 2003 – Last Subject Last Visit : 15 July 2006	
Study Design: Prospective, open-label, non-randomised, observational, post-marketing scientific study	
Centres: 120 to 150 urologists were planned to participate in the study. Data were collected from 70 Belgian study physicians/investigators.	
Indication: Benign Prostatic Hyperplasia	
Treatment: Avodart® was to be prescribed consistent with the indications specified in the European Summary of Product Characteristics (SmPC). Oral Dutasteride 0.5 mg/day for 12 months.	
Objectives: Safety and efficacy of Avodart® in the routine treatment of BPH.	
Primary Outcome/Safety Variable: Adverse events and serious adverse events reported during the 12 months of study duration.	
Secondary Outcome/Efficacy Variable(s):	
<ul style="list-style-type: none"> • Change from baseline in prostate volume • Change from baseline in total International Prostate Symptom Score (IPSS) , total BPH IMPACT INDEX (BII) score, IPSS QoL (question 8) score and peak urinary flow (Qmax) (Optional). • First episode of Acute Urinary Retention (AUR) during the course of the study • First BPH related surgery during the course of the study 	
Statistical Methods: The analysis was based on the total set, consisting of all subjects for whom data were available. The analysis was descriptive, no statistical tests were performed.	
Study Population: Males of at least 50 years of age with enlarged prostates (> 30cc) suffering from moderate to severe BPH-related symptoms, and willing to give written informed consent.	
Number of Subjects:	
Planned, N	1200
Entered , N	695
Completed, N (%)	285 (41.0%)
Total Number Subjects Withdrawn or not specified whether withdrawn, N (%)	410 (59.0%)
Withdrawn due to Adverse Events, n (%)	7 (1.0%)
Withdrawn for other reasons, n (%)	77 (11.1%)
Withdrawn, reason not specified, n (%)	1 (0.1%)
Lost to follow-up, n (%)	325 (46.8%)
Demographics	
N	694
Mean Age, years (SD)	68.9 (10.0)
Primary Outcome:	
<p>The primary objective of the study, the incidence of adverse events and serious adverse events reported by patients, could not be evaluated ultimately.</p> <p>This is because the study electronic Case Report Form was inadvertently designed only to collect results of the physical examination, BPH related information and information on continuation/discontinuation of therapy with Avodart. Therefore information on adverse events was not able to be systematically collected.</p> <p>However, it was reported separately that seven patients discontinued the study for adverse events. The nature of these adverse events was not collected. No serious adverse events which were considered 'potentially drug related' were reported to GSK. No other safety data were available for the analyses.</p>	

Secondary Outcome (Efficacy) Observations

Prostate Volume Determination (ml)

	Mean	St Dev.	Minimum	Median	Maximum	LL 95% CI	UL 95% CI	(N)	Missing
Baseline	60.87	23.77	10.0	60.00	130.0	59.10	62.64	695	0
Month 6	51.65	24.53	1.0	49.50	253.0	49.42	53.87	470	13
Month 12	50.92	24.69	4.0	46.00	250.0	48.25	53.59	331	10

Prostate Volume Determination (ml) - Difference from Baseline

	Mean	St Dev.	Minimum	Median	Maximum	LL 95% CI	UL 95% CI	(N)	Missing
Month 6	-10.15	15.98	-90.0	-8.00	154.0	-11.60	-8.70	470	13
Month 12	-12.12	16.30	-63.0	-11.00	151.0	-13.88	-10.36	331	10

Difference = Value at visit - Value at baseline

IPSS Score, IPSS QOL (Question 8) Score, and BII Score

	Mean	St Dev.	Minimum	Median	Maximum	LL 95% CI	UL 95% CI	(N)	Missing
IPSS Score (/35)									
Baseline	17.37	6.78	0.0	17.00	35.0	16.87	17.88	692	3
Month 6	12.64	6.62	0.0	12.00	34.0	12.04	13.24	470	13
Month 12	11.40	6.70	0.0	10.00	35.0	10.67	12.13	327	14
IPSS QOL (Question 8) Score (/6)									
Baseline	3.46	1.09	0.0	4.00	6.0	3.37	3.54	644	51
Month 6	2.53	1.18	0.0	2.00	6.0	2.42	2.64	443	40
Month 12	2.34	1.25	0.0	2.00	6.0	2.20	2.48	315	26
BII Score (/13)									
Baseline	5.81	3.01	0.0	6.00	13.0	5.58	6.04	680	15
Month 6	4.05	2.90	0.0	4.00	13.0	3.79	4.32	457	26
Month 12	3.79	2.63	0.0	4.00	12.0	3.50	4.08	318	23

IPSS Score, IPSS QOL Score, and BII Score - Change from Baseline

	Mean	St Dev.	Minimum	Median	Maximum	LL 95% CI	UL 95% CI	Number	Missing
IPSS Score (/35)									
Month 6	-4.89	5.55	-25.0	-4.00	15.0	-5.39	-4.39	470	13
Month 12	-5.76	6.38	-26.0	-5.00	15.0	-6.45	-5.06	327	14
IPSS QOL Score (/6)									
Month 6	-0.95	1.18	-5.0	-1.00	3.0	-1.07	-0.84	432	51
Month 12	-1.15	1.34	-5.0	-1.00	3.0	-1.30	-1.00	304	37
BII Score (/13)									
Month 6	-1.91	2.53	-12.0	-1.00	7.0	-2.14	-1.67	453	30
Month 12	-2.52	2.71	-11.0	-2.00	9.0	-2.82	-2.22	316	25

Difference = Value at visit - Value at baseline

Qmax (ml/s) (Optional)

	Mean	St Dev.	Minimum	Median	Maximum	LL 95% CI	UL 95% CI	(N)	Missing
Baseline	10.47	8.27	1.0	9.00	129.0	9.77	11.17	536	159
Month 6	13.77	25.85	2.0	12.00	400.0	11.08	16.47	356	127
Month 12	12.59	5.11	1.0	12.00	40.0	11.95	13.24	243	98

Qmax (ml/s) (Optional) - Difference from Baseline

	Mean	St Dev.	Minimum	Median	Maximum	LL 95% CI	UL 95% CI	(N)	Missing
Month 6	2.94	24.45	-111.0	1.50	389.0	0.32	5.56	337	146
Month 12	1.84	9.14	-112.0	2.00	29.0	0.65	3.03	228	113

Difference = Value at visit - Value at baseline

First episode of AUR during the course of the study: No data were available.
 First BPH related surgery during the course of the study: No data were available.

Conclusion: The primary objective of the study, the incidence of adverse events and serious adverse events reported by patients, could not be evaluated since information on adverse events was not systematically collected. It was reported that seven patients discontinued the study due to adverse events. All statistical analyses were descriptive and therefore no statistical tests were performed.

Publications: No Publications

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